UCL SCHOOL OF PHARMACY
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Development and feasibility study of a community pharmacy intervention to support self-management of patients with type 2 diabetes, in Cyprus

Thesis submitted in accordance with the requirements of University College London for the degree of Doctor of Philosophy by

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PLAGIARISM STATEMENT

This thesis describes research conducted in UCL School of Pharmacy, between September 2017 and October 2023 under the supervision of Professor Felicity Smith and Professor Cate Whittlesea. I, [Antria Pavlidou] confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Signature: ---------- Date: ----------

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Abstract

Background

The pharmacists' role has evolved over the past years towards a more clinical role to support patients in managing various prevalent health conditions. Cyprus had one of the highest prevalence of diabetes among other European countries in 2021. Motivational interviewing has been shown to be an effective tool in consultations. In recent years there has been increasing interest in the potential of mobile technologies in health care. However, effective implementation, management, and evaluation of those interventions aiming to improve type 2 diabetes self-management are still being researched.

Aim

The aim of this study was to design and implement a mobile health intervention delivered by a pharmacist applying motivational interviewing techniques, aiming to improve the self-management of type 2 diabetes patients. Then, primarily evaluate its feasibility, acceptability, and secondary, participants' medication adherence and self-care activity.

Method

Type 2 diabetes patients visiting a diabetes clinic in Cyprus were recruited. The intervention included: pharmacist online advice to patient queries, tracking and uploading blood glucose readings, graphical reports, reminders, education, and optimization of pharmacotherapy delivered over an initial face-to-face consultation and up to 3 follow-up telephone appointments at maximum intervals of 6-8 weeks. Feasibility was measured by recruitment and retention, use and workability of the intervention, and basic costs. Participants' and healthcare professionals' acceptability was assessed via two semi-structured interview schedules based on the Theoretical Framework of Acceptability (Sekhon et al., 2017). Participants' medication adherence and self-care activity were assessed by the adapted Diabetes Self-Care Activities Questionnaire - Greek version before and after the intervention (Intas et al., 2012).

Results

Twenty-seven patients agreed to participate, of whom 22 completed the intervention. Participants communicated with the pharmacist and agreed to use, education, and the review of patients' medications. A barrier to the intervention was the pharmacist accessing patients' data, as HbA1c (69%) and blood glucose (90%) were not accessible

to all participants. Based on the study findings, participants valued the motivational interview and pharmacist approach, while healthcare professionals highlighted the benefits of pharmacy service, specifically in increasing medication adherence. Participants reported improvements in self-care during the study period in three out of five domains (blood sugar testing, healthy eating, and foot care) assessed in the adapted DSCAQ – Greek version, whereas adherence to diabetes medications and physical activity remained the same.

Conclusion

The results suggest that individualised, evidence-based digital health interventions delivered by a pharmacist can potentially support diabetes self-management in the context of health care for diabetes in Cyprus. Further extrapolating of the proposed intervention in larger settings is required to draw robust conclusions about the interventions' cost-effectiveness.

Impact Statement

Non-conclusive results exist from extensive literature concerning the key components of complex interventions aiming to support diabetes patients manage their disease. Although some services offered in primary care are well established and studies had shown that evidence based, theory driven, multidimensional and patient centred intervention improve diabetes self-management, studies covering all these aspects are lacking (O'Connell et al., 2018; Vermeire et al., 2005; Renders et al., 2000). To address this gap, the past decades new digital health interventions (DHIs) are explored. Moreover, pharmacists' role is constantly expanding and playing a vital role within the healthcare team. Nevertheless, the published literature does not provide sufficient interventions and evaluation procedures, and guidance on feasible and effective interventions to improve self-management of T2DM. An additional barrier is the differences in the healthcare settings, regulations and policies applied worldwide.

This research describes the development, delivery and feasibility evaluation of an intervention aiming to improve T2DM self-management, delivered by pharmacists in Cyprus and employing technology. This is the first study conducted in Cyprus on self-management of diabetes delivered by pharmacists. Firstly, the results obtained here may inform national diabetes policy and practice use. Secondly, the findings obtained provide valuable information to guide individually driven complex interventions and will also inform local policies on diabetes management pathways.

In this research, robust evidence, theoretical frameworks, and current practices were underpinning the developed intervention. The intervention aimed to increase patients' knowledge, adherence, and patient empowerment through motivational interview and the philosophy of empowerment (Salimi et al., 2016; Anderson and Funnell, 2000; Funnell et al., 1991). To our knowledge, this is the first intervention in a Cypriot setting, individualizing each step based on participants' lifestyle, from the services provided to the media employed and the frequency of the follow-up. Also, the interventions' feasibility evaluation was based on the MRC framework. In this research work, the feasibility of the intervention was holistically assessed through crucial stakeholders' perspectives, workability (including investigation of the workability of the instruments employed), and an indication of the extent to which clinical outcomes were likely to be achieved. Triangulation of method was employed to assess the feasibility of the proposed

intervention and address all research objectives, increase the study's validity, and provide relevant recommendations.

The barriers that impact on the feasibility and the implementation of such intervention in Cyprus and similar settings were reported. Consequently, practical recommendations were developed to address future implementation of the developed intervention to current practices in Cyprus and in settings with similar healthcare system. The study highlights the opportunities and challenges and presents a series of recommendations derived from observation of practice and consultation with practitioners and other key stakeholders.

Finally, this research highlights opportunities for future research related to the intervention's impact on the advancement of the pharmacists' profession, DHI and the quality of diabetes self-management management.

Brief biography of the researcher

My name is Antria Pavlidou, I am a part-time PhD student at UCL and concurrently working in my home country, Cyprus. I obtained my degree from the University of Patras, Greece, following the Pharmacist Registration Certificate (Registration Number: 2094), and later completed my MSc studies at UCL on Clinical Pharmacy, International Practice and Policy. During my pharmacy degree and MSc studies, I was interested in learning about diabetes and the various pharmacy services employed worldwide. While I was working on a case study about diabetes, I was sure that I wanted to further expand my knowledge about diabetes. I was fascinated by the various tasks a diabetes person must perform each day, the importance of diabetes self-management, and the lack of pharmacists' contribution in my home country to support diabetes management. Through the International Health Perspectives course, I learned about the various clinical pharmacy services used worldwide and realized there is a need to expand the pharmacist's role beyond dispensing. I developed a clinical pharmacy service in the general surgery unit at the Nicosia General Hospital, in Cyprus, where pharmacists will attend the ward round with other HCPs in addition to their current dispensing role. I learned about the health care system, the pharmaceutical services, and the statistical services in Cyprus. For those reasons, I chose to develop a pharmacist-led diabetes service for my PhD studies. The information identified for diabetes in Cyprus and worldwide confirmed that diabetes disease is an area in which more needs to be done. In 2017, when I started my PhD and developed this intervention, I worked at the Kofinou medical centre where a diabetes clinic was operating. As such, there was solid ground on which to work to develop my new service, expand the pharmacists' role and support patients with diabetes. After that, I was transferred to the Pharmaceutical Services of the Ministry of Health, where I worked in the regulatory department. After two years working in the Pharmaceutical Services and after completing my data collection for my thesis, I transferred to the headquarters of the Ministry of Health in the Control Unit, where I am currently working. In the Control Unit, I work on how the processes of the Ministry of Health could be further improved.

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List of abbreviations

(DSCAQ - GREEK VERSION)	Diabetes Self-Care Activity Questionnaire – Greek version
ADA	American Diabetes Association
AADE	American Association of Diabetes Educators
App(s)	Application(s)
BG	Blood Glucose
BP	Blood Pressure
CDA	Cyprus Diabetes Association
CDAL	Cyprus Diabetes Association in Limassol
CP	Clinical pharmacy
DC	Diabetes Clinic
DCC	Diabetes Control Centre
DCP	Diabetes Care Profile
DDP-4	Dipeptidyl Peptidase Inhibitors
DES	Diabetes Empowerment Scale
DESMOND	Diabetes Education and Self-Management for Ongoing and Newly Diagnosed
DHI(s)	Digital Health Intervention(s)
DKA	Diabetes ketoacidosis
DKT	Diabetes Knowledge Test
DSCS	Diabetes Self-Care Scale
DSME	Diabetes Self-Management Education
DSME/S	Diabetes Self-Management Education and Support Services
EU	European Union
EUBIROD	European Best Information Through Regional Outcomes in Diabetes
FIP	International Pharmaceutical Federation
GDPR	General Data Protection Regulation
GESY	General Healthcare System
GDM	Gestational Diabetes
GLP-1	Glucagon-Like Peptide-1
GP(s)	General Physician(s)
HbA1c	Glycated Haemoglobin
HCP(s)	Healthcare professional(s)
HDL	high-density lipoprotein
HHS	Hyperosmolar Hyperglycaemic State
HIO	Health Insurance Organization
HTN	Hypertension
ID	Identification
IDF	International Diabetes Federation
IFG	Impaired Fasting Glucose
IGT	Impaired Glucose Tolerance
LDL	Low-density lipoprotein
LTC	Long Term Conditions
MARS	Medication Adherence Report Scale
MEMS	Medication Event Monitoring System
mERA	m-Health Evidence Reporting and Assessment
MeSH	Medical Subject Headings
MI	Motivational Interview
MMAS	Morisky Medication Adherence Scale
MOHRC	Ministry of Health of The Republic of Cyprus
MRC	Medical Research Council

NCDs	Non-Communicable Diseases
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
PIL	Patient Information Leaflet
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-analysis
PRISMA-P	Preferred Reporting Items for Systematic Reviews and Meta-analysis Protocols
PRISMA-ScR	PRISMA Extension for Scoping Reviews
PSMH	Pharmaceutical Services of Ministry of Health
RPS	Royal Pharmaceutical Society
SDSCA	Summary of Diabetes Self-Care Activity
SGLT2	Sodium-Glucose Transport Protein 2
SHSO	State Health Services Organisation
SMBG	Self-monitoring of Blood Glucose
SPC	Summary of Product Characteristics
SPSS	Statistical Package for the Social Sciences
T2DM	Type 2 Diabetes Mellitus
TFA	Theoretical Framework of Acceptability
UK	United Kingdom
USD	United States Dollars
WHO	World Health Organization

Abbreviations are spelled out in full the first time they are used in each chapter.

Chapter One

Background Information

1.1 Introduction

Chapter one is an introductory chapter providing background information about diabetes, potential roles of pharmacists in enhancing and supporting diabetes management, and information about the new approach in delivery health care called digital health. Discussion of the epidemiology of diabetes disease around the world and in Cyprus, an overview of diabetes disease and its comorbidities, and a particular focus on management and self-management of diabetes, including prevention of its comorbidities, which is studied in this thesis, are described. In addition, evidence of non-adherence to treatment, reasons for non-adherence, measurement of adherence, and strategies to address non-adherence are explored.

1.2 Burden of diabetes mellitus worldwide and in Cyprus

Diabetes is a chronic disease affecting people globally and has been characterised as an epidemic and pandemic. Diabetes is one of the fastest-growing global health challenges (IDF, 2021). In 2021 approximately 537 million people, 10.5% of the world's population (20-79 aged), had diabetes, while it is expected to rise to 783 million (12.2%) by 2045 (IDF, 2021). Halting the rise of diabetes and obesity was one of the nine voluntary global targets to be achieved by 2025. (WHO, 2016a; WHO, 2013). In 2022, for the first time ever, World Health Organization (WHO) Member States have supported the creation of global targets for diabetes to reach by 2030 as part of recommendations to strengthen and monitor diabetes responses within national non-communicable diseases (NCDs) programs (WHO, 2022a). The five new targets set included; 80% of people living with diabetes being diagnosed, having good control of glycaemia, and having good control of blood pressure (BP), 60% of people with diabetes of 40 years or older receiving statins, and 100% of people with type 1 diabetes have access to affordable insulin and self-monitoring blood glucose (SMBG) devices (WHO, 2022a).

Cyprus had one of the highest prevalences of diabetes among other European countries in 2021, accounting for 87,469 people, which counts for 8.6% of the total population, while the top 5 European countries accounted for 9.1% to 14.5%, with the highest recorded in Turkey (IDF, 2021). The lowest prevalence in Europe region was 3% recorded in Ireland (IDF, 2021).

Diabetes is a significant driver of mortality worldwide, causing 6.7 million deaths in 2021, or one every five seconds (IDF, 2021). Diabetes accounted for 12.2% of global all-

cause mortality (20-79 aged), while 32.6% of those deaths concern people before the age of 60 (IDF, 2021). The European region was the second of the seven International Diabetes Federation (IDF) regions, with the highest estimated number of diabetes-related deaths in 20-79 years old, calculating 1.1 million deaths, after Western Pacific with 2.3 million deaths. Similarly, diabetes is one of the leading causes of death in Cyprus, along with other chronic NCDs. Remarkably, it ranked 4th with 500 deaths after deaths due to cardiovascular disease (1,875), neoplasms (1,578), and respiratory diseases (625) in 2020 (6,579 total deaths) (Republic of Cyprus, 2020, p. 15). Data later than 2020 were not identified by the statistical services of the Republic of Cyprus (Republic of Cyprus, 2020). According to the IDF Atlas report in 2021, deaths attributed to diabetes in Cyprus were 1,101 (population size 1.244 million) among those aged 20-79 years old, ranging from 174 deaths in Estonia (population size 1.331 million) to 172,943 in Italy (population size 59.11 million) in the European region (IDF, 2021).

In addition, diabetes itself and related complications are imposing a significant economic impact on all countries, health systems, people with diabetes, and their families worldwide (IDF, 2021). In 2021, 966 billion dollars (in United States Dollars (USD)) were spent on diabetes globally, while 232 billion were spent in 2007, representing a 316% increase over 15 years. Europe region has the second highest average cost per person with diabetes (20-79 years old), counting 3,086 USD, and the third highest total diabetes-related health expenditure among the seven IDF regions (IDF, 2021). Europe's total diabetes-related health expenditure corresponds to 189.3 million USD, representing 19.6% of the total spent worldwide, after North America and Caribbean and Western Pacific with 42.9% and 25%, respectively (IDF, 2021). The health expenditure related to diabetes per person in Cyprus was USD 2,570.80, corresponding to a total of USD 224,866,163 (IDF, 2021). The largest estimates were found in Switzerland, with 12,828.4 USD, and the lowest, with 169.3 USD, in Tajikistan (IDF, 2021).

Some of the key numbers and facts about diabetes from 1980 until 2021 and what is expected in the future are shown in Table 1.1 (IDF, 2021; IDF, 2017a; WHO, 2016a).

Table 1.1 Key Numbers and facts about diabetes, from 1980 until 2021 and what is expected in the future (between 20-79 years old).

Date	Diabetes		
	People with diabetes (million)	**Health expenditure** (billion United States dollars)	**Deaths caused by diabetes** (United States dollars)
From 1980 -	108	232[1]	No data available
2014 -	422	548[2]	1.5 million (in 2012) 1.6 million (in 2016)
2017 -	425	727	4 *1 death every 8 seconds*
2021 -	537	966	6.7 *1 death every 5 seconds*
2045 (expected)	629	776	1.05 trillion

[1] in 2007 [2] in 2013.
Source: Adapted from WHO, 2016a; IDF, 2017a; IDF, 2021.

Diagnostic criteria for diabetes

Diabetes is a condition where blood glucose (BG) levels are raised due to the inability to produce enough or no insulin hormone or use insulin effectively. This causes hyperglycaemia, the major problem of diabetes, and if left untreated, can lead to other serious complications such as cardiovascular disease, neuropathy, nephropathy, and retinopathy. (IDF, 2021; IDF, 2017a)

Diabetes can be diagnosed by measuring glucose in blood while the patient is fasting (no calorie intake for at least 8 hours) or 2 hours after the patient takes a 75g oral load of glucose and by testing glycated haemoglobin (HbA1c). A combination of measuring fasting plasma glucose (FBG) and then 2 hours after drinking a 75g glucose drink is referred to oral glucose tolerance test (OGTT). Furthermore, HbA1c reflects the average BG concentration over the previous 8–12 weeks (NICE, 2012). An advantage of HbA1c is that it does not require special preparation (e.g., fasting) and can be performed at any time. Diagnostic criteria for diabetes mellitus are shown in Table 1.2 (IDF, 2021; WHO, 2016a).

Table 1.2 Diagnostic criteria for diabetes mellitus.

Diagnoses	Criteria						
	Fasting plasma glucose		**Two-hour plasma glucose** (Following a 75g oral glucose load)		**Glycated Haemoglobin HbA1c**		**A random glucose**
Diabetes	≥7.0mmol/L (126mg/dL)	Or	≥11.1 mmol/L (200mg/dL)	Or	≥ 6.5% (48mmol/mol)	Or	>11.1 mmol/L (200mg/dL)
Impaired Glucose Tolerance (IGT)	<7.0 mmol/L (126mg/dL)	And	≥7.8 < 11.1mmol/L (≥140 to <200mg/dL)	-			
Impaired Fasting Glucose (IFG)	6.1-6.9 mmol/L (110 to 125 mg/dL)	And	<7.8mmol/L (140mg/dL)	-			

Source: Adapted from IDF Atlas 10th edition, 2021 and World Health Organization (WHO) global report on diabetes, 2016.

Types of diabetes

There are three major types of diabetes, type I, type II, and gestational diabetes (GDM). Type 2 diabetes mellitus (T2DM) is the most common type of diabetes, accounting for over 90% of all diabetes worldwide (IDF, 2021). Type I is characterized by a lack of insulin production, while T2DM is by the inadequate production of insulin or the inability of the body to use insulin fully (IDF, 2021). GDM, in brief, is characterised by high BG during pregnancy (IDF, 2021). The exact cause of type 1 diabetes and T2DM causes are not entirely understood. However, the contributors for both type 1 and T2DM are thought to include a combination of genetic susceptibility (conferred by a large number of genes) and environmental triggers, such as viral infection, initiate the autoimmune reaction (IDF, 2021; IDF, 2019; WHO, 2016a; Atkinson et al., 2014; Craig et al., 2014). It is known that type 1 diabetes is caused by an autoimmune reaction where the body's defence system attacks the cells that produce insulin (IDF, 2019; WHO, 2016a). In addition, for T2DM, there is a strong link between being overweight, obesity, increasing age, ethnicity, and family history (IDF, 2021). T2DM is potentially preventable, and remission may sometimes be possible. Conversely, successful prevention strategies for type 1 are still being researched (IDF, 2021; WHO, 2016a).

1.3 Complications of diabetes mellitus

Diabetes patients are at higher risk of developing several life-threatening severe complications, increasing the chance of premature deaths, lower quality of life, and higher health costs (IDF, 2021; IDF, 2017a). Uncontrolled BG can cause acute diabetes complications and chronic complications. Acute complications compromise hypo- and hyperglycaemia, hyperosmolar hyperglycaemia state, and diabetic ketoacidosis (IDF, 2017a; WHO, 2016a). Diabetes complications are divided into macrovascular and microvascular. They include cardiovascular diseases, retinopathy leading to blindness, nephropathy leading to renal failure, and neuropathy disease leading to diabetic foot disorders, even amputation (WHO, 2019a; IDF, 2017a; WHO, 2016a). Specifically, T2DM patients are two to three times more likely to have cardiovascular disease than those without diabetes (IDF, 2021; IDF, 2017a; WHO, 2016a). Diabetes-related complications include other diseases and illnesses (IDF, 2017a; NICE, 2015b; WHO, 2016a). For instance, diabetes patients are at higher risk of developing depression and physical and cognitive disability (IDF, 2017a; WHO, 2016a). Similarly, studies showed that diabetes patients had a particularly high risk of developing severe complications from Covid-19 infection, and deaths were higher in countries that have a high prevalence of diabetes (IDF, 2021; Hu et al., 2020; Huang et al., 2020; Wu et al., 2019). Complications of diabetes are displayed in Table 1.3.

Table 1.3 Diabetes complications.

Acute Metabolic complications	Chronic Complications	Other Complications
• Hypoglycaemia. • Hyperglycaemia. • Hyperosmolar Hyperglycaemic State (HHS). • Diabetes ketoacidosis (DKA).	**Microvascular complications** • Retinopathy. • Nephropathy. • Neuropathy. **Macrovascular complications** *Cardiovascular disease:* • Angina. • Stroke. • Coronary artery disease. • Myocardial Infarction. • Peripheral Artery Disease. • Congestive Heart Failure.	• Erectile dysfunction. • Gastroparesis. • Physical and cognitive disability. • Dental problems (e.g., periodontal gum). • Other related illnesses and diseases (such as depression, cancer, tuberculosis).

Source: Adapted from WHO, 2019a; IDF 2017; WHO, 2016a; NICE, 2015b.

1.4 Type II diabetes prevention

T2DM is the most common type of diabetes, estimating that about 90% of adults currently diagnosed with diabetes have T2DM (IDF, 2021; NICE, 2015a; NICE, 2015b). Provoking factors of T2DM include unmodifiable variables such as genetics, ethnicity, and age and modifiable variables like being overweight or obese, having an unhealthy diet, insufficient physical activity, and smoking which can be largely prevented (IDF, 2021; IDF, 2017a; WHO, 2016a). Particularly, a large proportion of the global diabetes burden is estimated to be caused by overweight and obesity. Consequently, changing behavioural and environmental factors can prevent or delay the onset of T2DM in people at high risk (IDF, 2021; IDF, 2017a; WHO, 2016a).

The cornerstone for T2DM prevention and treatment is healthy eating, low consumption of sugar-sweetened food and beverages, and physical activity of at least 150 minutes of moderate-intensity or 75 minutes of vigorous-intensity throughout the week (for adults aged 18-64), smoking cessation (where appropriate) and maintaining healthy body weight (WHO, 2022b; IDF, 2021; IDF, 2017a; WHO, 2016a). Specifically, diet and physical activity changes are more effective than medication in delaying or preventing diabetes. (IDF, 2021; IDF, 2017a; WHO, 2016a)

1.5 Management of diabetes and prevention of its comorbidities

Diabetes patients can live long and healthy lives if their diabetes is detected and well-managed (IDF, 2021; IDF, 2107b; WHO, 2016a). Good management compromises several components, such as medicines, promoting healthy lifestyles, patient education to facilitate self-care, and regular screening for early detection and treatment of complications through a multidisciplinary team (IDF, 2017b; WHO, 2016a). All these strategies can prevent complications and premature death from diabetes. The provision of these facilities for diabetes diagnosis and management should be available in a primary healthcare setting with an established referral and back-referral system, and patients must have access to essential medicines and technologies (WHO, 2016a). Explanations of key components essential for diabetes management are described below.

Blood glucose management

The main goal for managing T2DM is to control hyperglycaemia to recommended targets and prevent other complications caused by long-term hyperglycaemia (IDF, 2021; IDF, 2017a; IDF, 2017b; WHO, 2016a; NICE, 2015b). Glycaemic control is crucial and has

been consistently associated with a reduction in the risk of microvascular and macrovascular complications (American Diabetes Association, 2016). However, decreasing HbA1c below the target could result in doing more harm than benefit with aggressive treatment that induces hypoglycaemia and weight gain. Guidelines suggest encouraging patients to reach a near-normal HbA1c target in cases where tight blood glucose control increases the patients' risk (e.g., hypoglycaemia), do not outrange the benefits or intensive management is not appropriate (NICE, 2022; IDF, 2017b; NICE, 2015b). Notably, IDF guidelines have published recommendations for a general target for glucose control of T2DM, presented in Table 1.4 (IDF, 2017b). This is also in line with the general recommendations in Cyprus (MOHRC, 2013). In addition, the National Institute for Health and Care Excellence (NICE) wrote a decision aid to help patients work together with their diabetes team to agree on the HbA1c target level (NICE, 2022).

Table 1.4 Recommendations for a general target for glucose control of type 2 diabetes mellitus.

Recommendations for a general target for glucose control of type 2 diabetes mellitus
• The general target for glucose control in T2D should be less than 7% (53 mmol/mol).
• Lower HbA1c targets are desirable or at least should be considered, as long as hypoglycaemia and weight gain can be avoided using appropriate treatments.
• Values of HbA1c above 8% (64 mmol/mol) are generally unacceptable.
• Blood glucose below 3 mmol/L (54 mg/dl) should be always avoided.

Source: Adopted from IDF, 2017b.

Medicines for the management of diabetes disease

In cases where lifestyle changes are not effective, oral medication is usually initiated (IDF, 2021; IDF, 2017b). Oral medication may include one or a combination of antidiabetic medication, with metformin being the first line drug, whereas sulphonylureas, thiazolidinediones, dipeptidyl peptidase Inhibitors (DDP-4), sodium-glucose transport protein 2 inhibitors (SGLT2), glucagon-like peptide-1 receptor agonists (GLP-1), etc. being other options to use depending on countries' guidelines and recommendation (IDF, 2017b; WHO, 2016a; NICE, 2015b; MOHRC, 2013). Aside from oral medication, insulin injection is another option to control BG levels within the target limits, depending on patients' needs. (IDF, 2017b; WHO, 2016a; NICE, 2015b). Moreover, guidelines for the optimal management of diabetes also focus on managing cardiovascular risk, including antiplatelet therapy and/or lipid management where appropriate (IDF, 2021; IDF, 2017b; NICE, 2015b; WHO, 2016a). Essential medicines

and basic technologies (e.g., BG, monitoring device) and provision for managing diabetes vary among countries worldwide. Access to essential medicines, technologies, and affordable insulin is worryingly limited in middle- and low-income countries (IDF, 2021; WHO, 2022a; WHO, 2016a). National guidelines and recommendations in Cyprus and access to pharmacotherapy for diabetes management are detailed and discussed in chapter 3, sections 3.7 and 3.8.

Individuality and self-care

Management and treatment of diabetes should be tailored to the needs and circumstances of each patient, taking into consideration personal preferences, comorbidities, and risks from polypharmacy and balancing the benefit and long-term interventions because of reduced life expectancy. A diabetes treatment plan should involve patient choices in partnership with their healthcare professionals (HCPs) (NICE, 2015b; NICE, 2012). In addition, necessary lifestyle changes, complex pharmacotherapy, and potential side effects of therapy make patient education and self-management significant aspect of diabetes management (NICE, 2015b). Consequently, patients should be encouraged to make their own choices and have a sense of ownership of their lifestyle goals and individual action plans (NICE, 2015b; NICE, 2012).

Diabetes disease management education

Patient education is one of the key priorities for the management of diabetes (IDF, 2017b; NICE, 2015b). Patients should understand that their education is an integral part of diabetes care. Structured education to patients or their family members or carers at the initial diagnosis and with annual reinforcement and review is recommended (NICE, 2015b). Also, the American Diabetes Association (ADA) recommends the assessment of self-management skills and knowledge of diabetes at least annually and providing or encouraging continuing diabetes education (Norris et al., 2002; Mensing et al., 2000). Simultaneously, HCPs should be aware of the education programs available, which should be part of the diabetes management pathway (NICE, 2015b). Local educational programs should be modified depending on patients' cultural, linguistic, cognitive, and literacy needs within the local area, considering patients' and their family members and carers' perceptions when designing them (NICE, 2015b).

Managing diabetes is a complex process involving lifestyle changes and treatments (NICE, 2015b; NICE, 2008). Patients must be educated and fully understand the

principles and importance of a healthy diet, adequate physical activity, avoidance of tobacco and harmful use of alcohol, medication adherence, foot hygiene, and appropriate footwear, and the need for periodic assessment of metabolic control and presence or progression of complications (WHO, 2016a; NICE, 2008).

The rationale of education provision is to empower and support patients in managing their disease (NICE, 2015b; NICE, 2008). Structured education programmes can support adults with T2DM to improve their knowledge and skills and help to motivate them to take control of their condition and self-manage it effectively (NICE, 2015b; NICE, 2008). Diabetes Self-Management Education (DSME) has been considered an essential part of the clinical management of diabetes since the 1930s. It is described as the process of teaching individuals with diabetes to manage their disease (Norris et al., 2002; Norris et al., 2001). Norris et al., 2002 and Norris et al., 2001 studies are systematic reviews and meta-analyses that evaluated the efficacy of self-management education, supported its effectiveness, and showed it could improve HbA1c (Norris et al., 2002; Norris et al., 2001). DSME is the fundamental step to empowering patients and a necessity for the optimal self-management of diabetes (Funnell and Anderson, 2004).

Primary healthcare level for the diabetes management

The primary care level is focused on responding to the burden of NCDs, including diabetes (IDF, 2017a; IDF, 2017b; WHO, 2016a; NICE, 2015b). Diabetes management can be addressed within the primary sector with regular check-ups, proper medication, lifestyle advice, education, and a tailored and continually updated diabetes care plan based on individual needs and lifestyles (IDF, 2017a; IDF, 2017b; WHO, 2016a; NICE, 2015b). Interventions aiming to strengthen the health system, especially primary healthcare settings, are highly prioritized (IDF, 2017a; WHO, 2016a).

1.6 Evidence on rates of non-adherence to treatment

Low adherence to prescribed medical interventions and lifestyle recommendations and advice is an ever-present and complex problem, apparent from abundant research, especially in the case of chronic diseases such as diabetes (Deshpande et al., 2017; Kennedy-Martin et al., 2017; Vrijens et al., 2017; Iuga and McGuire, 2014; Simpson et al., 2006; WHO, 2003; Vermeire et al., 2001).

Most research focuses on adherence to medication, but it also encompasses numerous health-related behaviours beyond taking prescribed pharmaceuticals (Vrijens et al., 2017; Simpson et al., 2006; WHO, 2003). During treatment, patients may seek medical attention, fill prescriptions, take medication, obtain immunization, attend follow-up appointments, and execute behaviour changes that address diet, healthy lifestyle, self-management of diabetes, smoking cessation, etc. All of these are examples of therapeutic behaviours (WHO, 2003). Patients are also increasingly managing multiple long-term conditions requiring managing multiple medicines, which poses an additional burden for patients with chronic diseases, including diabetes (NICE, 2015a; Barnett et al., 2012). Notably, polypharmacy, which applies when a person is taking multiple medications (prescribing four or more medications), is associated with low adherence (NICE, 2015a; Kardas et al., 2013)

Extensive literature reviews reveal that in developed countries, adherence to therapies averages 50%, and only half of the patients adhere to treatment to health care recommendations as proposed (NICE, 2015a; Clifford et al., 2010; Cushing and Metcalfe, 2007; Horne et al., 2006; WHO, 2003; Vermeire et al., 2001). While the NICE report stated that between a third and a half of all medicines prescribed for long-term conditions are not taken as recommended (NICE, 2009). Adherence rates were identified from 30-50% of all patients, irrespective of disease (WHO, 2003; Vermeire et al., 2001). Nieuwlaat et al., 2014, showed similar non-adherence to medication rates, occurring in the first months following initiation, with further attrition over time, while many patients who continue their medication do not consistently take it as prescribed. Hence, medication adherence rates average around 50% and range from 0% to over 100%, and there is no evidence of substantial change over the past 50 years. (Nieuwlaat et al., 2014). A more recent study in Ireland found that 31% of older patients with multimorbidity, above 2 chronic conditions, were non-adherent, with non-adherence rates varying across conditions and treatments (Kim et al., 2018).

Diabetes adherence to treatment and evidence of non-adherence

Control of diabetes is a complex, lifelong process requiring much effort beyond taking medication. This includes SMBG, dietary restrictions, regular foot care, ophthalmic examinations, etc (IDF, 2021; IDF, 2017b; NICE, 2015b; WHO, 2016a).

Studies showed poor adherence in all aspects of diabetes management for T2DM. (Mogre et al., 2019; WHO, 2003). A recent systematic review identified that adherence rates to diabetes self-care behaviours, from low- and middle-income countries, ranged from 29.9%-91.7% for diet, 26.0%-97.0% for medication taking, 26.7%-69.0% for exercise, 13.0%-79.9% for self-monitoring of BG and 17.0%-77.4% for foot care (Mogre et al., 2019). Another study showed that 67% of patients with T2DM did not monitor their BG as frequently as recommended in a study conducted in the United States (WHO, 2003; Karter et al., 2000), Similar findings were identified in a study conducted in India, with 23% of participants reporting performing glucose monitoring at home (WHO, 2003; Shobhana et al., 1999). In addition, studies evaluating adherence to dietary prescriptions varied from 37% - 70% adherence in following their meal plan (WHO, 2003; Schultz et al., 2001; Shobhana et al., 1999; Anderson and Gustafson, 1998; Wing et al., 1987). Similarly, results from studies about physical activity range from 7.7% to 37% in physical activity programmes and 26% to 52% of participants completing the counselling programme (WHO, 2003; Schultz et al., 2001; Searle and Ready, 1991). Dose omissions were the most prevalent form of non-adherence; however, over one-third of the patients took more doses than prescribed (WHO, 2003; Paes, et al., 1997). Moreover, another study showed that only 15% of patients who had been prescribed a single oral medication were still taking it regularly (WHO, 2003; Dailey et al., 2001).

1.7 Effects of non-adherence to treatment

The impact of medication non-adherence could be translated into patients not attaining the health gains expected from medication, can lead to patients requiring further intervention, and representing an avoidable cost to the healthcare system (Donovan et al., 2022; Cutler et al., 2018; Clifford et al., 2010; Department of Health, 2008; Cantrell et al., 2006; Elliott et al., 2005). Low adherence can lead to increased hospital and nursing home admission, length of stay, deaths, and increased healthcare expenditure admission to nursing homes and consist of ongoing frustration to physicians (Clifford et al., 2010; Department of Health, 2008; Cantrell et al., 2006; Elliott et al., 2005; Vermeire et al., 2001; Donovan, 1995; Morris and Schulz, 1992). Realizing the benefits of medication, which have been shown to do more good than harm in clinical trials, low patient adherence consists of a barrier and limits the benefits of medicines and results in a lack of improvement or deterioration in health (NICE, 2015a; Nieuwlaat et al., 2014). Evidence shows that low adherence, even to a placebo, is independently associated with an increased risk of death, called the healthy adhere effect (Nieuwlaat et al., 2014;

Simpson et al., 2006). Poor/low adherence is a significant problem causing personal and public health problems that impose a considerable financial burden (NICE, 2015a; Clifford et al., 2010; Department of Health, 2008; Cantrell et al., 2006; Elliott et al., 2005; Vermeire et al., 2001). The economic burden has been estimated to cost £100 million each year in the United Kingdom (UK), which is wasted on medication not consumed by the patients for whom they were prescribed (Cushing and Metcalfe, 2007; National Audit Office, 2007).

Similarly, in diabetes, poor adherence to recognized standards of care is strongly associated with and is the principal cause of the development of complications of diabetes (WHO, 2003; Vermeire et al., 2001). Adherence to treatment, such as dietary modification and/or physical activity, regular check-ups, and foot care, has effectively reduced complications and disability while improving patients' quality of life and life expectancy (WHO, 2016a; WHO, 2003). Consequently, strategies that could effectively improve and promote adherence to self-management of diabetes, the human, social and economic benefits would be substantial (WHO, 2003).

1.8 Definitions of medication taking and behaviour

Different terms were used regarding medication taking and behaviour, including compliance, adherence, and concordance, as described in Table 1.5. Another issue highlighted in the literature is that the patient is not a passive, acquiescent recipient of expert advice. On the contrary, the patient is an active collaborator in the treatment process (WHO, 2003). There is no uniform terminology related to self-care, but this term is often used interchangeably with "self-management," "compliance," and "adherence" (Soyoon and Ekaterina, 2022; Lu et al., 2016). In this study, self-management and adherence will be used.

Table 1.5 Descriptions of medication taking and behaviour; concordance, compliance, adherence, self-management/ self-care.

Terms	Description
Concordance	• Introduced by members of the Royal Pharmaceutical Society (RPS) of Great Britain in 1995. • Means agreement and harmony. • This concept recognises the need of the patient to be a decision maker in partnership with health care providers in a mutually agreed treatment programme.

Table 1.5 Descriptions of medication taking and behaviour; concordance, compliance, adherence, self-management/ self-care.

Terms	Description
	• Indicates the extent to which a patient's thoughts about his/her treatment match what the health caregiver thinks the patient actually does.
Compliance	• Defined as the extent to which a person's behaviour (e.g., taking medication, following diets, etc.) coincides with medical or health advice. • Its use has declined through the years as it implies a lack of patient involvement in the recommendations, and non-compliance shows the patient's disobedience to follow the physician's "instructions". • Follows the assumption that a "good" patient must precisely follow his/her medical advice and/or that the medical advice is good for the patient.
Adherence	• Attempts to emphasize the patient's freedom to decide whether to adhere to the doctor's recommendations, and failure to do so does not blame the patient. • Incorporates the broader notions of concordance, cooperation, and partnership among patients and health professionals about prescribers' recommendations. • Strongly emphasizes differentiating adherence from compliance, as adherence requires the patient's agreement to the recommendations. • Who 2003 report adopted the following definition of adherence to long-term therapy: "the extent to which a person's behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider" (WHO, 2003, p.3).
Self-management/ self-care	• Originally used in 1927, by the father of the British Diabetic Association, RD Lawrence, who referred to his patients learning the skills of how to manage their diabetes on a daily basis with thoroughness and self-confidence. • Both Johnson et al. And Glasgow et al. independently proposed the use of the terms "self-care" or "self-management" to describe the cluster of patients' daily activities and behaviours performed to manage their diabetes. • It has been widely adopted by the ADA, recognised by the Diabetes National Service Framework, and integrated into governmental health policy and National Institute for Health and Care Excellence (NICE) and Quality Standards in Diabetes. • It is gaining more growth as a promising strategy for managing chronic diseases, beyond education to teaching individuals to identify challenges and solve problems associated with their illness actively, and has shown to represent an effective paradigm across the prevention spectrum (primary, secondary, and tertiary).

Source: Adapted from NICE, 2016; NICE, 2015a; Grady and Gough, 2014; Carey and Doherty, 2012; WHO, 2003; Vermeire et al., 2001; Glasgow and Anderson, 1999.

1.9 Measurements of medication adherence and self-care

Measurement of medication adherence

Numerous tools are available to measure medication adherence; none are considered a gold standard, and thus, a combination of methods is usually recommended (Anghel et al., 2019; Lam and Fresco, 2015). There is non-definitive general guidance to assist researchers and HCPs in choosing appropriate tools that can investigate the extent of medication adherence and the reasons behind this problem to orchestrate follow-up interventions (Anghel et al., 2019; Lam and Fresco, 2015). Thus, choosing the appropriate method to measure medication adherence can be challenging. The selection of method(s) to monitor adherence should be based on each clinical setting, individual attributes, and goals/resources of the study. Economic consideration, practicability (easy to use), and accuracy are some parameters that can influence the decision (Anghel et al., 2019; Lam and Fresco, 2015).

Table 1.6 describes the adherence methods, including their advantages, disadvantages, and parameters measured. The variety of adherence methods can be divided into indirect and direct methods. Indirect detection methods include self-reporting and interviews, while direct measures include the detection of a chemical in a body fluid. (Anghel et al., 2019; Lam and Fresco, 2015; Chatterjee, 2006; Vermeire et al., 2005). Direct methods are usually more expensive, invasive, and difficult to perform. However, they are more reliable in assessing adherence, for example, measuring biomedical markers such as HbA1c, which represent adherence over a period of time (Anghel et al., 2019; Lam and Fresco, 2015; Chatterjee, 2006; Vermeire et al., 2005). However, poor glycaemic control may not necessarily be due to poor adherence. Another way is to measure drug concentrations which have limitations due to individual variations in their absorption, metabolism, and excretion of drugs. (Chatterjee, 2006). Generally, direct observation is mainly used in restricted situations, whereas indirect measures are more frequently used (Anghel et al., 2019; Lam and Fresco, 2015; Chatterjee, 2006; Vermeire et al., 2005). Indirect measures include process measures such as interviews, diaries, tablet counts, electronic devices, prescription filling dates, and therapeutic and preventive outcome measures (Vermeire et al., 2005). Patient self-report measures are known to overestimate adherence (Nieuwlaat et al., 2014). However, measurements with evidence of their validity and reliability are available (Nieuwlaat et al., 2014).

Table 1.6 Adherence methods, including their advantages, disadvantages, and parameters measured.

	Methods of assessment	Advantages	Disadvantages	Parameter measured
Direct	**Measurement of drug/ metabolite levels**	• Accurate. • Objective, proving the ingestion of the drug.	• Costly. • Invasive. • Inter individual differences.	• Concentration of the drug/metabolite.
Indirect	**Pill counts**	• Simple. • Mostly used in clinical trials.	• No evidence of ingested medication.	• Number of doses missed.
	Electronic databases	• Easy to use. • Inexpensive. • Non-invasive, patients not aware that they are being monitored. • Especially specific to identify non-adherent patients.	• Evidence of the drug being dispensed but not ingested.	• Medication possession ration (MPR). • Proportion of days covered (PDC).
	Self-reported (Questionnaires, visual analogue scales)	• Easy to use. • Inexpensive.	• Overestimate adherence. • Subjective, influenced by recall or reporting bias.	• A value that is interpreted in regard to a pre-established cut-off point.
	Electronic monitoring Systems (such as Medication event monitoring system (MEMS))	• Objective. • Additional information on the degree of adherence. • One of the most accurate methods.	• The patient is aware of the evaluation. No actual evidence that the medication is being ingested.	• Overall percentage of doses taken. • Dosing regimen.

Source: Adapted from Anghel et al., 2019

Morisky Medication Adherence Scale

The Morisky Medication Adherence Scale (MMAS; 4 items) is a brief, easy, and commonly used questionnaire to assess medication adherence in chronic diseases, including diabetes. MMAS was later revised to an 8-item tool. Both established and revised had poor internal consistency and acceptable convergent validity. Improvements in its psychometric properties are needed before being widely used (Lu et al., 2016).

The Medication Adherence Report Scale (MARS) is five items on a 5-point Likert-type scale, a self-reported measure of non-adherence behaviour to prescribed medications. Its

internal consistency was reported to range from .65 to .97, and there is a lack of evidence about its validity. Hence, further testing and modification of the instrument are needed before it is widely used (Lu et al., 2016).

Measurement of self-care

As already strengthened, self-management is a cornerstone for improving diabetes management, quality of life, and reducing the risk of complications and health care expenditure (Lu et al., 2016). Apart from medication adherence, self-management includes adhering to other relevant self-care activities (IDF, 2017b; WHO, 2016a). Thus, assessing all relevant components of diabetes patients is crucial (Lu et al., 2016). Consequently, apart from the tools used for solely evaluating medication taking, various self-care instruments exist to assess patients' diabetes self-care, such as healthy eating, physical activity, SMBG, foot care, etc. Various strategies have been reported in the literature. According to Lu et al., 2016 systematic review instruments evaluating diabetes self-care are still developing, with 22 of 30 tools reviewed being developed during the past years (Lu et al., 2016; WHO, 2003). Those measurements might be multidimensional or unidimensional (Lu et al., 2016). Table 1.7 presents some of the instruments used to measure diabetes self-care activities.

Psychometrically sound instruments are a prerequisite to accurately assessing and detecting an intervention program's impact on diabetes control behaviours (Lu et al., 2016). However, despite this seeming abundance of measurement options, the number of practical and psychometrically satisfactory instruments is indeed limited (Lu et al., 2016). Moreover, 20 of the 30 instruments included in the Lu et al., 2016 systematic review were validated only once (Lu et al., 2016).

Indisputably, there is no "gold standard" for measuring adherence behaviour. Lu et al., 2016 concluded that the Summary of Diabetes Self-Care Activity (SDSCA), Diabetes Care Profile (DCP), Medication Adherence Report Scale (MARS), and MMAS are the most widely used and well-validated instruments among the identified instruments (Lu et al., 2016). It is also practicable to combine multidimensional and unidimensional instruments. Initially, identifying general problems with a multidimensional tool and then finding the specific underlying problem using a specific instrument. This could provide patient-centred, culturally specific care by using it individually for each patient (Lu et al., 2016; NICE, 2015a; WHO, 2003). In addition, after identifying the optimum instrument

to use, the interpretation of scoring is also an essential factor. However, information about interpreting scores obtained from the self-care instruments was frequently omitted. Lu et al., 2016 stated the importance of identifying a meaningful threshold to enhance the clinical utility of self-care assessment tools. They highlighted the need for further research to identify it (Lu et al., 2016).

Table 1.7 Instruments used to measure diabetes self-care activities.

Methods of assessment	Content areas	Number of items assessed	Response format	Validity and Reliability	Advantages	Disadvantages	Source of information/ references
Diabetes Care Profile (DCP)	• Self-care adherence and diet adherence. • Evaluates individuals' adherence to a treatment regimen, SMBG, weight control, medication, exercise, and diet adherence.	8	5-point Likert-type	Its validity and reliability are tested and evident.	A comprehensive standardized self-administered instrument.	Does not fully address the scope of important self-care behaviours of T2DM management, such as foot care.	(Lu et al., 2016).
Diabetes Self-Care Scale (DSCS)	• Modified from the Insulin Management Diabetes Self-Care Scale.	35	6-point Likert-type	The reliability of this scale is satisfactory (ranging from .80 respondent separation reliability and .99 item separation reliability).	The DSCS was adapted in Turkish with great internal consistency.	Further validation is needed.	(Lu et al., 2016).
Summary of Diabetes Self-Care Activity (SDSCA)	• Overall diet, dietary intake of specific foods, exercise, medication taking, and SMBG.	12	4–7 point Likert-type	Demonstrated evidence of adequate psychometric testing is generally reliable and recommended for a standardized evaluation of quality improvement intervention in T2DM in Canada.	Reliability was not demonstrated for the specific diet subscale.	Generally, reliability was not resulted for the specific diet subscale. In 2000, the SDSCA was revised to include foot care and cigarette smoking items. However, most recent studies revealed unsatisfactory	(Lu et al., 2016; Hernandez-Tejada et al., 2012).

Table 1.7 Instruments used to measure diabetes self-care activities.

Methods of assessment	Content areas	Number of items assessed	Response format	Validity and Reliability	Advantages	Disadvantages	Source of information/ references
						internal consistency for the revised scale. The revised SDSCA validity needs further rigorous testing.	
Diabetes Self-Care Activity Questionnaire – Greek version Diabetes Self-Care Diabetes Self-Care Activity Questionnaire – Greek version (DSCAQ - Greek version)	• Adjusting four existing questionnaires: SDSCA, Patient Health Questionnaire, 12-item Short Form Health Survey, and Diabetes Self-care Behaviours and Barriers Instrument. • Covers 7 areas: sociodemographics, risk factors, physical and mental health, physician-patient communications, self-care activities, self-care recommendations, and compliance.	38 items	-	The validity of this instrument was evaluated in Greece and yielded satisfactory internal consistency, test-retest reliability, and supported evidence of validity.	It can be used to reliably measure treatment adherence among Greek people with T2DM.	Validity of this instrument is limited to those in Greece unless further validation is done with diverse populations and languages.	(Lu et al., 2016; Intas et al., 2012)
Diabetes Knowledge Test (DKT)	• It tests general knowledge of diabetes, with the 14	23	-		Some items of the DKT may be useful if there is a good	The DKT is not recommended for evaluating self-management	Fitzgerald et al., 2016; Hernandez-Tejada, 2012;

Table 1.7 Instruments used to measure diabetes self-care activities.

Methods of assessment	Content areas	Number of items assessed	Response format	Validity and Reliability	Advantages	Disadvantages	Source of information/ references
	items addressing individuals not using insulin and the entire 23 items to patients who use insulin.				item-to-program content match.	education programs, as it is not correlated to the particular educational content of the program.	Collins et al., 2011
Diabetes Empowerment Scale (DES)	• The original questionnaire contained 37 items; the current DES consists of 28 items, and the DES (DES-short form) consists of an 8-item short form. • Managing psychosocial aspects of diabetes, assessing dissatisfaction and readiness to change, setting and achieving goals, overcoming barriers, motivating oneself, asking for support, etc.	37	-	Preliminary evidence exists about DES-SF and DES validity and reliability.	Measure the psychosocial self-efficacy of people with diabetes.	Further research is needed for its validity and reliability.	(Hernandez-Tejada, 2012; Anderson et al., 2003; Anderson et al., 2000)

1.10 Ways of improving adherence to treatment

Adherence to medication taking

Reasons for medication non-adherence are also complex (Donovan et al., 2022; Easthall and Barnett, 2017). Literature in this area describes a range of theories and models to explain and predict medicating taking behaviours (Donovan et al., 2022; Easthall and Barnett, 2017). It is well known that non-adherence may consist of two overlapping categories; intentional and unintentional (Horne et al., 2006). Unintentional non-adherence occurs when the patient wants to follow the agreed treatment but fails to do so (Horne et al., 2006). This can be caused by barriers beyond patients' control, such as poor recall or difficulties in understanding instructions, inability to pay for the treatment, or simply forgetting to take it. Intentional occurs when the patient decides not to follow treatment. This may be led by beliefs and preferences that influence the person's perceptions of the treatment and motivation to start and continue with it (NICE, 2009; Horne et al., 2006).

To date, a plethora of interventions have been developed to address the challenge of medication non-adherence in adults. However, these have shown limited effectiveness in improving adherence and clinical outcomes (Nieuwlaat et al., 2014). A Cochrane review of adherence interventions designed to target older patients prescribed multiple medications found a lack of high-quality evidence on intervention effectiveness, and interventions were not commonly tailored to individual patient-reported barriers to adherence (Cross et al., 2020). It has been proposed that psychological theories may guide the development of more effective complex adherence interventions by targeting causal determinants of behaviour (Easthall and Barnett, 2017). Methods to develop such interventions are lacking, but updated guidance on complex intervention development from the Medical Research Council (MRC) suggests that approaches such as patient-centred design could be helpful (Skivington et al., 2021; O'Cathain et al., 2019; Bleijenberg et al., 2018; Craig et al., 2008a; Craig et al., 2008b).

Some reviews of digital communication to improve medication adherence have also suggested that their use may be optimized when delivered alongside other components such as face-to-face consultations or telephone appointments (Donovan et al., 2022; Mistry et al., 2015; Nieuwlaat et al., 2014; Ciciriello et al., 2013; Fenerty et al., 2012). However, the contribution of these additional components to overall effectiveness is unclear (Donovan et al., 2022).

The results of Nieuwlaat et al. 2014 systematic review, focusing on enhancing medication adherence, again showed generally complex and different interventions (Nieuwlaat et al., 2014). The interventions were provided by HCPs, including a pharmacist, to support family, patients, and peers. Health professionals delivered education, counselling, or daily treatment support. Once again, which of the interventions improved adherence was not identified. More advanced methods are needed, including better interventions, better ways of measuring adherence, and studies that include sufficient patients to draw conclusions (Nieuwlaat et al., 2014).

Adherence to self-management

A systematic review focusing on improving self-management (not solely improving medication-taking) to a wide range of diseases in primary health care practice resulted in evidence-based strategies based on theoretical models in a collaborative partnership approach between patients and providers, tailored to patients' needs, ongoing follow-up, and include combinations of services aiming to improve patient's disease or treatment knowledge, independent monitoring of symptoms, encouraging self-treatment through a personalized action plan and enhancing responsibility in medication adherence and lifestyle choices were the components of more effective interventions (Dineen-Griffin et al., 2019). Theoretical models provided a strong base for effective SMS interventions, which led to improvements in clinical indicators, health-related quality of life, self-efficacy (confidence to self-manage), and disease knowledge or control (Dineen-Griffin et al., 2019). It concluded that future research should build on these findings for optimal self-management support service design and upskilling healthcare providers to effectively support patients in this collaborative process (Dineen-Griffin et al., 2019).

Furthermore, a thematic analysis review identified that self-management characteristics among patients with complex health needs are exacerbated by socioeconomic insecurity (Gobeil-Lavoie et al., 2019). Self-management challenges included the lack of prioritisation of self (the number of self-care activities surpasses the amount of time available) and motivation, greater risk for depression, increased risk of presenting poor self-efficacy, and increased risk of receiving conflicting information by the numerous HCPs that they meet (Gobeil-Lavoie et al., 2019). However, the review emphasized the opportunity to use personal experience and knowledge acquired in the past and apply them in various situations to manage their health better (Gobeil-Lavoie et al., 2019).

Two other reviews on interventions focusing on improving adherence to treatment recommendations (not solely improving medication-taking but excluding physical and diet) for diabetes patients were identified (Vermeire et al., 2005; Renders et al., 2000). Heterogeneous outcomes were revealed with various adherence measurement instruments (Vermeire et al., 2005; Renders et al., 2000). Vermeire et al., 2005 concluded that pharmacist-led interventions, nurse-led interventions (which mainly included a telephone follow-up), home aids (mailed educational materials, appointment reminders, or home health aides visits), diabetes education, an adaptation of dosing and frequency of medication taking showed a negligible effect on a variety of outcomes including HbA1c (Vermeire et al., 2005). Furthermore, arrangements for follow-up (organisational intervention), multiple interventions in which patient education was added or the nurse's role was enhanced, reported favourable effects on patients' health outcomes (Renders et al., 2000). Pharmacist-led interventions included mailed prescription-refill reminders, specialised packaging, making recommendations regarding diabetes therapy, diabetes education, medication counselling, or a combination, with various outcomes and evaluating different areas (Vermeire et al., 2005; Renders et al., 2000; Jaber, 1996; Hawkins 1979).

However, the reviews identified concluded that interventions aimed at improving adherence to treatment in diabetes required further research (O'Connell et al., 2018; Vermeire et al., 2005; Renders et al., 2000). A notable gap in interventions focusing on multimorbidity was observed (O'Connell et al., 2018). Moreover, comprehensive description of the services provided were not identified in most of the studies reviewed (O'Connell et al., 2018; Vermeire et al., 2005; Renders et al., 2000). Also, adherence and valid adherence measurements were not well defined (Renders et al., 2000; Vermeire et al., 2005). This increasing the bias in research and hinder drawing reliable and valid conclusions (Renders et al., 2000; Vermeire et al., 2005). Finally, the interventions short-term and long-acting effects or need to be repeated periodically was neither well explained (Vermeire et al., 2005).

1.11 Patient-centred design

Patient centred design has been increasingly highlighted to play a valuable role in healthcare (Joint Commission of Pharmacy Practitioners, 2023; Abubakar and Sinclair, 2020; O'Cathain et al., 2019; NICE, 2015b; NICE, 2012). Patient self-care or self-management implies that the patient actively monitors and responds to changes in

environmental and biological conditions by making adaptive adjustments in the different aspects of diabetes treatment to maintain adequate metabolic control and avoid the probability of developing complications (WHO, 2003). Therefore, it is beyond following rigidly prescribed rules and is conceptualized as the active voluntary involvement of the patient in managing his/her disease in close collaboration with healthcare providers (WHO, 2003). Based on the FIP statement, the future healthcare system will move to a more personalized and patient-centred one, allowing people to take much more responsibility for managing their healthcare and thus maximize the chances of a successful outcome (FIP, 2021b).

In the UK National Health Service (NHS), it has been recognised that patient involvement in decision-making and managing their long-term conditions enable health services to deliver better health outcomes and reduce pressures and health costs (National Health Services, 2006). Pharmacists' Patient Care Process outlined by the Joint Commission of Pharmacy Practitioners highlights the cyclical nature of patient care, starting with collecting pertinent patient information, assessing, and analysing the collected information, developing and implementing a plan in collaboration with the patient, and following up on key metrics (Joint Commission of Pharmacy Practitioners, 2023; Abubakar and Sinclair, 2020). In this manner, allowing the patient to take a more active role in their care may be positively associated with the satisfaction of care and contribute to improved outcomes (Abubakar and Sinclair, 2020; Kuipers et al., 2019). There is an appreciation that patients can become 'experts' in living with their condition and, through collaboration with HCPs, can play a role in the healthcare system as engaged agents to ensure that their own needs are appropriately met (McDowell et al., 2009). Moreover, results from studies show that patients are becoming increasingly interested in playing a more prominent role in their health (Abubakar and Sinclair, 2020).

1.12 The philosophy of empowerment

Empowerment is defined as supporting the patient to discover and develop the inherent capacity to be responsible for one's own life (Funnell et al., 1991). It is a concept developed or discovered to address the non-adherence problem, especially to chronic disease (such as diabetes), which radically differs from the treatment of acute illness (Anderson and Funnell, 2000; Funnell et al., 1991). It is based on the recognition that each person makes many diabetes-related choices every day, and successful diabetes self-care necessitates that patients will be able to make the appropriate choices and decisions

to achieve their personal diabetes care plans and goals (Carey and Doherty, 2012; Anderson and Funnell, 2000; Funnell et al., 1991).

Health professionals are the experts on diabetes care, but only the patient is expert in their own lives. Moreover, patients are the primary decision-makers in control of the daily self-management of their diabetes. Once they leave HCP's clinic, they are in control of which recommendations they implement or ignore. The consequences of not following the guidelines only accrue directly to patients. Thus, it is the right and responsibility of the patient to manage diabetes in the way best suited to the context and culture of their lives (Funnell and Anderson, 2004; Funnell et al., 1991). HCPs will provide the knowledge and expertise about diabetes and its treatment, and patients bring expertise on their livers and what suits them the best. This approach encompasses the philosophy of empowerment or patient empowerment (Funnell and Anderson, 2004; Funnell et al., 1991). This concept is recognized among healthcare commissioners and providers with the aim of enabling health services to deliver better health outcomes and reduce health costs (McDowell et al., 2009; National Health Services, 2006).

1.13 Motivational Interview

Motivational Interview (MI) was developed in 1983 as an intervention and treatment for problem drinking, and during the 1990s was examined for other physical and chronic disorders (Salimi et al., 2016). Evidence indicates the effectiveness of MI in disease management (Salimi et al., 2016; Song et al., 2014; Welch et al., 2006). MI emphasizes understanding patients' values and their long-term interests to empower positive lasting change to empower patients and evoke them to be part of managing their disease (Salimi et al., 2016). It helps people consider why change might be important to them, evoke their personal interests to guide the conversation towards commitment to a specific action and develop a plan. To achieve these goals, therapists, in this case, the pharmacist, employ four processes: engaging, focusing, evoking, and planning (Salimi et al., 2016). MIs follow a specific structured approach and questioning technique which helps the HCPs, in this case, the pharmacist, to guide the conversation and work with patients to identify and achieve aims (Salimi et al., 2016).

In order to create "informed and active" diabetes patients, patients must be educated in self-management, equipped with information and motivation, and have self-confidence. Those elements can be achieved using MI (Salimi et al., 2016). MI is a coherent,

teachable, evidence-based approach to behaviour change counselling and a vehicle for creating a strong therapeutic alliance with healthcare specialists in long-term treatments (Salimi et al., 2016; Welch et al., 2006). Evidence indicates the effectiveness of MI in disease management (Salimi et al., 2016; Song et al., 2014; Welch et al., 2006). A systematic review (concerning various diseases, including diabetes and weight control, exercise, and eating disorders) concluded that adding MI produced significant adherence effects and helped patients move from one level of treatment adherence to a higher one (Welch et al., 2006). Similar results were identified in studies evaluating the impact of MI in decreasing HbA1c level (short-term use), loss of weight, improvement of physical conditions, self-management, etc. (Salimi et al., 2016; Song et al., 2014; Welch et al., 2006).

1.14 Pharmacists' contribution to diabetes management

Evolution of pharmacists' role

World Health Organization (WHO) recognized that pharmacists are uniquely qualified, and their knowledge and expertise extend to all aspects of preparation, distribution, action, and medication use (Thamby and Subramani, 2014; WHO, 1994). In 1997, the concept of a 'seven-star pharmacist' was proposed at the third WHO Consultative Group on the Role of the Pharmacist, which defines the roles of the pharmacist as being a caregiver, decision-maker, communicator, leader, manager, life-long learner, and teacher (Thamby and Subramani, 2014; WHO, 1997). Hepler and Strand established pharmaceutical care in 1990, and with a slight change, it was accepted and used in 1998 by the International Pharmaceutical Federation (FIP) (Wiedenmayer et al., 2006). It compromises a patient-centred, outcomes-oriented practice of pharmacy, which have been associated with improved quality and cost-effectiveness of healthcare systems, reduced medicine-related adverse events, morbidity, and mortality, and improved quality of life (Wiedenmayer et al., 2006). This practice model promoted pharmacists' role as critical healthcare team members responsible for medication therapy outcomes, seeking to optimize patient outcomes and ensuring the effectiveness, rationale, and safety of medicines use (Thamby and Subramani, 2014; Wiedenmayer et al., 2006).

A more recent update to the pharmacists' profession is the decision that all registered pharmacists within the UK will automatically be annotated as independent prescribers from 2026 (General Pharmaceutical Council, 2022). Moreover, the RPS Wales stated the ambition that every patient-facing pharmacist will be qualified to prescribe by 2030 (RPS,

2023). Pharmacists acquire skills and knowledge to support other healthcare workers' efforts to ensure patients receive high-quality healthcare (Lauren and Ekpenyong, 2021; Liu et al., 2017). Due to the growing global shortage of healthcare workers, estimated to reach 15 million by 2030, it is more crucial than ever to incorporate pharmacists as critical healthcare team members (Lauren and Ekpenyong, 2021; Liu et al., 2017). FIP Policy Statement in 2010 and 2019 emphasized the need for interprofessional collaboration, enhancing pharmacists' expertise across available medicines and in supporting the global effort to address the growing issue of diabetes (Lauren and Ekpenyong, 2021; FIP, 2019b; FIP, 2010; FIP, 2006). Some barriers and regulations in some countries may prevent pharmacists from performing services outlined earlier (Bajis and Khadir, 2022; Lauren and Ekpenyong, 2021; FIP, 2019a). Nevertheless, clinicians and health policymakers should always consider incorporating pharmacists into multidisciplinary HCPs' teams (Bajis and Khadir, 2022; Lauren and Ekpenyong, 2021; FIP, 2019a).

Despite these worldwide changes in the profession of pharmacists, the organisation of pharmacy services in Cyprus remains limited. Pharmacists' main activities (both community and hospital pharmacists) are dispensing activities, and there is limited development of health professional collaboration and multidisciplinary working (PSMH, 2019b; GESY, 2018e). Although community and hospital pharmacists have the authority to access patients' records, they do not have the authority to make any changes to patients' prescriptions (PSMH, 2019b; GESY, 2018e). Upon the GESY implementation, pharmacists had the right to change a medicine only if the medicine has the same active substance and pharmaceutical form as the one prescribed, is cheaper in its drug classification and class, and the patient consents to this change (GESY, 2022). In other cases, pharmacists must contact the physicians to change the prescription. In addition, there are no standard procedures on how the pharmacist should make recommendations or clarifications to the prescriber, and the HCPs collaboration and communication depend on each individual (PSMH, 2019b; GESY, 2018e). Similarly, there is a lack of pharmacy research in Cyprus about pharmacy-led interventions (Cyprus National Bioethics Committee, 2023; PSMH, 2019b; GESY, 2018e). There are no pharmacy services such as medication review, medical rounds, and prescribing services (PSMH, 2019b). There are no regulations or supporting protocols on how pharmacists should provide advice, evaluate, and improve patients' adherence or how to review patients' medication. There is no continual professional development, training, or educational courses available in Cyprus. Universities abroad offer online courses that are not recognized in Cyprus

(KYSATS, 2024). Pharmacists could pursue a master's degree or PhD after their pharmacy degree. However, this qualification will not necessarily lead to the pharmacist's upgrade or promotion to a better role. For pharmacists, the technology is employed to order and store medication but not to view patient medication history (PSMH, 2019b). Home delivery of medicines is prohibited, and there is no regulation on virtual services by pharmacists (PSMH, 2019b). The few pharmacist-led research identified in the Cyprus National Bioethics Committee mainly concerned drug costs, drug availability and a support program for patients with β-Med anemia (Cyprus National Bioethics Committee, 2023).

Community pharmacists

There is a growing appreciation of the potential contribution of the expanded pharmacist role in primary care (Stewart et al., 2021; Anderson et al., 2019; Bradley et al., 2018). Community pharmacists have been identified as an easily accessible HCP and cost-effective platform for delivering healthcare and public health services worldwide (Bajis and Khadir, 2022; Power et al., 2020; Thomson et al., 2019;). Due to their unique position and expertise, they can offer a wide range of services; they prevent, identify, manage diseases, and collaborate with other HCPs (Bajis and Khadir, 2022). Pharmacists are community-based knowledge resources who can support patients in understanding the dangers of chronic diseases and the importance of prevention (Lauren and Ekpenyong, 2021; FIP, 2019b). In addition, they provide a less stigmatising place to identify and offer support for mood problems, as they offer a link to local health and social care (Chew-Graham et al., 2022; NICE, 2018). 89% of people in the UK live within a 20-min walk of a community pharmacy, representing a convenient and plausible public health setting to offer brief psychological interventions (Todd et al., 2014).

People with long-term conditions (LTCs), including diabetes, should be comprehensively supported within their communities, as they are twice as likely to be admitted to hospital, compared to individuals without LTCs (RPS, 2016). Community pharmacists are the HCPs that patients regularly visit without needing an appointment, are educated and aware of LTC and LTC comorbidities signs and symptoms and can detect non-treatment of valid indications, inappropriate prescribing, patients' non-adherence, inadequate monitoring, and follow-up. (RPS, 2016; Hepler, 2004). They have been recognised as appropriate in delivering care to patients following hospital discharge and services such as medicines use review or new medicines service consultation post-discharge (Khayyat

et al., 2021). Community pharmacists must be a coordinating point for hospital admission and discharge, a link between physicians and other HCPs, and a source of information for patients and HCPs (RPS, 2016; Hepler, 2004; WHO, 1994).

Pharmacist and chronic diseases

FIP Statement of Policy in 2006 and, more recently, in 2019 underlined the role of pharmacists in the prevention and treatment of chronic disease (Lauren and Ekpenyong, 2021; FIP, 2019b; FIP, 2006). The massive burden of chronic disease, including diabetes, an ever-growing and complex range of medicines, the low rate of adherence to long-term therapy for chronic conditions, and more than half of people failing to use their medication correctly, require a redefined and reoriented of the pharmacists' role (Lauren and Ekpenyong, 2021; RPS, 2016; Wiedenmayer et al., 2006). The RPS and FIP Council highlighted the need to enhance the pharmacists' role in encouraging adherence to long-term treatments to improve medication adherence (RPS, 2016; Wiedenmayer et al., 2006; FIP, 2003).

Pharmacists can support individuals to maintain good health and well-being, avoid complications associated with their existing LTC, and prevent the development of further LTCs (Lauren and Ekpenyong, 2021; RPS, 2016). Pharmacists have the expertise to develop individual drug treatment care for each patient. Pharmacists can empower patients by providing helpful information and counselling and engaging them in dialogue, enabling them to manage their health and treatment (RPS, 2016; Wiedenmayer et al., 2006). Shared-decision-making on how to take medicines in concordance approach will optimize health outcomes, reduce the number of medicine-related adverse events, minimize the number of medicines wasted, and improve adherence to medical treatment (RPS, 2016; Wiedenmayer et al., 2006).

Pharmacists and diabetes disease

Pharmacist-led interventions can improve clinical outcomes for diabetes patients, including reductions in HbA1c, BP, and low-density lipoprotein cholesterol (LDL) (Bajis and Khadir, 2022; Lauren and Ekpenyong, 2021; AADE, 2020; Power et al., 2020; FIP, 2019a; Fazel et al., 2017; Chisholm-Burns et al., 2010).

A meta-analysis concluded that pharmacists' interventions supported self-management of diabetes through education on diabetes, medicines, and lifestyle and resulted in reducing

HbA1c, BP, and cholesterol levels (LDL and total), reduced adverse events, increased self-management skill development and medication adherence, and improved quality of life compared to usual care (Desse et al., 2021). In addition, studies stated that pharmacists' diabetes services are cost-effective and can potentially save healthcare costs (Bajis and Khadir, 2022; Lauren and Ekpenyong, 2021; Abdulrhim et al., 2020; Wang et al., 2016).

Furthermore, the Primary Care Diabetes Society publication reinforced the importance of pharmacists' role, as part of a multidisciplinary team to address diabetes disease (Lauren and Ekpenyong, 2021; Primary Care Diabetes Society, 2021). Pharmacy services to prevent and manage T2DM can include counselling in diet and nutrition, screening patients (BG, BP levels, etc.), and referring them to appropriate care where relevant (Lauren, 2021; FIP, 2020). Pharmacists can reinforce diabetes education, including medication, exercise, dietary, and diabetes management (Lauren, 2021; Lauren and Ekpenyong, 2021). They can reinforce the other healthcare providers' recommendations and support patients in appropriately managing their diabetes disease (Lauren, 2021).

1.15 Digital health interventions

Population growth, rising incidence of diabetes (and other chronic diseases), and unmet needs for more personalised care demand a new approach to delivering healthcare services worldwide, enhancing access, quality, efficiency, and cost-effectiveness (WHO, 2019b; World Health Assembly, 71, 2018a; Stroetmann et al., 2010; WHO, 2010). Digital health interventions (DHIs), including m-Health, provide a significant new opportunity to achieve these goals and offer integrated care (WHO, 2019b; World Health Assembly, 71, 2018a; Stroetmann et al., 2010; WHO, 2010). It is one of the top priorities of the WHO's urgent health challenges for the next decade, and together with the International Telecommunication Union proposed the creation of a joint mHealth Hub for the European Union (EU), the EU mHealth Hub Project - Horizon 2020 (FIP, 2021b; WHO, 2020; WHO, 2019b; World Health Assembly, 71, 2018a; World Health Assembly, 71, 2018b). Also, the 2030 Sustainable Development Goals agenda, set by the United Nations, includes mHealth as an integral component of reaching Universal Health Coverage by 2030 (FIP, 2019c).

Technology has been rapid expansion in the past decades, changing the lifestyle of individuals and revolutionizing how they communicate with each other and seek and

exchange information (FIP, 2021b; WHO, 2010). Modern technology includes computers, the internet, cell phones, web-based apps, such as email, teleconsultations, and multimedia approaches (WHO, 2010). As of January 2023, 5.16 billion people around the globe were active Internet users compared to 4.54 billion in 2020 (Petrosyan, 2023; FIP, 2021b). The number of smartphone users worldwide reached almost 6.6 billion in 2022 and is forecast to exceed 7.8 billion by 2028 (FIP, 2021b; Taylor, 2023). As patients are interconnected via mobile devices and different technologies in other aspects of their life, the healthcare industry is leveraging this technology to engage patients and assist in managing chronic disease states (Abubakar and Sinclair, 2020). Simultaneously, patients use the internet to retrieve health information and obtain various health services or products (Söderlund and Griffin, 2021).

The Coronavirus disease (COVID-19) pandemic was catalysed in the technology uptake (FIP, 2021b). The digitalisation of healthcare practices was growing exponentially and shifted to virtual visits, virtual care, remote patient monitoring, and websites and chatbots (for risk assessment, screening, and triage) (FIP, 2021b; Fagherazzi et al., 2020). This has also driven a rapid shift in consumer behaviour in pharmacy practice (FIP, 2021b). This transformation created a need for researchers, policymakers, and HCPs to integrate DHI into current practices (FIP, 2021b). Consequently, it is essential to leverage the opportunity created by the COVID-19 pandemic on DHIs, emphasising the need for solidarity between HCPs in harnessing technology for digital health (FIP, 2021b; The Pharmaceutical Journal, 2020).

Classifications of Digital Health Interventions

DHIs encompass an endless list of definitions related to interventions employing technology (FIP, 2021b; WHO, 2018, WHO 2011 reports). Many definitions were identified through the literature which concern the use of technology to provide health care, including eHealth, telemedicine/telehealth, mobile health, etc. (WHO, 2017). A study in 2007 found 104 peer-reviewed definitions of the word “telemedicine” (WHO, 2010). A lack of generally accepted and standardized definitions and loose terminology have been identified in the literature (WHO, 2018; WHO, 2011; WHO, 2010). The latest formal report found through the literature aiming at the classification of technologies employed in health was published in 2018 and uses the term DHI to articulate interventions using technology to address health needs (FIP, 2021b; WHO, 2018). Table

1.8 describes the four primary overarching grouping of DHI. In this study, all technology interventions will be mentioned using the term DHIs adopted by WHO, 2018 report.

Moreover, an attempt to present subcategories/synonyms of digital health and provide descriptions or definitions of those terms found in WHO and FIP reports was made and displayed in Appendix 1.1.

Table 1.8 Organization of digital health interventions into the following overarching groupings based on the targeted primary user, adopted by WHO, 2018

Four overarching groupings of digital health interventions	
Interventions for clients	Clients are members of the public who are potential or current users of health services, including health promotion activities. Caregivers of clients receiving health services are also included in this group.
Interventions for healthcare providers	Healthcare providers are members of the health workforce who deliver health services.
Interventions for health system or resource managers	Health system and resource managers are involved in the administration and oversight of public health systems. Interventions within this category reflect managerial functions related to supply chain management, health financing, and human resource management.
Interventions for data services	Data services are consisted of crosscutting functionality to support a wide range of activities related to data collection, management, use, and exchange.

Source: Adopted from FIP, 2021b; WHO, 2018.

1.16 Pharmacists and digital health interventions

A significant number of published studies on DHIs evolving pharmacists could also be retrieved (Viegas et al., 2022). The majority were published between 2019 and 2022, during the time of the COVID-19 pandemic, and highlighted the importance of pharmacists to continue to deliver pharmaceutical care, despite face-to-face delivery not being possible (Viegas et al., 2022; Killeen et al., 2020). FIP statement reports in 2021, 2019, and 2017 emphasized the need for pharmacists to integrate evidence based DHIs into their daily practices to facilitate better patient care and improve patient outcomes (FIP, 2021a; FIP, 2019c; FIP, 2017). It also highlighted the need for pharmacists to educate patients in digital literacy so patients can feel empowered to make informed choices (FIP, 2021a).

1.17 Digital health effectiveness evidence and future research

Digital health has become one of the essential strategies in ameliorating the delivery of health care, showing promising results in improving health outcomes by improving quality and coverage of care, increasing access to health information, services, and skills, promoting positive changes in health behaviours and enabling a more patient- centred care models. (World Health Assembly, 71, 2018a; WHO, 2017).

Mobile diabetes support generated a statistically significant improvement in patient glycaemic control in the short- and long-term (over six months) and medication adherence (Vervloet et al., 2014; Liang et al., 2011). Many reviews support their potential to enhance patient self-management and medication adherence and reduce adverse drug events (Viegas et al., 2022; Niznik and Kane-Gill, 2018; Fang, Maeder, and Bjering, 2016; Lee, Ralston, Beautrais, and Larkin, 2014; Sarabi, Sadoughi, Orak, and Bahaadinbeigy, 2016; Sarkar and Sivashankar, 2015; Schneider, 2013; Vervloet et al., 2012). A meta-analysis has also found that text messages can improve medication adherence (Thakkar et al., 2016). Some reviewers have also concluded that two-way communication may be more effective than one-way (Donovan et al., 2022). Also, studies in the literature support that DHI are acceptable to patients (Anglada-Martinez et al., 2015; Park et al., 2014). However, reviews on using a wide range of digital communication technologies to support medication adherence have drawn mixed conclusions.

In addition, effective implementation, management, and evaluation are needed to be valuable (WHO, 2017; WHO, 2016b; Agarwal et al., 2016). Although eHealth, particularly m-Health activity, is growing in countries, standardized approaches for applying digital health in health systems and services are still being researched (World Health Assembly, 71, 2018b). Disadvantages or areas which need further address regarding DHIs include operational difficulties, initial time, money, and effort to start up new DHIs, security, ethical and legal concerns (concerning issues such as ownership, privacy, human rights, commercialisation, and monetisation of health data), and reluctance to use technology by patients and providers (FIP, 2021a; Poudel and Nissen, 2016). However, pharmacists are in a position and acquire the skills to support and guide patients in making informed healthcare choices involving digital health solutions in their digital journey while also helping ensure their patients' rights are maintained (FIP, 2021a; FIP, 2021b; The Pharmaceutical Group of the European Union, 2021). However, the lack of pharmacy regulation laws, pharmacists' digital health training, and remuneration

models to enable pharmacist-led use of digital technologies for pharmaceutical care to benefit patients while ensuring sustainability are aspects that require to be resolved in the future (FIP, 2021a; Söderlund and Griffin, 2021; Poudel and Nissen, 2016).

Limited literature is available on the design and implementation of digital health training curricula, particularly emphasizing the pharmacist's role in promoting digital health use (FIP, 2021b; Hincapie et al., 2016; Vlashyn et al., 2020). Contrary to that, it is apparent that a clear need for enhancing training for digital skills and digital literacy would be beneficial for improving patient outcomes (FIP, 2021b; MacLure K, Stewart DC, 2018; European Union, 2019). Such skills could positively affect pharmacists' professional development and job satisfaction (FIP, 2021b; Alhaqan et al., 2021).

Moreover, interoperability should be a prerequisite to any digital technology development (FIP, 2021a; Lehne et al., 2019). Interoperability can be defined as *"the ability of different applications to access, exchange, integrate and cooperatively use data in a coordinated manner through the use of shared application interfaces and standards, within and across organizational, regional and national boundaries, to provide timely and seamless portability of information and optimize health outcomes"* (WHO, 2021, page 42). Medical information is only helpful if it can be turned into meaningful information, which could be accomplished by implementing interoperability (Lehne et al., 2019). The need for internationally recognised interoperability standards, in addition to recognised terminology and taxonomy, should be strongly advocated. It is crucial for a prosperous, swift, and fluid flow of information access, exchange, integration, cooperative use, and seamless portability within health information systems worldwide (FIP, 2021a).

Findings from a FIP survey published in 2021 titled "Digital health in pharmacy education: Developing a digitally enabled pharmaceutical workforce" highlighted that new digital technologies must be people-centred, high-quality, evidence-based, effective, efficient, inclusive, equitable, and trustworthy to be integrated into practice. The FIP report concluded that further work is required to wholly leverage digital health technologies in community pharmacies. The biggest challenges in practice are the lack of enabling policies and guidance, technical limitations, and access to data (FIP, 2021b).

1.18 Conclusion

Diabetes is a chronic disease affecting people globally and has been characterised as an epidemic and pandemic (IDF, 2021). Cyprus had one of the highest prevalences of

diabetes among other European countries (IDF, 2021). Achieving optimal management of diabetes can essentially prevent or delay the progression of diabetes (IDF, 2017a; WHO, 2016a; NICE, 2015b). Self-management of diabetes is fundamental for the optimal management of diabetes. However, studies indicate low adherence rates and a lack of patient empowerment and knowledge, which result in sub-optimal diabetes management. The establishment of a standardized protocol and facilities for patient-oriented interventions through DSME, continuous review of patients, and multifactorial interventions, within primary health-care settings, with an established referral and back-referral system involving multifaceted professionals are the fundamental principles for sound management of diabetes (IDF, 2017a; WHO, 2016a). Evidence suggests that interventions should focus on the patient centred model based on psychological theories and address multimorbidity (Joint Commission of Pharmacy Practitioners, 2023; Abubakar and Sinclair, 2020; O'Cathain et al., 2019; O'Connell et al., 2018; Easthall and Barnett, 2017; NICE, 2015b; NICE, 2012). Moreover, pharmacists must leverage their accessibility and expertise to address this pressing global health issue in their communities. Also, new technologies, such as DHIs, can be a catalyst for providing the type of intervention mentioned above and are a promising area for further research (WHO, 2016b).

Despite studies identifying successful strategies to improve diabetes management, the best way to deliver them and which intervention is more effective are still being searched. Nevertheless, future research is required to meet the complexity of self-management of T2DM. Further rigorous studies are necessary to identify the optimum type of intervention and how it should be delivered (Nieuwlaat et al., 2014). Those intervention and evaluation processes should be clearly explained (O'Connell et al., 2018; Vermeire et al., 2005; Renders et al., 2000).

End of Chapter One

Chapter Two

Scoping review

2.1. Introduction

The present chapter demonstrates a scoping review of research on digital health interventions (DHIs) supporting the self-management of type 2 diabetes mellitus (T2DM). Heterogeneity in methods and discipline exists regarding DHI improving diabetes adherence to treatment. For these reasons, a scoping review was chosen as the appropriate method to map the research done in this area (Tricco et al., 2018). Preferred Reporting Items for Systematic Reviews and Meta-analysis Extension for Scoping Reviews (PRISMA-ScR), described in Tricco et al., 2018 study, were used to guide the reporting of this scoping review (Tricco et al., 2018). The objectives, methods employed, results, and discussion of the scoping review results are reported in this chapter.

2.2. Scoping literature review aim and objectives

Research question: "What has been done, primarily delivered by pharmacists or which can potentially be feasible in a pharmacy setting and fit pharmacists' professional skills, to support self-management of T2DM using DHIs? / "To what extent can DHIs, which fit pharmacists' profession, support self-management of T2DM."

Aim: To identify ways DHIs are used (mainly by a pharmacist) to support self-management of T2DM and which were effective.

Objectives:

- To identify the range and uses of DHIs in improving self-management of T2DM primarily delivered by pharmacists or which can potentially be feasible in a pharmacy setting and fit pharmacists' professional skills.
- To identify specific outcomes where DHIs aimed to improve self-management of T2DM and whether they were effective.

2.3. Methods of the scoping literature review

Protocol of the scoping literature review

A protocol was drafted based on the PRISMA - Protocols (PRISMA-P) (Shamseer et al., 2015; Moher et al., 2015). The protocol was developed *a priori* based on pre-defined eligibility criteria and a methodological approach to ensure consistency and provide a clear and explicit plan for the scoping review (Moher et al., 2015).

Eligibility criteria of the scoping literature review

DHIs are significantly developing and offering a list of services, and heterogeneous terminology currently exists, as described in chapter 1. Thus, interventions involving mobile phones, phones, applications (apps), websites, internet platforms, or wireless devices were included. Studies were eligible according to the criteria outlined below and summarized in Table 2.1.

Table 2.1 Eligibility criteria.

Inclusion criteria		
Study design	Evaluation studies; randomized controlled trials, non-randomized clinical trials, interrupted time series, and case studies. Quantitative, qualitative, and mixed-method studies.	
Setting	All settings included aspects that could also work in primary settings/outpatient services and could potentially be feasible in a pharmacy setting and fit pharmacists' professional skills. For example, diabetes clinics in a hospital setting that serves outpatients.	
	Inclusion criteria	**Exclusion criteria**
Intervention	• Primary/outpatient services. • Interactive digital health interventions. • Primarily delivered by pharmacists or which can potentially be feasible in a pharmacy setting and fit pharmacists' professional skills.	• Not interactive. • Solely integration of electronic records. • Solely tracking and sending diabetes -related measurements (such as blood glucose) to healthcare professionals. • Do not fit pharmacists' profession (e.g., psychological support).
Participants	• 18 years or older. • Solely type 2. • Type 1 and 2 diabetes. • Type 2 diabetes and other comorbidities/diseases.	• Solely type I diabetes. • Solely assessing the engagement of family/friends. • Solely evaluating other diseases and comorbidities of diabetes (e.g., gestational diabetes, kidney function, pain, etc.). • Specific populations (e.g., Veterans).

Information sources of the scoping literature review

PubMed and IPA bibliographic databases were searched from 23/02/2018 (PubMed) and 15/04/2018 (IPA) to 18/02/2023 to identify potentially relevant documents. Literature search strategies were developed using medical subject headings (MeSH). The final search results were exported into EndNote.

Due to the heterogeneity of terminology in DHIs, particularly m-Health, MeSH terms definitions were searched in the PubMed database. The results indicated that

"telemedicine" was the most appropriate term for the proposed scoping review. The MeSH term definitions identified in the PubMed database are shown in Table 2.2.

The MeSH terms searched in PubMed were "Telemedicine," "Diabetes Mellitus," and "Self Care." Through the IPA database, two keywords were employed, namely "Diabetes Mellitus" and "Telemedicine". The search strategy and number of retrieved studies for each database are reported in Table 2.3.

Table 2.2 Mesh terms definition as found in PubMed database.

Definition	Explanation
Telemedicine: (mobile health, m-Health, eHealth)	Delivery of health services via remote telecommunications. This includes interactive consultative and diagnostic services. Year introduced: 1993
Self-Care	Performance of activities or tasks traditionally performed by professional health care providers. The concept includes care for oneself or one's family and friends. Year introduced: 1981

Table 2.3 Search strategy and studies retrieved after reading title and abstract.

Database	Date of search	Search strategy	Citations retrieved
PubMed	From 23/02/2018 to 18/02/2023	"Telemedicine"[Mesh]) AND "Diabetes Mellitus"[Mesh]) AND "Self Care"[Mesh]	346
IPA	From 15/04/2018 to 18/02/2023	"Telemedicine" AND "Diabetes Mellitus"	27
Total			**373**

Selection of sources of evidence

The search strategy was to initially screen titles yielded by the search against the inclusion criteria, and if found relevant, the abstract was read. After that, if the abstract met the eligibility criteria, the entire article was retrieved, read, and evaluated. In addition, reference lists of review studies generated by the search were also screened for other studies not found in the search. The reasons for excluding each study were recorded.

Data charting process

When reading the studies, an inductive thematic approach was taken to identify common patterns and categorize them into themes. Thus, initially, the studies were read without specific predefined categories (Ritchie et al., 2014; Gale et al., 2013). In this way, themes

emerged naturally from the data and captured the different DHIs present in the literature (Ritchie et al., 2014; Gale et al., 2013). Then, the categories resulted were; the theoretical framework underpinning the DHIs, the type of DHIs, their services, the media used, by whom they were delivered, and the interventions' effectiveness. The nature of each intervention was comprehensively documented. Furthermore, information about the study design, setting, country, type, number of participants, sampling, recruitment, and methodology was recorded. The studies' intervention, measurement tools, and outcome measures were compared for differences and similarities. Those variables assessed were arranged in tables to enable analysis.

2.4. Results of the scoping literature review

Literature search yield

The search yielded 373 citations, 346 from PubMed, and 27 from IPA. However, after removing duplicates and screening their title and abstracts with inclusion criteria, 187 studies were included for further reading and evaluation (Figure 2.1). The full texts of these studies were retrieved, and the reference lists were hand searched for more relevant papers. Finally, 24 studies were eligible for the inclusion criteria.

The flow diagram below summarises the selection process adopted by PRISMA (Figure 2.1) (Page et al., 2021).

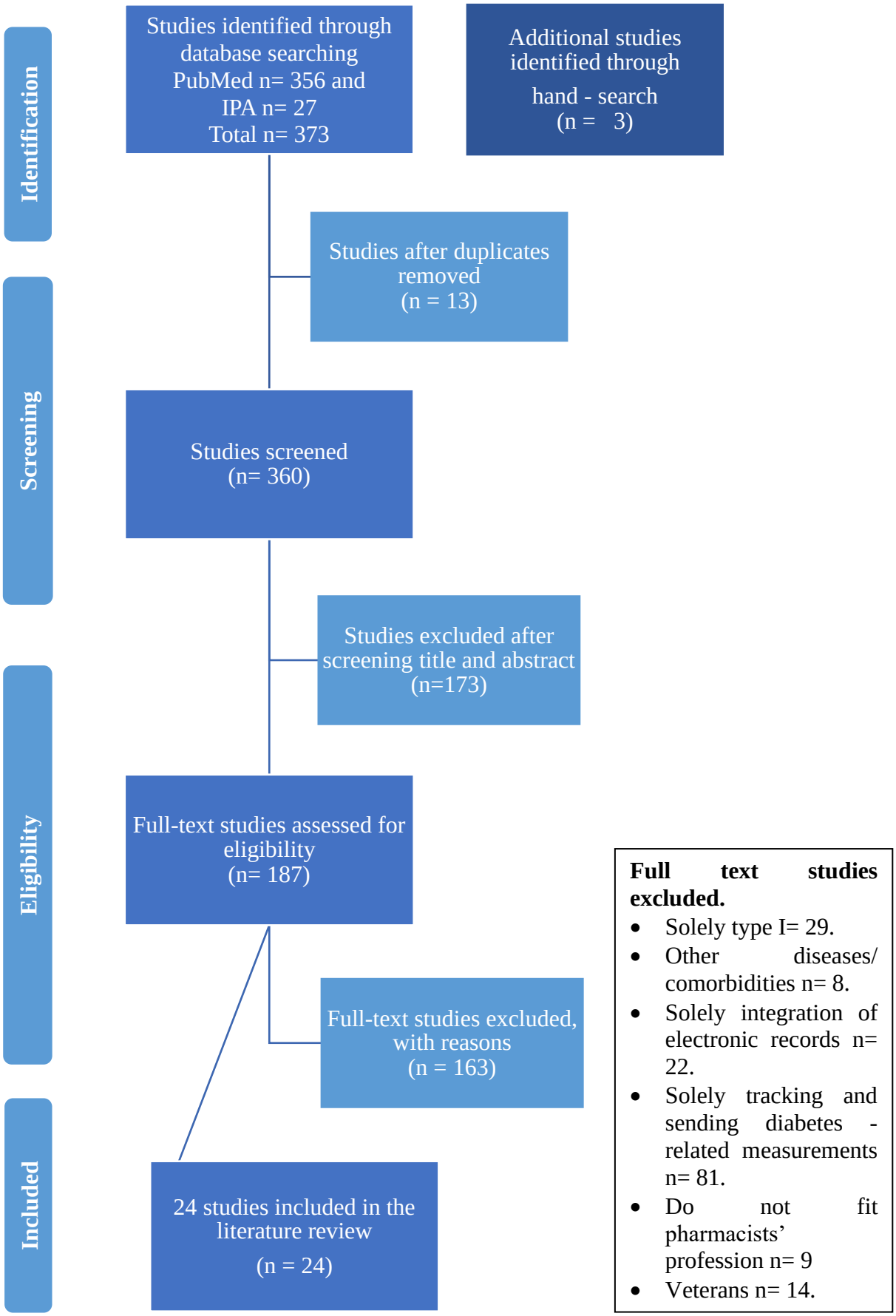


Figure 2.1 The PRISMA flow diagram (Page et al., 2021).

2.5. Results of the scoping review

Twenty-four studies met the inclusion criteria and are analysed below. Five studies concerned evaluations of interventions conducted by pharmacists, and the rest were conducted by other HCPs to improve diabetes self-management. A summary of the studies offered by pharmacists and HCPs is displayed in Table 2.4 and Table 2.5.

Table 2.4 Summary of studies included in the scoping literature review (pharmacist-led intervention).

Study design	Study	Setting *Country*	Intervention duration (months)	Intervention	Number and eligibility criteria	Outcome measures	Study findings
Comparison control groups	Threatt and Ward, 2017	Carolina	6	1. Online education via a real time video. 2. Setting goals.	33 *(n=12 intervention)* 1. Type 1 and 2 2. Pre-diabetes/ newly diagnosed diabetes. 3. HbA1c>7%	1. HbA1c 2. Body mass index 3. BP	1. HbA1c was statistically significant decreased.
	McWhorter et al., 2015	Utah	6	1. Log information relevant to diabetes management[1]. 2. Reminder to log on. 3. Education Assessment Questions.	150 *(n= 75 intervention)* 1. T2DM HbA1c >7%, with/without HTN	1. HbA1c 2. BP 3. Cholesterol 4. Disease state knowledge, adherence, and self-efficacy	1. HbA1c decrease statistically significant greater in the intervention group. 2. Patient activation measure, diabetes/HTN knowledge, and medication adherence with HTN medications (but not diabetes medications) statistically improved in the telemonitoring group.
Pre – post studies	Hawes et al., 2018	Carolina	12	1. Messages. 2. BG readings and insulin dosing in a chart format. 3. Management plan. 4. Medication adjustments. 5. Lifestyle modifications. 6. Education.	36 T2DM with HbA1c >9% or warfarin-treated adults	1. HbA1c. 2. Proportions of patients with HbA1c values of <8% and <7% and controlled BP. 3. Medication adherence. 4. Utilization. 5. Frequency of hypoglycaemia.	1. Statistically significant decrease from baseline in HbA1c. 2. Significant improvements in frequencies of statin use, aspirin use and BP control. 3. The margin was $100 per patient.

Table 2.4 Summary of studies included in the scoping literature review (pharmacist-led intervention).

Study design	Study	Setting *Country*	Intervention duration (months)	Intervention	Number and eligibility criteria	Outcome measures	Study findings
				7. Follow-up strategy.		6. Reimbursement outcomes. 7. Patients' satisfaction.	4. The overall median patient satisfaction survey score was 39 out of 40.
Pre – post studies	McWhorter et al., 2014	Utah	6	1. Log information relevant to diabetes management[1]. 2. Reminder to log on. 3. Education. 4. Assessment Questions.	109 *(pre/post) patients (n=83 diabetes and HTN n=12 diabetes, n=14 HTN)* 1. HbA1c >7%, and or uncontrolled HTN[2].	1. HbA1c, BP, cholesterol, weight 2. Patient engagement. 1. Diabetes and HTN knowledge. 2. Medication adherence. 3. Patients' perceptions of the intervention	1. Statistically significant decrease in HbA1c, systolic BP, and LDL. 2. Knowledge of diabetes and HTN increased statistically significantly. 3. Patient engagement and medication adherence improved non-significantly. 4. Patients felt the telemonitoring program was useful.
	Klug et al., 2011	Oregon	4	1. Alert patients to scheduled health sessions. 2. Prompts patient to test and transmit BG and/or BP. 3. Individuals' assessment questions. 4. Educational videos.	28 1. Type 1 and 2. 2. HbA1c >8%.	1. HbA1c. 2. BG levels. 3. Participants' knowledge and the degree of participant engagement.	1. Mean HbA1c and BG decreased statistically significantly at the study end. 2. Participants were satisfied with the telehealth system.

Table 2.4 Summary of studies included in the scoping literature review (pharmacist-led intervention).

Study design	Study	Setting *Country*	Intervention duration (months)	Intervention	Number and eligibility criteria	Outcome measures	Study findings
[1]such as BG, weight, dietary activity, BP, and insulin doses where applicable (each study examined different variables). [2] Uncontrolled HTN= BP > 140/80 mmHg. ADA/AADE is American Diabetes Association/American Association of Diabetes Educators. HbA1c is Glycated Haemoglobin. BG is blood glucose. BP is blood pressure. HTN is hypertension. LDL is low-density lipoprotein. DSME/S is Diabetes Self-Management Education and Support Services. CP is clinical pharmacy.							

Table 2.5 Summary of studies included in the scoping literature review (led by other healthcare professionals apart from pharmacists).

Study design	Study	Setting *Country/ state*	Intervention duration (months)	Intervention	Number and eligibility criteria	Outcome measures	Study findings
Randomized control trials	Clark et al., 2020	USA	6	1. Educational, motivational medication reminders. 2. BG monitoring prompt text messages. 3. Medication reminders.	126 *(63 intervention group)* 1. Hispanic 2. T2DM 3. HbA1C >7.5%	1. Diabetes distress.	1. Baseline levels of diabetes distress (DD) prospectively moderated the effect of Dulce Digital (vs usual care) on glycaemic control over 6 months. 2. The effect of the intervention on A1C change was 178% larger among individuals experiencing moderate/high versus no/low DD.
	Lee et al., 2020	Republic of Korea	6	1. Education. 2. Individualized feedback messages.	72 *(n=41 in the intervention group)* 1. T2DM	1. HbA1c 2. Body mass index. 3. BP	1. HbA1c, total cholesterol level, and Problem Areas in Diabetes scores statistically significantly decreased.

Table 2.5 Summary of studies included in the scoping literature review (led by other healthcare professionals apart from pharmacists).

Study design	Study	Setting *Country/ state*	Intervention duration (months)	Intervention	Number and eligibility criteria	Outcome measures	Study findings
				3. Entered their medical information[1] (accessible to providers through a secure website. 4. Encouragement and reminders if the patient had not used the app recently.	2. HbA1c = 6.5% within the last three months	4. Cholesterol. 5. Questionnaire scores.	2. Total diet and self-monitoring of BG level scores, statistically significant increased within the intervention group.
	McLeod et al., 2020	New Zealand	12	1. Individualised health coaching. 2. Goal setting and tracking. 3. Peer support in an online forum. 4. Educational resources. 5. Behaviour-change tools (cognitive behaviour theory, motivation interviewing, intrinsic rewards). 6. Reminders.	429 *(n = 215 intervention group)* 3. 18 to 75 years old 4. T2DM or pre-diabetes 5. HbA1c of 5.9–8.6%	1. HbA1c. 2. Weight 3. Waist circumference 4. BP 5. Diabetes-specific behaviours.	1. HbA1c and BP levels at 12 months did not differ between study arms. 2. Weight reduced slightly at 12 months for participants in both study arms, with no difference between arms. 3. Improvements to behaviours were increased in both study arms.
	Sun et al., 2019	China	6	1. Glucometers capable of data transmission. 2. Advice pertaining on medication, diet, and exercise.	91 *(44 in the intervention group)* 1. Older than 65 years 2. T2DM 3. HbA1c level 7.0% to 10.0%	1. Post-prandial plasma glucose level 2. HbA1c	1. Statistically significant improvement in postprandial BG and HbA1c in the intervention group.

Table 2.5 Summary of studies included in the scoping literature review (led by other healthcare professionals apart from pharmacists).

Study design	Study	Setting *Country/ state*	Intervention duration (months)	Intervention	Number and eligibility criteria	Outcome measures	Study findings
	Jeong et al., 2018	Republic of Korea	6	1. Remote, live and interactive DSME/S program. 2. Log information relevant to diabetes management[1]. 3. Automated short message feedback. 4. Educational resources.	N= 338 *(n= 113 telemonitoring, n= 112 telemedicine, n= 113 control)* 1. T2DM 2. HbA1c from 7% to 11%	1. HbA1c 2. BG 3. Hypo-glycaemia 4. Medication adherence.	1. The adjusted net reductions in HbA1c were similar in control, telemonitoring, and telemedicine. 2. Fasting BG was lower in the telemonitoring and telemedicine groups than in the control group. 3. Rates of hypoglycaemia were lower in the telemedicine group than in the other two groups. 4. Medication adherence was better in the telemonitoring and telemedicine than in the control group.
	De Vasconcelos et al., 2018	USA	6	1. Programme of guidance/coaching on the disease via telephone calls.	31 *(n =16 in the intervention group)* T2DM	1. BP 2. BMI 1. Fasting venous BG and HbA1c. 2. Cholesterol.	1. No statistically significant difference was observed between intervention and control group.
	Baron, Hirani, and Newman 2017	United Kingdom	9	1. Store and transmit diabetes-related data[1]. 2. Colour-coded graphical feedback.	81 *(n=45 in the intervention group)* 1. Type 1 and 2	1. HbA1c 2. BP 3. Daily insulin dose	1. No statistically significant difference was observed between intervention and control group.

Table 2.5 Summary of studies included in the scoping literature review (led by other healthcare professionals apart from pharmacists).

Study design	Study	Setting *Country/ state*	Intervention duration (months)	Intervention	Number and eligibility criteria	Outcome measures	Study findings
				3. Feedback on out-of-range clinical readings as needed. 4. Education on lifestyle changes (six weekly educational calls).	2. HbA1c ≥ 7.5%	4. Diabetes outpatient appointments 5. Questionnaire data	
	Fortmann et al., 2017	USA	6	1. Educational, motivational medication reminders. 2. BG monitoring prompt text messages. 3. Medication reminders.	126 *(n=63 intervention)* 1. T2DM. 2. HbA1c ≥7.5%. 3. 18–75 years old.	1. HbA1c 2. Cholesterol 3. BP 4. BMI 5. Satisfaction 6. Acceptability	1. Statistical significantly decrease in HbA1c. 2. The number of blood glucose values texted in by participants was a statistically significant predictor of month 6 HbA1c. 3. Satisfaction and acceptability ratings were high.
	Tang et al., 2013	USA	12	1. Log information relevant to diabetes management[1]. 2. Online messaging with patients' health team and feedback. 3. Personalized educational text and video (dispensed electronically by the care team).	382 *(193 in the intervention group)* HbA1c ≥ 7.5%	1. HbA1c 2. BP 3. Cholesterol 4. Weight 5. 10-year Framingham cardiovascular risk 6. Knowledge 7. Satisfaction 8. Psychosocial well-being.	1. HbA1c was significantly reduced at 6 months. At 12 months the differences were not significant. 2. Statistically significantly better control of LDL, treatment distress scores and knowledge in the intervention group. 3. Overall treatment satisfaction in the intervention group.

Table 2.5 Summary of studies included in the scoping literature review (led by other healthcare professionals apart from pharmacists).

Study design	Study	Setting *Country/ state*	Intervention duration (months)	Intervention	Number and eligibility criteria	Outcome measures	Study findings
	Orsama et al., 2013	Finland	10	1. Information, motivation, and behavioural skills feedback messages. 2. Feedback messages based on data patient logged in. 3. Log information relevant to diabetes management[1]. 4. Graphs. 5. Access to their personal health record.	48 *(Intervention group n=24)* 1. T2DM. 2. HbA1c >6.5%	1. HbA1c 2. BP 3. Weight 4. Patient acceptance and usability and usefulness of the feedback system	1. Statistically significant reduction of HbA1c and weight. 2. The app was found easy and useful.
	Bond et al., 2007	USA	6	1. Communication with the nurse. 2. Log information relevant to diabetes management[1]. 3. Problem-solving discussion. 4. Educational discussion.	62 *(31 in the intervention group)* 1. 60 years or older. 2. Type 1 and 2.	1. HbA1c 2. BP 3. Weight 4. Cholesterol	Statistically significant decrease in HbA1c, BP, weight, and cholesterol levels.
Pre and post studies	Ladner et al., 2022	USA	1.5	1. Remote, live and interactive DSME/S program.	42 1. 18 years of age or older 2. T2DM 3. Prediabetes 4. Care	1. Diabetes knowledge 2. Self-care 3. Sense of self-efficacy 4. BP	1. Statistically significant postintervention knowledge increased. 2. Overall treatment satisfaction.

Table 2.5 Summary of studies included in the scoping literature review (led by other healthcare professionals apart from pharmacists).

Study design	Study	Setting *Country/ state*	Intervention duration (months)	Intervention	Number and eligibility criteria	Outcome measures	Study findings
					givers	5. HbA1c 6. Weight 7. Participants' acceptability	
	Majithia et al., 2020	USA	4	1. Remote personalized lifestyle coaching from Certified Diabetes Care and Education Specialists. 2. Connected BG meters and real-time continuous glucose monitoring devices. 3. Live video.	55 with T2DM	1. HbA1c 2. Weight 3. BG monitoring 4. BP 5. Cholesterol.	1. Statistically significant decrease in HbA1c, mean weight, BP, total cholesterol. 2. Continuous glucose monitoring–measured statistically significant increased.
	Dixon et al., 2019	USA	6	1. Remote lifestyle coaching. 2. Clinical support with a mobile app. 3. Live video consultations with board-certified endocrinologists for medication management. 4. Real-time continuous glucose monitor use for higher-risk participants.	740 T2DM	HbA1c	Statistically significant improvement in HbA1c with up to 6 months.
	Nundy et al., 2014a	USA	6	1. Automated, interactive message system. 2. Educational messages. 3. Reminders.	67 *(pre/post)* Type 1 and 2 diabetes	Behaviour measures; social support, health	1. Statistically significant improvements in 5 of 6 domains of self-care (medication taking, glucose

Table 2.5 Summary of studies included in the scoping literature review (led by other healthcare professionals apart from pharmacists).

Study design	**Study**	**Setting** *Country/ state*	**Intervention duration** (months)	**Intervention**	**Number and eligibility criteria**	**Outcome measures**	**Study findings**
						beliefs, and self-care	monitoring, foot care, exercise, and healthy eating) and in 1 or more measures of self-efficacy, social support, and health believes. 2. Knowledge, attitude, and ownership were reported by participants as positively affected by the program.
	Nundy et al., 2014b	USA	6	1. Automated, interactive message system. 2. Educational messages. 3. Reminders.	67 *(pre/post)* Type 1 and 2 diabetes	1. Patient engagement and experience. 2. Care management, clinical and behaviour results.	1. 52% constant response rate. 2. High satisfaction rate. 3. Statistically significant improvement in self-care and in HbA1c. 4. Net cost savings of 8.8 percent.

Table 2.5 Summary of studies included in the scoping literature review (led by other healthcare professionals apart from pharmacists).

Study design	Study	Setting *Country/ state*	Intervention duration (months)	Intervention	Number and eligibility criteria	Outcome measures	Study findings
	Bond et al., 2006	USA	6	1. Access an electronic library. 2. Online counselling. 3. Self-management instruction and development of personal goals. 4. Problem-solving discussion. 5. Post diabetes goals and provide problem-solving suggestions. 6. Log information relevant to diabetes management[1].	15 *(patients with fewer comorbidities n=8, patients with more than six n=7)* Type 1 and 2	Self-reported BG readings	1. Participants with more than six self-reported medical comorbidities experienced increased BG levels over the study period, while participants with fewer than six comorbidities experienced a decline in BG levels.
Comparison control group	Lau et al., 2014	USA	24	1. Library of medical education documents. 2. Journal entry app. 3. Access to up-to-date personal laboratory values. 4. Secure email/messaging system between patients and diabetes caregivers.	157 *(Users n=50)* Type 1 and 2	HbA1c	1. Statistically significant higher proportion of users achieved HbA1c compared to non-users.
	Chen et al., 2013	Taiwan	18	1. Asynchronous online text messages among patients and caregivers. 2. Access BG tests.	162 *(N=59 intervention group)* Type 1 and 2	1. 7 self-care activities 2. HbA1c	1. Statistically significant difference in monitoring BG and HbA1c at the beginning and end of the study.

Table 2.5 Summary of studies included in the scoping literature review (led by other healthcare professionals apart from pharmacists).

Study design	**Study**	**Setting** *Country/ state*	**Intervention duration** (months)	**Intervention**	**Number and eligibility criteria**	**Outcome measures**	**Study findings**
				3. Log information relevant to diabetes management[1]. 4. Graphs. 5. Alerts.			2. Five behaviours were statistically significant different between the intervention and control groups[2].

[1]such as BG, weight, dietary activity, exercise, BP, and insulin doses where applicable (each study examined different variables). [2]physical activity, healthy eating, taking medication, healthy coping, problem-solving. RCT is randomized control trial. HbA1c is glycated haemoglobin. BP is blood pressure. App is application. HDL is high-density lipoprotein. LDL is low-density lipoprotein. T2DM is type 2 diabetes mellitus. DSME/S is diabetes self-management education and support services.

Healthcare professionals' training for the intervention's provision

In two out of five pharmacy-led studies, pharmacists were mentioned as clinical pharmacists (Hawes et al., 2018; Klug et al., 2011), while in the rest three studies, pharmacists were certified diabetes educators and specialized trained in diabetes (Threatt and Ward, 2017; McWhorter et al., 2015; McWhorter et al., 2014).

Concerning the remaining 19 out of 24 intervention studies provided by other HCPs, their qualification varied. Eight studies were led by a nurse (McLeod et al., 2020; de Vasconcelos et al., 2018; Baron et al., 2017; Nundy et al., 2014a; Nundy et al., 2014b; Orsama et al., 2013; Bond et al., 2007; Bond et al., 2006). Eleven of the remaining 19 studies described interventions offered by a medical team. Notably, in Lee et al. 2020 study, two endocrinologists and a nurse were the medical team, while Jeong et al., 2018 study endocrinologists, a diabetes nurse, and a physician. Moreover, three studies included a dietician and a nurse in their team (Ladner et al., 2022; Chen et al., 2013; Tang et al., 2013), with one study stating that the dietician and the nurse were certified diabetes educator (Ladner et al., 2022). Lau et al. 2014 study included diabetologists and a medical team, endocrinologists, behavioural psychologists, optometrists, podiatrists, and diabetes case managers. Finally, three studies did not describe the HCPs' profession. Two studies included endocrinologists and primary care providers without explaining their qualifications (Majithia et al., 2020; Dixon et al., 2019). Clark et al., 2020 and Fortmann et al., 2017 (which evaluated the same intervention) stated that the study coordinator offered the intervention.

Study location of the eligible studies

From the 24 studies that met the inclusion criteria, 17 studies were conducted in the USA (Ladner et al., 2022; Clark et al., 2020; Majithia et al., 2020; Dixon et al., 2019; Hawes et al., 2018; de Vasconcelos et al., 2018; Fortmann et al., 2017; Threatt and Ward, 2017; McWhorter et al., 2015; Lau et al., 2014; Nundy et al., 2014a; Nundy et al., 2014b; McWhorter et al., 2014; Tang et al., 2013; Klug et al., 2011; Bond et al., 2007; Bond et al., 2006). The remaining 7 eligible studies were conducted in different countries, namely, two in Korea (Lee et al., 2020; Jeong et al., 2018) and single studies in the United Kingdom (UK) (Baron et al., 2017), Taiwan (Chen et al., 2013), China (Sun et al., 2019), New Zealand (McLeod et al., 2020) and Finland (Orsama et al., 2013).

The setting of the eligible studies

Regarding the setting of the studies included, 18 of them were single centres, and the 6 were multicentred studies (Ladner et al., 2022; Majithia et al., 2020; McLeod et al., 2020; Sun et al., 2019; Jeong et al., 2018; Fortmann et al., 2017). Seventeen studies out of 24 were conducted in primary care settings and 7 studies (out of 24) were conducted in an outpatient hospital setting (Ladner et al., 2022; Lee et al., 2020; Sun et al., 2019; Jeong et al., 2018; Lau et al., 2014; Chen et al., 2013; Tang et al., 2013).

Study design of the eligible studies

All studies (n=24) included in the scoping review were evaluation studies, of which 12 were randomized controlled trials, 8 were pre- and post-interventions, and 4 were comparison group studies. Of the five intervention studies delivered by pharmacists, three were pre-post studies (Hawes et al., 2018; McWhorter et al., 2014; Klug et al., 2011) and two were comparison group studies (Threatt and Ward, 2017; McWhorter et al., 2015). The comparison group in the McWhorter et al., 2015 study was identified through a retrospective chart review, while Threatt and Ward, 2017 did not explain how they chose the control group. (McWhorter et al., 2015; Threatt and Ward, 2017). Finally, 11 of the remaining 19 evaluation studies, which were led by other HCPs, were randomised controlled trials (Clark et al., 2020; Lee et al., 2020; McLeod et al., 2020; Sun et al., 2019; Jeong et al., 2018; de Vasconcelos et al., 2018; Baron et al., 2017; Fortmann et al., 2017; Tang et al., 2013; Orsama et al., 2013; Bond et al., 2007), 6 were pre-post intervention studies (Ladner et al., 2022; Majithia et al., 2020; Dixon et al., 2019; Nundy et al., 2014a; Nundy et al., 2014b; Bond et al., 2006), and another two studies (Lau et al., 2014; Chen et al., 2013) were comparison group studies.

Inclusion criteria of the eligible studies

Age of participants

Participants' age is stated in Table 2.4Table 2.4 and Table 2.5. All studies (n=24) included adults above 18 or 19 years old, of which 7 studies added additional restrictions based on patients' age. Three studies included an upper age limit until 70 or 75 years old (McLeod et al., 2020; Fortmann et al., 2017; Orsama et al., 2013), and four studies recruited patients aged over 30 or elderly population (above 60 or 65 years) (Sun et al., 2019; Orsama et al., 2013; Bond et al., 2007; Bond et al., 2006).

Type of diabetes

Fifteen studies (out of 24) solely included T2DM patients (Ladner et al., 2022; Clark et al., 2020; Lee et al., 2020; Majithia et al., 2020; McLeod et al., 2020; Dixon et al., 2019; Sun et al., 2019; Jeong et al., 2018; de Vasconcelos et al., 2018; Hawes et al., 2018; Fortmann et al., 2017; McWhorter et al., 2015; McWhorter et al., 2014; Tang et al., 2013; Orsama et al., 2013). Furthermore, the remaining 9 studies (out of the 25) included both type 1 and 2 diabetes patients (Baron et al., 2017; Threatt and Ward, 2017; Nundy et al., 2014a; Nundy et al., 2014b; Lau et al., 2014; Chen et al., 2013; Klug et al., 2011; Bond et al., 2007; Bond et al., 2006). Particularly, Baron et al., 2017 refined as inclusion criteria patients with type 1 or T2DM who were taking insulin.

Control of patients' diabetes and comorbidities

Concerning the control of patients' diabetes, 13 studies (out of 24) included patients with uncontrolled diabetes (the definition of uncontrolled diabetes differed among the studies see Table 2.4 and Table 2.5) (Clark et al., 2020; Majithia et al., 2020; Sun et al., 2019; Hawes et al., 2018; Jeong et al., 2018; Baron et al., 2017; Fortmann et al., 2017; Nundy et al., 2014a; Nundy et al., 2014b; Chen et al., 2013; Orsama et al., 2013; Tang et al., 2013; Klug et al., 2011).

McWhorter et al., 2014 and Orsama et al., 2013 studies also included patients with uncontrolled hypertension (HTN) and/or diabetes and Hawes et al., 2018 patients with uncontrolled diabetes and/or warfarin-treated adults. Furthermore, McWhorter et al. 2015 study included new or existing T2DM with or without HTN irrespectively of their BG and/or BP levels. In comparison, Threatt and Ward, 2017 study included pre-diabetes and/or uncontrolled diabetes or newly diagnosed diabetes patients. De Vasconcelos et al., 2018 included patients who had T2DM for at least one year, while patients with pre-diabetes and caregivers were included in Ladner et al., 2022.

Exclusion criteria of the eligible studies

The exclusion criteria stated in each study are analysed here. Notably, exclusion criteria concerning insulin were; currently receiving insulin treatment (McLeod et al., 2020), use of an insulin pump (Majithia et al., 2020; Sun et al., 2019), and only included if on basal insulin or premixed insulin twice daily or less than a day (Jeong et al., 2018). Moreover, 9 studies excluded patients with severe diabetes complications or terminal illness, (which was defined differently in each study) (Majithia et al., 2020; Sun et al., 2019; Jeong et al.,

2018; Baron et al., 2017; Fortmann et al., 2017; McWhorter et al., 2015; Chen et al., 2013; Orsama et al., 2013; Tang et al., 2013). Six studies mentioned that they excluded pregnant patients (Majithia et al., 2020; McLeod et al., 2020; Baron et al., 2017; Threatt and Ward, 2017; McWhorter et al., 2015; Tang et al., 2013; Orsama et al., 2013)

Furthermore, two studies excluded patients with previous experience with similar programs (Baron et al., 2017; Tang et al., 2013), and three studies excluded patients staying in a nursing home or having home visits by a nurse (Baron et al., 2017; McWhorter et al., 2015; Klug et al., 2011). In contrast, two studies (Tang et al., 2013; Orsama et al., 2013) excluded patients with expected poor study compliance and unwillingness to perform any self-monitoring at home. Moreover, patients with cognitive inability and/or active psychiatric disorders were excluded in five studies (Clark et al., 2020; McLeod et al., 2020; McWhorter et al., 2014; Orsama et al., 2013; Klug et al., 2011).

Restrictions regarding patients' knowledge/ability to use technology

Further to the above exclusion criteria, some studies excluded patients due to the inability to use technological intervention. Four studies excluded patients who did not own a mobile phone (Dixon et al., 2019; Majithia et al., 2020; Nundy et al., 2014a and Nundy et al., 2014b), three studies excluded patients unable to use technology (McLeod et al., 2020 and Sun et al., 2019; Jeong et al., 2018), two studies excluded patients with a lack of internet access (Tang et al., 2013 and McLeod et al., 2020), and Jeong et al., 2018 and McWhorter et al., 2014 studies excluded patients if they had neither of the above. Moreover, Lee et al., 2020 included patients with an Android smartphone, de Vasconcelos et al., 2018 with a telephone number, and Lau et al. 2014 with an e-mail address. In addition, patients with disabilities compromising the use of technology, such as impaired vision, were excluded in 3 studies (McLeod et al., 2020; Baron et al., 2017; Klug et al., 2011).

Language restrictions

From the studies identified in the literature review, in four studies, participants were restricted to English speakers (McLeod et al., 2020; Baron et al., 2017; Threatt and Ward, 2017; Tang et al., 2013), whereas in four studies (Clark et al., 2020; Fortmann et al., 2017; McWhorter et al., 2015; McWhorter et al., 2014) patients were either English or/and Spanish speakers.

The sample size of the eligible studies

Sample sizes of the studies ranged from 15 patients (Bond et al., 2006) to a maximum of 740 patients (Dixon et al., 2019) (see Table 2.4 and Table 2.5).

Training of patients to use the technology employed to provide the intervention

Nine (out of 19) of the eligible studies offered by other HCPs (apart from pharmacists) trained participants to use the equipment employed to deliver the DHI (Ladner et al., 2022; Lee et al., 2020; Sun et al., 2019; Baron et al., 2017; Fortmann et al., 2017; Chen et al., 2013; Orsama et al., 2013; Tang et al., 2013; Bond et al., 2007). Regarding the eligible studies led by pharmacists, three (3 out of 5) trained patients to use the equipment employed (McWhorter et al., 2015; McWhorter et al., 2014; Klug et al., 2011). Whereas a clinical staff member logged into the system, no further training was provided in the Threatt and Ward, 2017 study. Finally, Hawes et al., 2018 study used a website and portal called Epic EMR and the MyChart but did not state whether training was offered to patients.

2.6. Digital health interventions employed by healthcare professionals to improve self-management of diabetes mellitus

This section describes the intervention type of all studies identified in the literature. Studies are described in a manner of the theoretical framework underpinning the intervention and interventions' services.

The theoretical framework underpinning the intervention provided in the eligible studies

Of the twenty-four studies identified, 8 (8/24) based their intervention on a theoretical framework (McLeod et al., 2020; de Vasconcelos et al., 2018; Nundy et al., 2014a; Nundy et al., 2014b; Orsama et al., 2013; Tang et al., 2013; Bond et al., 2007; Bond et al., 2006). Two studies (out of 8 studies) stated that the intervention provided was based on motivational interview (MI) (McLeod et al. 2020; Tang et al., 2013). However, none of the 8 studies thoroughly described the theoretical framework underlying the intervention. Although all 8 studies provided some examples of quotes which were used, general instructions, tables or figures of the intervention's procedure and underpinning theoretical framework, but not a step-by-step process of how to replicate the intervention. Particularly, three other studies only stated that the messages sent were motivational or encouraging (Clark et al., 2020; Lee et al., 2020; Fortmann et al., 2017).

The technology employed to provide the intervention evaluated in the eligible studies

A range of technology and equipment was employed for the interventions' provision included in the scoping literature review, as summarized in Table 2.6. Those technology and equipment were telephones, apps, websites, emails, glucometers, specifically developed devices, other devices measuring diabetes-related data (e.g., pedometer, scale, etc.), and a combination of equipment.

Table 2.6 The technology employed to provide the intervention evaluated in the eligible studies.

Studies		Technology employed						
		Combination of technology	Websites	Applications	Incorporation of glucometer devices	Telephone devices	Developed a specific device[1]	Email
Pharmacists	Hawes et al., 2018	✓	✓			✓		
	Threatt and Ward, 2017		✓					
	McWhorter et al., 2015; McWhorter et al., 2014						✓	
	Klug et al., 2011	✓	✓		✓		✓	
Other healthcare professionals	Ladner et al., 2022		✓					
	Clark et al., 2020; Fortmann et al., 2017			✓	✓			
	Majithia et al., 2020			✓	✓			
	McLeod et al., 2020		✓					
	Lee et al., 2020			✓				
	Dixon et al., 2019			✓				
	Sun et al., 2019			✓	✓			
	Jeong et al., 2018		✓		✓			
	de Vasconcelos et al., 2018					✓		
	Baron et al., 2017	✓	✓	✓	✓			
	Lau et al., 2014	✓	✓			✓		
	Nundy et al., 2014a; Nundy et al., 2014b	✓	✓	✓		✓		
	Tang et al., 2013	✓	✓	✓	✓			
	Chen et al., 2013	✓	✓		✓			
	Orsama et al., 2013	✓	✓	✓	✓	✓		
	Bond et al., 2007; Bond et al., 2006		✓					✓

[1]Klug et al., 2011 device compromised a personal health system 6000, a touch screen, remote, stand-alone patient management unit placed in the patient's home and a health care management suite, a clinician-user interface accessible via a secure internet link through a broadband connection in the patient's home. Used the Authentidate [tm] electronic house call [tm] and a food and drug administration 510 (k) cleared remote monitoring device.

Intervention services offered in the eligible studies

Although the provided interventions' services and the technology employed in each study differed, all twenty-four eligible studies had some similarities. Interventions could be classified into three categories: delivery of education, a combination of education and monitoring services, and combining multiple services. Services provided in the studies identified through the literature are presented in Table 2.7. The interventions' services identified in the eligible studies analysed in this section were; communication with a healthcare professional (24/24 studies), education and general information related to diabetes disease (21/24 studies), tracking and uploading for diabetes-related data (either manually or wireless) (19/24 studies), notifications /reminders (10/24 studies), out -of range alerts (8/24 studies), graphical diabetes-related records (6/24 studies), developing personal goals (5/24 studies), access to personal patient records/ integration of patient records (5/24 studies).

Table 2.7 Digital health interventions' services provided in the eligible studies identified from the scoping literature review.

Studies		Interventions (Services)							
		Communication with a healthcare professional	Education/ diabetes information	Track and upload data diabetes-related data	Notifications/ reminders	Out - of range alerts	Graphical report	Developing personal goals	Integration of patient records
Pharmacists	Hawes et al., 2018	✓	✓	✓				✓	
	Threatt and Ward, 2017	✓	✓					✓	
	McWhorter et al., 2015; McWhorter et al., 2014	✓	✓	✓	✓	✓	✓		✓
	Klug et al., 2011	✓	✓	✓	✓	✓			
Other healthcare professionals	Ladner et al., 2022	✓	✓						
	Clark et al., 2020; Fortmann et al., 2017	✓	✓	✓	✓	✓			
	Majithia et al., 2020	✓	✓	✓					
	McLeod et al., 2020	✓	✓	✓	✓			✓	
	Lee et al., 2020	✓	✓	✓					
	Dixon et al., 2019	✓	✓	✓	✓				
	Sun et al., 2019	✓		✓	✓				
	Jeong et al., 2018	✓	✓	✓					
	de Vasconcelos et al., 2018	✓	✓					✓	
	Baron et al., 2017	✓	✓	✓		✓	✓		

Table 2.7 Digital health interventions' services provided in the eligible studies identified from the scoping literature review.

Studies		Interventions (Services)							
		Communication with a healthcare professional	Education/ diabetes information	Track and upload data diabetes-related data	Notifications/ reminders	Out - of range alerts	Graphical report	Developing personal goals	Integration of patient records
	Lau et al., 2014	✓	✓	✓			✓		✓
	Nundy et al., 2014a; Nundy et al., 2014b	✓	✓		✓	✓			
	Tang et al., 2013	✓	✓	✓			✓	✓	✓
	Chen et al., 2013	✓		✓			✓	✓	✓
	Orsama et al., 2013	✓		✓			✓		✓
	Bond et al., 2007; Bond et al., 2006	✓	✓	✓				✓	

Communication with a healthcare professional

Communication with a healthcare professional (HCP) was identified in all the studies as it was part of the eligibility criteria of the scoping literature review. This service was provided through messages sent from HCPs to patients replying to their uploaded diabetes-related data or self-management support or motivational messages, support for medication adjustments, individual advice, teleconsultation, and/or answering questions. These messages were either individual texts or prepared messages sent to all participants, asynchronously or synchronously (see Table 2.8). The follow-up appointments were scheduled from every 1-3 weeks to every 3-month intervals (Sun et al., 2019; de Vasconcelos et al., 2018; Threatt and Ward, 2017; Klug et al., 2011; Bond et al., 2006). Five studies stated that the follow-up was scheduled as needed (Clark et al., 2020; Majithia et al., 2020; Fortmann et al., 2017; Lau et al., 2014; Tang et al., 2013). Three studies did not state the follow-up frequency (Dixon et al., 2019; Jeong et al., 2018; Chen et al., 2013).

Table 2.8 Ways communication with a healthcare professional service was provided in the eligible studies identified from the scoping literature review.

Studies		Individual texts	Prepared messages	Follow-up appointment	Combination of synchronous and asynchronous	Synchronous	Asynchronous
Pharmacists	Hawes et al., 2018	✓					✓
	Threatt and Ward, 2017	✓		✓			✓
	McWhorter et al., 2015; McWhorter et al., 2014	✓	✓				✓
	Klug et al., 2011	✓		✓		✓	
Other healthcare professionals	Ladner et al., 2022	✓					✓
	Clark et al., 2020; Fortmann et al., 2017	✓		✓	✓		
	Majithia et al., 2020	✓		✓	✓		
	McLeod et al., 2020	✓				✓	
	Lee et al., 2020	✓			✓		
	Dixon et al., 2019	✓		✓	✓		
	Sun et al., 2019	✓		✓			✓
	Jeong et al., 2018	✓	✓	✓	✓		
	de Vasconcelos et al., 2018	✓		✓			✓
	Baron et al., 2017	✓					✓
	Lau et al., 2014	✓		✓		✓	
	Nundy et al., 2014a; Nundy et al., 2014b	✓	✓		✓		
	Tang et al., 2013	✓	✓	✓		✓	
	Chen et al., 2013	✓		✓		✓	
	Orsama et al., 2013	✓	✓		✓		
	Bond et al., 2007; Bond et al., 2006	✓		✓	✓		

Provision of education

Most interventions (21/24) identified in the literature provided education, and particularly all pharmacy-led interventions included this service (see Table 2.7). The education offered was either individual or followed a predefined curriculum (see Table 2.9). For instance, Klug et al. 2011 study provided individualized educational information based on patients' responses (about hypoglycaemia, hyperglycaemia, HTN, and hypotension) and in three intervention studies, the patients could stop or continue the education or complete the curriculum on their path (Threatt and Ward, 2017; Nundy et al., 2014a; Nundy et al., 2014b). The curriculum used for the education sessions in each study varied, and only studies (10 out of 21) described where their education curriculum was based (see Table 2.9).

Table 2.9 Provision of education identified in the eligible studies from the scoping literature review.

Studies		Individually driven	Education curriculum		
			American diabetes association (ADA)	Culturally appropriate curriculum ("Project Dulce")	Did not specify
Pharmacists	Hawes et al., 2018				✓
	Threatt and Ward, 2017	✓	✓		
	McWhorter et al., 2015; McWhorter et al., 2014		✓		
	Klug et al., 2011	✓			✓
Other healthcare professionals	Ladner et al., 2022		✓		
	Clark et al., 2020; Fortmann et al., 2017			✓	
	Majithia et al., 2020	✓			✓
	McLeod et al., 2020				✓
	Lee et al., 2020	✓	✓		
	Dixon et al., 2019	✓	✓		
	Jeong et al., 2018		✓		
	de Vasconcelos et al., 2018				✓
	Baron et al., 2017				✓
	Lau et al., 2014				✓
	Nundy et al., 2014a; Nundy et al., 2014b	✓			✓
	Tang et al., 2013	✓			✓
	Bond et al., 2007; Bond et al., 2006		✓		

Track and upload diabetes-related information

Track and upload diabetes-related information was similar in all 19 studies offering this service. Initially, the patients were prompted to track their diabetes-related data (e.g., BG, BP, weight) and transmit them to the HCPs. This was either done manually or automatically through the device/app used. Afterward, the HCPs would give patients feedback and comments respecting their data asynchronously or in real time. The most common diabetes-related information tracked in the interventions, as stated in the eligible studies, is presented in Table 2.10.

Table 2.10 Track and upload diabetes-related information services provided in the eligible studies identified from the scoping literature review.

Studies		Diabetes -related information tracked						
		Blood glucose	Physical activity	Diet	Weight	Blood pressure	Medication	Insulin dose
Pharmacists	Hawes et al., 2018	✓						✓
	McWhorter et al., 2015; McWhorter et al., 2014	✓			✓			
	Klug et al., 2011	✓				✓		
Other healthcare professionals	Clark et al., 2020; Fortmann et al., 2017	✓						
	Majithia et al., 2020					✓		
	McLeod et al., 2020	✓	✓	✓	✓		✓	
	Lee et al., 2020	✓	✓	✓	✓	✓	✓	
	Dixon et al., 2019	✓	✓	✓			✓	
	Sun et al., 2019		✓	✓		✓		
	Jeong et al., 2018	✓	✓	✓	✓			
	Baron et al., 2017	✓	✓	✓	✓	✓		✓
	Lau et al., 2014	✓						
	Tang et al., 2013	✓	✓	✓				✓
	Chen et al., 2013	✓	✓	✓	✓	✓		✓
	Orsama et al., 2013	✓	✓		✓			
	Bond et al., 2007; Bond et al., 2006	✓	✓	✓	✓	✓	✓	

Graphical reports

Seven interventions identified offered the patients to view their records in graphical form (Baron et al., 2017; Lau et al., 2014; McWhorter et al., 2015; McWhorter et al., 2014; Tang et al., 2013; Chen et al., 2013; Orsama et al., 2013).

Notifications/ reminders/ alerts

Below half of the studies (10/24) remind the patients to perform self-care activities, such as taking their medication, self-monitoring of blood glucose (SMBG), or other related diabetes behaviour (e.g., foot examination) (Clark et al., 2020; McLeod et al., 2020; Dixon et al., 2019; Sun et al., 2019; Fortmann et al., 2017; McWhorter et al., 2015; McWhorter et al., 2014; Nundy et al., 2014a; Nundy et al., 2014b; Klug et al., 2011). Alerts were employed to alert practitioners of an out-of-range value of patients' records, e.g., BG, and were employed in 8 studies (Clark et al., 2020; Baron et al., 2017; Fortmann et al., 2017; McWhorter et al., 2015; McWhorter et al., 2014; Nundy et al., 2014a; Nundy et al., 2014b; Klug et al., 2011).

Integration of patients' records

Another function found was enabling patients to view their personal records, including his/her personal care plan and goals, medication, and laboratory results identified in six studies (Lau et al., 2014; McWhorter et al., 2015; McWhorter et al., 2014; Orsama et al., 2013; Tang et al., 2013; Chen et al., 2013).

Developing personal goals

Eight studies included setting a personal goal or patients participating in a problem-solving discussion with their HCP (McLeod et al., 2020; de Vasconcelos et al., 2018; Hawes et al., 2018; Threatt and Ward, 2017; Tang et al., 2013; Chen et al., 2013; Bond et al., 2007; Bond et al., 2006).

Medication adjustments

Three studies stated that the intervention offered the medication adjustment service (Hawes et al., 2018; Baron et al., 2017; Tang et al., 2013). Notably, Baron et al., 2017 stated that insulin titration was part of the intervention, Tang et al., 2013 adjusted medication and one pharmacy-led intervention (Hawes et al., 2018) specified that the pharmacists were able to make medication adjustments, ordered laboratory tests, and sent prescriptions.

2.7. Outcome measures and effectiveness of the digital health interventions identified in the scoping review in improving self-management of diabetes management

This section presents all outcome measures employed through the eligible studies to evaluate the intervention. Each study evaluated different aspects of diabetes self-management, set different outcome measures, and the outcome of each study varied.

Clinical measures

Apart from three studies (Clark et al. 2020; Nundy et al., 2014a; Bond et al., 2006), the rest 21 eligible studies evaluated the following clinical measures; HbA1c levels, blood pressure, weight/ body mass index cholesterol levels, and blood glucose readings is presented in Table 2.11. BG readings were compared between the telemonitoring, telemedicine groups and the conventional group in the Jeong et al. 2018 study, which concluded that the fasting BG was lower in the telemonitoring and telemedicine groups than in the conventional group. Also, Bond et al. 2006 study evaluated the effectiveness of a web-based intervention in improving BG readings among adults with six or more comorbidities and adults with fewer than six self-reported medical comorbidities, resulting in participants with fewer than six comorbidities being more likely to experience linear decline on BG.

Furthermore, Jeong et al. 2018 study evaluated the frequency of hypoglycaemia and found that the rates of hypoglycaemia were lower in the telemedicine group than in the other telemonitoring and control groups. Three studies evaluated the adverse effects that occurred during the intervention, and two studies did not record any adverse effects (Majithia et al., 2020; McLeod et al., 2020), while the other compared the adverse effects that occurred between the two study groups with no significant results (Jeong et al., 2018).

Table 2.11 Digital health interventions' services provided in the eligible studies identified from the scoping literature review.

Studies		Interventions (Services)				
		Glycated haemoglobin	Blood pressure	Weight/ body mass index	Cholesterol levels	Blood glucose readings
Pharmacist	Hawes et al., 2018	SS	N/A[1]	N/A[1]	N/A[1]	N/A[1]
	Threatt and Ward, 2017	SS	-	-	N/A[1]	N/A[1]
	McWhorter et al., 2015	SS	-	N/A[1]	-	N/A[1]
	McWhorter et al., 2014	SS	SS	-	SS	N/A[1]
	Klug et al., 2011	SS	N/A[1]	N/A[1]	N/A[1]	SS
Other healthcare professionals	Ladner et al., 2022	SS	-	SS	-	-
	Majithia et al., 2020	SS	SS	SS	SS	N/A[1]
	McLeod et al., 2020	-	-	-	N/A[1]	N/A[1]
	Lee et al., 2020	SS	-	-	SS	N/A[1]
	Dixon et al., 2019	SS	N/A[1]	N/A[1]	N/A[1]	N/A[1]
	Sun et al., 2019	SS	N/A[1]	N/A[1]	N/A[1]	SS
	Jeong et al., 2018	-	N/A[1]	N/A[1]	N/A[1]	-
	de Vasconcelos et al., 2018	-	-	N/A[1]	S	S
	Baron et al., 2017	-	S	N/A[1]	N/A[1]	N/A[1]
	Fortmann et al., 2017	SS	-	N/A[1]	-	N/A[1]
	Lau et al., 2014	SS	N/A[1]	N/A[1]	N/A[1]	N/A[1]
	Nundy et al., 2014b	SS	N/A[1]	N/A[1]	N/A[1]	N/A[1]
	Tang et al., 2013	S[2]	-	-	SS	N/A[1]
	Chen et al., 2013	SS	N/A[1]	N/A[1]	N/A[1]	N/A[1]
	Orsama et al., 2013	SS	-	SS	N/A[1]	N/A[1]
	Bond et al., 2007	SS	SS	SS	SS	N/A[1]

SS is for statistically significant reduction. S is for significant reduction. – is for not statistically significant or significant change.
[1]Variable not evaluated. [2]Achieved a significant reduction of HbA1c at six months, while at 12 months was stated as not significant.

Behaviour changes measures

For the interventions' evaluation of the behaviour changes, self-efficacy, adherence, knowledge, mental health, quality of life, and patients' satisfaction, different instruments were employed and are displayed in Table 2.11. Behaviour changes were evaluated in four studies with all concluding statistically significant improvements in the intervention group (Ladner et al., 2022; Nundy et al., 2014a; Nundy et al., 2014b; Chen et al., 2013). Nundy et al., 2014, studies succeeded in 5 of 6 domains of self-care (medication taking, glucose monitoring, foot care, exercise, healthy eating) and improvements in 1 or more measures of self-efficacy, social support, and health beliefs. Similarly, six behaviours were statistically significantly improved in the intervention group (physical activity, healthy eating, taking medication, healthy coping, SMBG, and problem-solving) by Chen et al., 2013 study. Moreover, in two studies, SMBG testing and weekly exercise were significantly improved (Ladner et al., 2022; Lee et al., 2020). The statistically significant improvement resulted in the diet in Lee et al., 2020 study. In addition, patients in the Ladner et al., 2022' study expressed confidence in their ability to set goals to help them control their disease. Patients' behaviour changes were statistically significantly improved in one study (McWhorter et al., 2015) and non-significant in another Klug et al., 2011).

Four studies assessed medication adherence (Hawes et al., 2018; Jeong et al., 2018; McWhorter et al., 2015; McWhorter et al., 2014). All showed improvement, apart from McWhorter et al. 2015 study. Particularly, McWhorter et al. 2015 study found that although medication adherence in antihypertensive was improved, in diabetes, medication results did not show improvement. Secondary outcome measures were patients' knowledge of diabetes and/or HTN and were assessed in five studies (Ladner et al., 2022; McWhorter et al., 2015; McWhorter et al., 2014; Tang et al., 2013; Klug et al., 2011). Four of those studies (Ladner et al., 2022; McWhorter et al., 2015; McWhorter et al., 2014; Tang et al., 2013) showed a statistically significant increase in patients' knowledge, while Klug et al., 2011 revealed no statistically significant improvement.

Five intervention studies examined mental health objectives and were measured differently in each study (Clark et al. 2020; McLeod et al., 2020; Lee et al., 2020; Baron et al., 2017; Tang et al., 2013). Lee et al., 2020 and Tang et al., 2013 study evaluated diabetes-related stress using the "Problem areas in diabetes" questionnaire (which assesses patients' responses to 20 common diabetes situations) and found that the

intervention group had statistically significantly lower diabetes-related stress scores. However, other mental-health-related quality of life outcomes were not different between the two groups in the two studies (McLeod et al., 2020; Tang et al., 2013) and were borderline significant in Baron et al., 2017's study. In addition, Clark et al. 2020 study examined whether baseline levels of diabetes related stress impacted clinical benefit from a mobile health intervention. It has resulted that the baseline levels of diabetes distress prospectively moderated the effect of the intervention on glycaemic control.

Patients' satisfaction regarding their intervention was investigated in 10 studies and each study employed different satisfaction measure (see Table 2.12). All studies concluded that patients were generally satisfied with the program used. The only study identified through the literature evaluating HCPs' satisfaction or perception of DHIs is Klug et al., 2011. The study revealed that CP found the device easy to use, and some efficiency was gained.

Table 2.12 Evaluation measures employed in the eligible studies identified through the scoping literature review.

Evaluation Measures		Studies								
		Ladner et al., 2022	Lee et al., 2020	McLeod et al., 2020	Baron et al., 2017	McWhorter et al., 2015	McWhorter et al., 2014	Nundy et al., 2014a	Tang et al., 2013	Klug et al., 2011
Knowledge	Diabetes Knowledge Test					✓	✓		✓	
	Hypertension Knowledge Test					✓	✓			
Self-management	Patient Activation Measure					✓	✓			✓
	Diabetes Self-Care Activities Measures							✓		
	Diabetes Empowerment Scale							✓		
	Subscales of the Risk-Perception Survey for Diabetes							✓		
	Diabetes-Related Health Problems							✓		
	Diabetes Health Profile				✓					
	Diabetes Self-Care Activities			✓						
	The Korean version of the Summary of Diabetes Self-Care Activities Questionnaire (SDSCA)		✓							
	Korean version of the Appraisal of Diabetes Scale (ADS)		✓							
	Partners in Health scale			✓						
	18-question survey; adapted from a survey used in the	✓								

Table 2.12 Evaluation measures employed in the eligible studies identified through the scoping literature review.

Evaluation Measures		Studies								
		Ladner et al., 2022	Lee et al., 2020	McLeod et al., 2020	Baron et al., 2017	McWhorter et al., 2015	McWhorter et al., 2014	Nundy et al., 2014a	Tang et al., 2013	Klug et al., 2011
	Centres for Medicare and Medicaid Services program Everyone with Diabetes Counts.									
	Participant self-management knowledge questionnaire made by a multidisciplinary team (including clinical pharmacist)									✓
Medication Adherence	Morisky 4-item self-report Measure of Medication - Taking Behaviour							✓		
	Medication Adherence scale					✓	✓			
Mental health/ quality of life	Short Form Health Survey				✓					
	Problem Areas in Diabetes		✓						✓	
	Centre for Epidemiologic Studies Short Depression scale				✓					
	Short Trait Anxiety Inventory				✓					
	Patient Health Questionnaire								✓	
	Audit of Diabetes Dependent Quality of Life		✓							
	Diabetes Distress Scale			✓						
	EuroQol-5D			✓						

Table 2.12 Evaluation measures employed in the eligible studies identified through the scoping literature review.

Evaluation Measures		Studies								
		Ladner et al., 2022	Lee et al., 2020	McLeod et al., 2020	Baron et al., 2017	McWhorter et al., 2015	McWhorter et al., 2014	Nundy et al., 2014a	Tang et al., 2013	Klug et al., 2011
Patients' satisfaction	Diabetes Treatment Satisfaction Questionnaire		✓						✓	
	CAHPS Clinical and Group Survey								✓	
	Diabetes Treatment Satisfaction Questionnaire		✓						✓	
	Telehealth Patient Survey, a developed 16-item survey	✓								

Evaluation of intervention' usability

Usability measure was evaluated in different ways in each study (see Table 2.13).

Table 2.13 Evaluation of intervention' usability

Studies	Use of the intervention	Completion of sessions	Estimation of messages
McLeod et al., 2020	N/A[1]	• 92% an initial health coaching session. • 74% had any active engagement.	N/A[1]
Fortmann et al., 2017;	N/A[1]	N/A[1]	• Participants received an average of 354.17 text messages (SD 44.94). • Participants texted back 3–352 blood glucose values (mean 57.77 blood glucose values, SD 60.01). • Neither the number nor the total duration of coordinator phone calls per participant predicted month 6 HbA1c levels.
McWhorter et al., 2015;	N/A[1]	80%	N/A[1]
McWhorter et al., 2014;	N/A[1]	81%	N/A[1]
Nundy et al., 2014b	N/A[1]	• 52% responded to self-assessment questions	• Participants sent and received an average of 4 (range: 2–7) text messages per day.
Lau et al., 2014	21%	• The number of logins varied among the users (from 1 to more than 20 times).	N/A[1]
Chen et al., 2013	90%	• On average patients logged in 1.3 (SD2.2) times every week and performed 1.1 (SD1.3) SMBG daily.	• More patients used the phone call service than the messaging service to contact the HCPs (61% vs 56%).
Tang et al., 2013	88%	N/A[1]	• More messages were initiated to providers from the intervention group than the usual (72% vs 38% p<0.001)
Klug et al., 2011	83%	78%	N/A[1]

[1]Usability method not employed.

Evaluation of medication management

Medication management was also examined as a secondary outcome in five studies, four concerning medication orders (McLeod et al., 2020; Hawes et al., 2018; Orsama et al., 2013; Tang et al., 2013) and the other one regarding daily insulin dose (Baron et al., 2017). Only one study resulted in statistically significant changes between the intervention and control group. Particularly, initiation of new medication or increasing the dose of an existing medication and/or insulin was increased in the intervention group in one study (Tang et al., 2013).

Evaluation of interventions' effects on healthcare utilization and costs

Four intervention studies measured the number of healthcare appointments as a secondary outcome, and all concluded that there was no significant difference between the intervention and comparison groups (Baron et al., 2017; McWhorter et al., 2015; Nundy et al., 2014b; Tang et al., 2013). In addition, two intervention studies involving pharmacists evaluated the average duration of the appointments. The one found that they were longer than the existing traditional program (Klug et al., 2011), and the other one recorded shorter duration of the virtual visits compared to the traditional (Hawes et al., 2018). Furthermore, Hawes et al., 2018 and Nundy et al., 2014b studies evaluated the HCPs' workload for providing the intervention and, therein, the costs for delivering the intervention. The intervention was cost-effective, with the margin being $100 per patient in Hawes et al., 2018, and the six-month program costs in Nundy et al., 2014b study were estimated to be $375 per participant.

2.8. Scoping literature review results

Studies involving pharmacists using DHIs were limited. Specifically, only five studies were identified in the literature. Thus, to evaluate DHIs and thoroughly understand them, interventions made by other HCPs were included in the analysis. The conclusion was that various technology/equipment, services offered, outcome measures, and terminology/definitions employed were found in the literature. This suggested that DHIs use for managing chronic diseases, including diabetes, is evolving, particularly in the past few years due to the Covid-19 pandemic.

Despite these differences in interventions' services offered in each study, some similarities were concluded. For instance, most studies offered communication with HCPs, education, tracking, and uploading of diabetes-related measurements. In addition,

graphical reports, notifications/alerts, reminders, patient record integration, and personal goal development were other services identified through the scoping literature review. However, each intervention offered each service differently, and the number of services offered varied. Also, few interventions were developed based on evidence and theoretical frameworks.

Furthermore, various outcome measures were employed to evaluate the interventions' effectiveness. Those included HbA1c, BG readings, BP / cardiovascular risk, cholesterol levels, weight/ body mass index, frequency of hypoglycaemia, adverse effects, behaviours changes and self-management, medication adherence, patients' knowledge, mental health/ quality of life, intervention' usability, medication management, interventions effects on healthcare utilization and costs, patients' satisfaction, and clinical pharmacists' satisfaction. The reasoning for choosing each outcome measure was not thoroughly described. Thus, robust conclusions on the interventions' effectiveness could not have resulted. Nevertheless, a trend toward improvement in diabetes self-management behaviours and clinical outcomes was concluded (Lee et al., 2020; Majithia et al., 2020; Dixon et al., 2019; Sun et al., 2019; Hawes et al., 2018; Fortmann et al., 2017; Threatt and Ward, 2017; McWhorter et al., 2015; Lau et al., 2014; McWhorter et al., 2014; Nundy et al., 2014b; Chen et al., 2013; Orsama et al., 2013; Klug et al., 2011; Bond et al., 2007). Notably, interventions using technology provided by either pharmacists or other HCPs showed generally positive results, and patients expressed positive thoughts. However, the optimal services, frequency, and volume were not concluded, and further analysis is required.

Although it is essential for the successful implementation and continuation of an intervention to consider all stakeholder's perceptions, only one study assesses the perception of HCPs (Klug et al., 2011). Patients' acceptability and satisfaction were the centres of focus, and other relevant stakeholders' opinions were not as thoroughly evaluated. Also, the usability of DHIs over a period of time was not evaluated in most of the studies.

In summary, it seems that DHIs may positively improve the management of diabetes and assist patients in their self-management. However, there was a lack of studies offering interventions delivered by pharmacists and thus important aspects such as medication adherence were not included in other studies offered by other healthcare professionals

(apart from three Jeong et al., 2018; Nundy et al., 2014a; Chen et al., 2013). Furthermore, a diversity of services, frequency, manners in which they are delivered, and devices used to provide DHIs were identified. Similarly, a range of outcome measures were employed. Descriptive procedures and reasoning for each outcome measure needed to be more adequately provided. Thus, robust conclusions have not resulted. In addition, although patients' acceptance of DHIs was analysed in most studies identified, other stakeholders' opinions and acceptance of intervention were not further evaluated. Consequently, it can be said that there is more to explore to identify the optimal intervention, including the best services offered in the optimal way to address diabetes self-management.

2.9. Limitations of the review

The reviewed studies have sufficiently highlighted and discussed how DHIs could be used and which services can be offered using technology. Most of the studies were conducted in the USA and were provided in English. None of those studies nor apps were conducted in the Cypriot or Greek language.

Furthermore, in each study DHIs were provided differently and using different equipment (mobile phone, internet access, etc.). Similarly, each study's volume and frequency of each intervention were different. Some services were found in most studies, and some were not. Some services were offered synchronously, some asynchronously, and some were individual based. This will not provide a rigorous conclusion of which intervention and technology/equipment were the most effective. Most of the studies did not fully report the exact procedure and role of the HCP in the interventions, which biases their studies' reliability. Evidence-based and theoretical frameworks were identified in only a few eligible studies (McLeod et al., 2020; de Vasconcelos et al., 2018; Nundy et al., 2014a; Nundy et al., 2014b; Orsama et al., 2013; Tang et al., 2013; Bond et al., 2007; Bond et al., 2006). Similarly, outcome measures varied and were not systematically presented, and reasoning for choosing each outcome measure was lacking. Notably, evaluating interventions' feasibility and usability varied through the eligible studies. Usability was measured from text messages and phone calls to logs and submissions to the device employed. Also, feasibility was not thoroughly evaluated in all studies. Medication management, healthcare utility, and delivery costs were a few other measurements employed.

In the same manner, diabetes self-efficacy/ self-management was assessed through a range of measurements and instruments. From medication adherence, behaviours change in other diabetes-related tasks (such as exercise and diet) to knowledge and patients' capability to manage their disease. Thus, meaningful results could not be concluded. In addition, this made it difficult to draw definitive results regarding evaluating the feasibility and effectiveness of the interventions. Several studies have a concise duration of four to six months. This will not capture the reduction of effectiveness and usability of DHIs, which was found in Tang et al., 2013 to reduce after an average of 6 months. Moreover, each study's inclusion and exclusion criteria were also different. From participants' characteristics, age to the ability to use technology, smartphone ownership, etc. All those different eligibility criteria might bias the validity of the data obtained through each study. Finally, qualitative studies evaluating HCP's perception regarding intervention were not identified, apart from one study (Klug et al., 2011).

2.10. Conclusion

The above findings have important public health implications, especially in Cyprus, which has one of the highest diabetes prevalence in Europe (IDF, 2021). DHIs are a promising area for research for the optimization of diabetes management. Although only some studies were found with interventions delivered by pharmacists, an extensive list of services and services' frequency and volume were identified. A combination of services, the way each service could be delivered, and HCPs' involvement were concluded. Also, the interventions' procedure and outcome measures varied. It could be said that the intervention procedures provided in all eligible studies were not thoroughly described, lacked evidence and theory, and did not allow for the replication of the intervention. In contrast, despite small-scale and not always robust study design and outcome measures, positive evidence was obtained regarding the potential efficacy of DHIs and patient acceptance.

Consequently, this study aimed to develop an evidence-based- theory-driven individual intervention delivered by pharmacists in a setting where pharmacy services do not exist. Also, a thorough description of the development and procedure of the proposed intervention to enable the evaluation and potential impact of the intervention. Furthermore, intervention evaluation should be evidence-based and consider all stakeholders' opinions, including HCPs and patients.

End of Chapter Two

Chapter Three

Preliminary fieldwork and data collection

3.1. Introduction

This chapter explores essential stakeholders' perceptions regarding the intervention's development and considers cultural beliefs. Identifying the existing practice, guidelines, and pathways is extremely valuable for developing a new intervention (Bleijenberg et al., 2018; Moore et al., 2015). The proposed intervention was established in Cyprus, where no published literature was identified regarding pharmacist interventions nor digital health interventions (DHIs) involved in managing diabetes. Consequently, gathering comprehensive background information about the health care system, diabetes care, pharmacists' role, DHIs, and being aware of essential stakeholders' opinions in Cyprus provided valuable insights into the context in which the new intervention was to be implemented. The identified information guided the aims and objectives of this current study, shaped the intervention to closely fit the current practice and enhance its workability (Bleijenberg et al., 2018; Moore et al., 2015). Also, it assisted in identifying possible setting(s) for the intervention and for making an appropriate choice of the population to be targeted. This chapter is divided into the following subheadings: methods and results of the preliminary data collection.

3.2. Preliminary fieldwork and data collection methods

The data/ information gathered during the preliminary fieldwork and data collection were obtained through formal websites or social media platforms of relevant official bodies involved in diabetes management and informal interviews with local stakeholders. Official relevant bodies were the Ministry of Health of the Republic of Cyprus (MOHRC), the Pharmaceutical Services of the Ministry of Health (PSMH), the General Healthcare System of Cyprus (GESY), the Health Insurance Organization (HIO), the State Health Services Organisation (SHSO), and Cyprus Diabetes Association (CDA). Relevant studies about diabetes and DHIs in Cyprus and records about the Cypriot diabetes population were searched. Moreover, relevant websites, essential materials (such as educational leaflets), and diabetes events were identified through discussions with stakeholders.

Data gathering and informal meetings with people associated with diabetes were achieved with the "snowball" technique (Smith, 2010). Speaking to different people within these groups linked to diabetes care referred the researcher to important stakeholders who provided essential information relevant to this study. The researcher initiated the search from the Kofinou medical centre (where she was working at that time), and after that, she

was referred to other stakeholders. The researcher visited several times the diabetes clinics (DCs) of the Nicosia General Hospital and Kofinou medical centre, the CDA, and attended the World Diabetes Day event organized by the CDA (see Table 3.1). In addition, she contacted members of HIO and SHSO. Discussions lasted for one year, from January of 2018 until January of 2019. Discussion topics were the management pathways for diabetes in Cyprus, possible gaps in diabetes management pathways, opportunities for pharmacists to address those gaps, and the operational aspects of the proposed intervention. The information found is described below.

Table 3.1 Discussions and informal meetings with key stakeholders during preliminary fieldwork.

Stakeholders	Setting	Topic of discussion
Diabetes patients	Diabetes clinics of the Nicosia General Hospital and at the Kofinou medical centre	• Needs and gaps in diabetes self-management pathways. • Mobile phone use. • Applications use. • Possible gap in diabetes self-management.
	Cyprus Diabetes Association	
	World Diabetes Day event	
Healthcare professionals	Manager of the diabetes clinic of the Nicosia General Hospital (SHSO)	• Management pathways for diabetes in Cyprus. • Different diabetes services were offered in Cyprus. • Diabetes patients' needs and possible gaps. • Pharmacist's role in diabetes management. • Authorization to carry out the intervention.
	Manager of the Nicosia General Hospital (SHSO)	
	Former manager of the Nicosia General Hospital (SHSO)	
	Diabetes nurses and general physicians (Nicosia General Hospital and Kofinou medical centre)	• Management pathways for diabetes in Cyprus. • Needs and gaps in diabetes self-management pathways. • Different diabetes services were offered in Cyprus. • Diabetes patients' needs and possible gaps. • Pharmacist's role in diabetes management. • Perception regarding the development of the proposed intervention. • Referral to other stakeholders. • Mobile phone use. • Applications use.

Table 3.1 Discussions and informal meetings with key stakeholders during preliminary fieldwork.

Stakeholders	Setting	Topic of discussion
Board of directors of the Cyprus Diabetes Association	Cyprus Diabetes Association	• The different diabetes services offered in Cyprus. • Diabetes patients' needs and possible gaps. • Referral to other stakeholders.
Health Insurance Organization	Department of centralized information system	• Information about the centralized information system. • Authorization to access the centralized information system.
SHSO is State Health Services Organisation.		

3.3. Ethical considerations underpinning the fieldwork

The Foster framework was employed to examine ethical issues that may arise during the preliminary fieldwork (Foster, 2001). This framework involves the application of three perspectives to identify and consider ethical issues, and these are the goal-based, duty-based, and rights-based perspectives (Foster, 2001). Those three perspectives were applied to the stakeholders involved in the preliminary fieldwork. These were HCPs working at two DCs, patients and members of the Diabetes Association. The preliminary fieldwork was necessary to understand the current Cyprus health care system and potential gaps and consider the perspectives of all stakeholders before designing and shaping the proposed intervention.

Discussion with HCPs working in DCs, and members of the diabetes association was required to identify the diabetes pathways being followed in practice, potential gaps, and potential solutions to improve diabetes management and how the pharmacy profession could potentially address those gaps from their perspective. The goal of this preliminary fieldwork was to develop an intervention that addresses gaps in current diabetes pathways, increase pharmacist involvement and improve the collaboration among HCPs. No study assessing their perspective on interventions for diabetes in Cyprus was identified. Even though it would not be possible and efficient to involve all HCPs and board members of the diabetes association, all HCPs working at two DCs were involved and all relevant to the intervention members of the Board of Directors of the Cyprus Diabetes Association were included. The fact that the pharmacist conducting the preliminary fieldwork was working with the HCPs at the Kofinou medical centre may lead to more positive feedback about the developed intervention. To overcome this, the

pharmacist prepared an introduction before each discussion to inform all stakeholders of the purpose of the informal discussions, which was to develop an intervention which could potentially assist diabetes patients and not receive positive feedback. To minimize their duty-based perspectives, they were all informed at the beginning of the informal discussion about the reason for the questions and their content. In addition, the time and duration of the discussion were predetermined to minimize their burden and interaction with their workload. The amount of information and material provided by HCPs and members of the diabetes association was based on their willingness and personal time constraints. For example, all discussions with the HCPs working at the Kofinou medical centre were conducted at the end of the day which was their preferred time. To minimize the stakeholder risks due to their participation in the preliminary fieldwork, the pharmacist informed them which information would be contained in the thesis and asked for their consent. All had the opportunity to ask questions, were able to view the thesis material and understood that their participation was voluntary, and that any publication would not contain their names.

Similar to HCPs and members of the diabetes association, ethical issues were considered for patients' participation in the preliminary fieldwork. The aim was to understand patients' views of the current healthcare system, their problems, and how to overcome these problems. Patients are essential stakeholders, and their perception and potential satisfaction are required for a successful intervention. Issues of power between the pharmacist and the patients and possible distress during the discussions were considered. For example, patients who visited the Kofinou medical centre (where the pharmacist worked) may feel compelled to participate in the study and provide more positive feedback. On the other hand, patients identified from other DCs, and diabetes association members may feel more frustrated and reluctant to answer the pharmacist's questions. To avoid patients feeling obligated or distressed, the pharmacist prepared an introduction before moving on to the informal discussion. All patients were informed about the purpose of the informal discussions, the content of the question and how their responses would be used. The pharmacist emphasized that their participation was voluntary, they had the right to ask any questions and were informed that the information provided would be anonymous and their confidentiality and anonymity would be maintained. Only patients who were willing to participate participated in these exploratory discussions and their time commitment and confidentiality were respected throughout the discussions. This may also have resulted in the development of an intervention based on a self-selected

patient sample that does not represent all perspectives. Also, patients included in the preliminary fieldwork could not represent all Cypriot populations. However, the aim of the preliminary fieldwork was not to statistically evaluate patients' perceptions but to develop an intervention based on current practices and consider all direct stakeholders.

Consequently, conducting the preliminary fieldwork in this way informed the development of the intervention with the perception of the direct stakeholders. Nevertheless, it does not represent all HCPs in Cyprus in other settings. In addition, the fact that the pharmacist was working in the DC, may potentially influence stakeholders' engagement and lead to more positive results. Their responses may be influenced by their personal views which may not reflect the actual state of diabetes management in Cyprus. Moreover, the preliminary fieldwork was conducted in the form of informal discussions. This may have its limitations compared to a study evaluating stakeholders' perceptive with ethical approval and a clear structured plan. However, this preliminary fieldwork aimed to conduct exploratory discussions which will inform the development of the intervention understand the current healthcare practices and consider the HCPs and patients' needs. A further robust research study involving a statistically powered population would be beneficial at a later stage after the intervention development and in case the intervention's feasibility evaluation provided reasons for further expansion of the proposed intervention.

3.4. Results of the preliminary fieldwork

Relevant information retrieved from the preliminary data collection is summarised and described below.

3.5. Health care system in Cyprus

Cyprus is the third largest and most populous island in the Eastern Mediterranean Sea and a member state of the European Union (EU). It is located west of Syria and Lebanon, northwest of Israel, north of Egypt, south of Turkey, and east of Greece (Press and information office, 2017). Since 1960, the political system of Cyprus has been a presidential democracy (Republic of Cyprus House of Representatives, 2016). In 1974 Turkey invaded Cyprus and occupied one-third of the island. All information mentioned in this thesis is related to the southern part of Cyprus, which is the internationally

recognized government of Cyprus, hereafter mentioned as Cyprus. The total population of Cyprus was estimated at 1,251,488 in 2022[1] (The World Bank, 2023)

Restructuring of the health care system in Cyprus and development of general healthcare system

Between 2019 to 2020, the healthcare system in Cyprus was restructured, from two parallel sectors, public and private services, to the development of the National Health Service (NHS), referred as GESY. GESY aims to deliver quality healthcare services to beneficiaries with universal coverage of the population, the equal and equitable treatment of all beneficiaries, provision of a comprehensive package of healthcare services, freedom of choice of provider by the beneficiaries, and social reciprocity (GESY, 2018b; MOHRC, 2015). GESY covers a broad spectrum of beneficiaries, whereas public services, before implementing GESY, covered specific populations (including diabetes patients) for healthcare benefits (see Table 3.2) (MOHRC, 2015).

Table 3.2 The beneficiaries prior to and after general healthcare system (GESY) implementation.

Beneficiaries within public services (Prior GESY implementation)	Beneficiaries within GESY
• Persons in need who were poor.	• All citizens of the Republic of Cyprus and ordinary residents of the areas controlled by the Republic of Cyprus.
• Persons with chronic life–threatening diseases (including diabetes patients).	• European Union (EU) citizens who are working in Cyprus or have permanent residence.
• Persons with disabilities.	• Family members of the above categories in accordance with the provisions of national law.
• Civil servants and their families.	• Refugees or persons with subsidiary protection status in accordance with the refugee's law.
	• Non- European Union (EU) citizens who have a permanent residence or have the right to equal treatment in the social insurance sectors in accordance with the aliens and immigration law.

Source: Adapted from GESY, 2018c**;** MOHRC, 2015**.**

[1]https://data.worldbank.org/indicator/SP.POP.TOTL?locations=CY
The World Bank. (2023). Population, total - Cyprus

Operational aspects for the implementation of general healthcare system

The MOHRC is responsible for all aspects and regulations of health operating in Cyprus (including management of both sectors GESY and private sector) and cooperating with other European and worldwide organisations (MOHRC, 2014). For the implementation of the GESY, the HIO was established and consists of the executive authority for the implementation of the GESY with the mission of establishing and continuing the GESY (GESY, 2018h).

Financing of health care system prior to and after general healthcare system implementation

Until the implementation of GESY, the public sector was entirely managed by the MOHRC. GESY is funded from contributions, co-payments, personal contributions (I), donations and legacies, income from assets of the HIO, and any other income accrued from the activities of the HIO. Relevant contributors are employees, employers, state, self-employed, pensioners, income-earners, government officials, and persons responsible for paying remuneration to government officials. (GESY, 2018d). The private sector is financed mainly through individual payments, and hospitals, clinics, diagnostic centres.

Service fee (before GESY implementation) or co-payments (after GESY implementation) is the payment of beneficiaries to the providers for the services received, as described in Table 3.3. Fee for service or personal contribution (I) is the payment in cases where a beneficiary directly visits an outpatient specialist without a referral from their general physician (GP) (see Table 3.4) (GESY, 2018d). Ultimately, personal contribution (II) refers to the payment beneficiaries must pay if they choose a more expensive brand of pharmaceutical product than the one covered by the GESY. Personal Contribution (II) is equal to the difference between the price of the pharmaceutical product covered by the GESY and the price of the pharmaceutical product that the beneficiary chose (GESY, 2018d). Personal contribution (II) was not available prior to the implementation of GESY. The patients could not choose the brand name of the pharmaceutical product, and only one brand of each product was available (MOHRC, 2014; MOHRC, 2015).

Table 3.3 The healthcare services requiring a co-payment and the co-payment amount for each service before and after general healthcare system (GESY) implementation.

Healthcare Services	Public services Amount of fee for service € (euros) (Before GESY)	GESY Services Amount of Co-Payment € (euros)
Per pharmaceutical product	0.50	1.00
Per medical device or medical supplies	0.50	1.00
Per lab test or group of lab tests (note 2)	0.50	1.00
Per visit to a nurse or midwife	6.00	6.00
Per healthcare service performed by a specialist physician in radiology/diagnostic radiology	6.00	10.00
Per visit to allied health professionals	6.00	10.00
Per visit to a hospital to receive healthcare services in cases of accidents and emergencies	6.00	10.00
Note 1: No co-payment is paid in cases where the healthcare services are provided within the context of inpatient healthcare.		
Note 2: The total maximum charge per category of lab tests is 10 euro		

Source: Adapted from GESY, 2018d.

Table 3.4 Personal contribution in case a beneficiary visits an outpatient specialist directly without a referral from their GP before and after general healthcare system (GESY) implementation.

Healthcare Services	Public services Amount of fee for service € (euros) (Before GESY)	GESY Services Personal Contribution I Amount € (euros)
Outpatients visit without a referral from General Physician	Not offered[1]	25.00
A female beneficiary who has attained the age of 15 and visits an Outpatient Specialist in Gynaecology/Obstetrics	6.00	No charge
A beneficiary who is serving his compulsory military service in the National Guard of the Republic and holds a referral by a military doctor referring him to an outpatient specialist	6.00	No charge
[1]This service was not offered prior to the implementation of GESY.		

Source: Adapted from GESY, 2018d.

Access and services of general healthcare system

Within the GESY, beneficiaries have direct access to their chosen GP, gynaecologist/obstetrician, accident and emergency department, dentist, and ambulance. To the other HCPs, a referral from their GP, accident, emergency department, or hospital is needed (GESY, 2018i). Direct access to specialist healthcare service as an outpatient,

without a referral, must be paid with a personal contribution (I) (see Table 3.4) (GESY, 2018d). Beneficiaries have access to laboratories, nurses, midwifes, and allied health professionals after the issue of a referral by a GP or outpatient specialist (GESY, 2018i). They also have access to all GESY pharmacies to provide healthcare services after a prescription by a GP, outpatient specialist, dentist, or Accident and Emergency Department (GESY, 2018i).

All services in the public sector were immediately transferred to the GESY. HCPs and other services offered in the private sector (individuals, hospitals, laboratories, pharmacists, etc.) can either decide to register GESY or offer private practice for payment. According to the online GESY database for healthcare providers, after GESY implementation in August 2022, 702 GPs, 2008 specialist physicians, of which only 20 are endocrinologists, and 199 laboratories were registered to the GESY (GESY, 2019a). The services provided in the GESY and private sector regarding diabetes management are displayed in Table 3.5 and 0, respectively (Azina et al., 2016).

Table 3.5 General healthcare system (GESY) services regarding diabetes management (transferred from the public sector) in Cyprus.

Department/ Specializations[1]	
General physicians General physicians with an interest in diabetes Endocrinologist Diabetologist 24-hours Service for glucose monitoring Insulin Pump Clinics Gestational diabetes clinics in collaboration with obstetric clinics	Plastic surgeries Children's endocrinology clinic Hyperbaric oxygen chamber Diabetes clinic Transplant centre Clinical dieticians Diabetic foot clinic
[1]Established at primary care medical centres and secondary and tertiary hospitals, accordingly.	
Source: Adapted from PSMH, 2007; Azina et al., 2016.	

Table 3.6 Private sector services regarding diabetes management.

Primary Sector	**Secondary Sector**
Private physicians Radiology and radiation therapy services Private podiatrists	Private clinics for inpatients and outpatients, Diabetic Foot Clinics which are operating with specialist physicians
Source: Adapted from PSMH, 2007; Azina et al., 2016.	

Patient health records

Integration of patient health records

Upon implementing GESY, an extensive project to implement a centralized information system was established in Cyprus. The information system is divided into two

subsystems; the Beneficiary and Provider Portal (GESY, 2018f). The services provided by the two subsystems are displayed in Table 3.7.

Table 3.7 The services provided by the two subsystems of the general healthcare system (GESY) information system.

Beneficiary Portal	Provider Portal
• Enrol as a GESY beneficiary and register in the list of the General Physicians of their choice.	• Apply for enrolment and contracting.
	• Have access to their personal information.
	• Manage the beneficiaries list for general physicians.
• Submit questions and lodge complaints.	• Issue and execute referrals.
	• Issue and execute prescriptions for pharmaceutical and consumable products.
• Access to their personal information.	• Issue and execute orders (or referrals) for lab and diagnostic tests.
	• Submit lab and diagnostic tests results.
• Access to their medical history and the medical history of their children.	• Access and update beneficiaries' electronic files.
	• Submit payment requests.
• Access to directories of providers.	• Submit questions and lodge complaints.
	• Receive automated reminders and announcements.
Source: Adapted from GESY, 2018f	

Healthcare professionals' access to patients' electronic data of general healthcare system

Restricted access to the centralized information system of the GESY is authorized for each HCP. HCPs who have access to the centralized information system of GESY are only the GPs and specialist physician. The pharmacist and diabetes nurse did not have access to the centralized information system of GESY. Only the pharmacist executing the prescription could have access to patients' prescriptions. The community pharmacists have restricted access to the centralized information system of the GESY and only have access to patients' pharmacotherapy and to the previous pharmacists, which the patient filled their prescriptions before. Hence, community pharmacists are not able to review patients' pharmacotherapy related to the diagnosis of the GP, patients' laboratory results, and medical histories.

3.6. Pharmaceutical Services of the Ministry of Health (PSMH)

Pharmaceutical Services of the Ministry of Health (PSMH) is responsible for providing high-quality, safe, and effective pharmaceuticals and cosmetics to the Cypriot population and is divided into nine subcategories (PSMH, 2018). At the same time, PSMH is

responsible for operating and controlling all pharmacies. All the sectors of the PSMH and a brief description of their responsibilities are displayed in Table 3.8 (PSMH, 2018).

Table 3.8 The sectors of Pharmaceutical Services of the Ministry of Health (PSMH) and a brief description of their responsibilities.

Sectors	Brief Description
Procurement	• Supplies all pharmaceutical drugs and medical consumables to all State Pharmacies.
Regulation of the Pharmaceuticals	• Regulates the pharmaceutical drugs imported or manufactured in Cyprus by providing drug marketing authorization or withdrawal drugs that failed to pass their controls.
Computerization	• Provides computerized packet of Pharmaceutical Services of the Ministry of Health and all software regarding drugs and stock organization (e.g., the Product Information Management system, Cyprus Drug Information System).
Pharmaceutical Pricing	• Liable for the price of pharmaceutical drugs • participated in the Transparency Committee of the European Union
Inspection	• Inspect all private pharmacies. • Provide registration licenses for the opening of new pharmacies and pharmacist licence. • Licensing import and export of narcotic psychotropic drugs and precursors.
Clinical Pharmacy Administration	• Evaluates the need for new drugs entry to the State Formulary. • Provided the revised State Formulary in 2007. • Responsible for the provision of guidelines and protocols regarding the prescription of drugs. • Attend medical councils and committees. • Examine drugs' costs by preparing pharmacoepidemiology and pharmacoeconomic studies aiming at the optimal use of medicines. • Controlling the rate of increase in drug expenditure.
Harmonization Of Legislation and International Relations	• Liable for the legalization of all Pharmaceutical Services of Ministry of Health activities and must follow European Union regulations.
Cosmetics	• Responsible for the licence and trading of cosmetic products in Cyprus.
Other	• Responsible for the operation and control of pharmacies.
Source: Adapted from PSMH, 2018, p.7-53.	

In 2018, PSMH in Cyprus employed 251 employees, of which 186 were pharmacists, 30 pharmacy technicians, 10 secretarial workers, one account inspector, one general accountant, and 25 hourly-paid workers (PSMH, 2018, p.5). Information about the personnel of PSMH has not been updated after 2018 (PSMH, 2018, p.5).

GESY implementation brought significant changes to pharmacies and the role of PSMH. Table 3.9 presents the number of pharmacies in Cyprus before and after implementing GESY (GESY, 2019a; PSMH, 2019a; PSMH, 2007). With the implementation of GESY, all state pharmacies stopped outpatient services (apart from some exceptions described below) and pharmacists who owned private pharmacies were invited to register in the GESY. The list of pharmacies registered to GESY on the island was 599 and 912 in 2019 and 2022, respectively (GESY, 2019a). Apart from the co-payment paid by the beneficiaries to the private pharmacies, pharmacies are supported by the owner's money. The pharmacy owner must be a licensed pharmacist within the EU and follow the rules and regulations of the PSMH (PSMH, 2000, p 11-25). (GESY, 2018d; PSMH, 2015). Because outpatients' prescriptions are dispensed in all private pharmacies (registered to GESY), the state pharmacies not offering inpatient services and located in a setting where a private pharmacy is available were closed by September 1st, 2019. Some state pharmacies in rural Cyprus, where private pharmacies are unavailable, continue their service, offering outpatient services under the laws of GESY, similar to private pharmacies until a private pharmacy is established. Hence, those pharmacies are dispensing pharmaceutical products offered in GESY, but not over-the-counter medication. All hospital state pharmacies are registered to the GESY. In addition, hospital state pharmacies continue to dispense high-cost pharmaceutical products for chronic diseases to outpatients, as decided by HIO and MOHRC (HIO, 2022).

Table 3.9 Total number of pharmacies in Cyprus, by type and services provided before and after general healthcare system (GESY) implementation (all pharmacies in Cyprus are registered to GESY).

	Type of pharmacy and services					
Region	**Hospital State pharmacies**		**State pharmacies (medical centres)**		**Private Pharmacies**	
Implementation of GESY	**Before**	**After[1]**	**Before**	**After[2]**	**Before[3]**	**After[3]**
	Inpatients and Outpatients	**Inpatients**	**Outpatients**		**Outpatient services**	
Nicosia	3	2	16	3	204	334
Larnaca	2	1	4	2	89	128
Famagusta	1	1	2	0	41	65
Limassol	3	1	5	5	191	273
Paphos	1	1	4	4	76	114
Total	10	6	31	14	599	912

[1] Continue dispensing specific pharmaceutical products with costly treatments for chronic diseases to outpatients. [2] Operating in rural areas where private pharmacies are not available. [3] rom June 1st, all private pharmacies registered to GESY, prior to June 1st, 2020, and after August 4th, 2022.

Source: Adapted from GESY, 2019a; PSMH, 2019a; PSMH, 2007

Pharmacists' role and clinical pharmacy services in Cyprus

The pharmacists' role is mainly focused on dispensing drugs, the provision of information and advice on the correct, safe, and responsible use of medicinal products, and the possibility of substitution with the cheapest medicinal product of the same active substance and pharmaceutical form (generic substitution) (GESY, 2018e). In addition, private pharmacies sell over-the-counter drugs, cosmetics products, pharmaceutical creams, herbal and homeopathy drugs. Other services offered in a private pharmacy are patient consultation, demonstration of the drug use (such as inhalers), measurement of blood pressure (BP), blood glucose (BG), according to the pharmacist's vision for the pharmacy (PSMH, 2000, p 11-25). Pharmacists working in hospital settings in Cyprus undertake dispensing, but none offer clinical pharmacy service. Pharmacists have the authority to access medical notes and records of patients, but they do not have the authority to make changes to a doctor’s prescription (PSMH, 2019b; PSMH, 2018, p.46-47). For any recommendations or prescription clarifications, pharmacists should contact physicians and their HCPs.

3.7. Diabetes mellitus pharmacotherapy

The drugs provided for treating diabetes mellitus by GESY and anti–diabetic drug treatment not covered by GESY are listed in Table 3.10 and Table 3.11, respectively.

(PSMH, 2019c; HIO, 2019d). The PSMH publishes each year an updated drug database, which includes the summary of product characteristics (SPC) and patient information leaflet (PIL) of all available products in Cyprus, covered by GESY or not (PSMH, 2019c).

In Cyprus, diabetes patients are entitled to healthcare benefits according to the laws of GESY (see beneficiaries, Table 3.2). Pharmacies provide all prescribed medicines and associated delivery and testing devices for the management of diabetes, including insulin, oral anti–diabetic drugs, insulin pumps, needles, glucose test strips, and BG monitors (HIO, 2019c). Each drug/product costs €1 (co-payment), and in case patients choose a more expensive pharmaceutical product than the one covered by the GESY, they must pay personal contribution (II). Patients have the freedom of choice among all available pharmacies within GESY. The pharmacist dispensing the prescription is able to find the prescription in the information system of GESY with the patient's date of birth and identification (ID) number (HIO, 2022). In addition, pharmacists are able to identify whether the prescriptions were dispensed. Repeat prescriptions are dispensed at monthly intervals and are valid for a maximum of six months. Beneficiaries who hold a repeat prescription are able to receive their medicinal products without having to revisit the doctor to issue a new prescription (HIO, 2022). The provision of pharmacotherapy and technologies within GESY follows the guidelines and treatment pathways of the laws and regulations of the HIO and GESY (HIO, 2022).

Protocols/guidelines and the catalogue of medicinal products

Currently, only liraglutide is listed in the restricted prescription list concerning diabetes pharmacotherapy (HIO, 2019a, HIO, 2019b). All protocols published by HIO must be followed and implemented by all physicians working within the GESY (GESY, 2018e). In the private sector (not GESY), those protocols are not implemented, and physicians have the authority and are free to prescribe the pharmacotherapy of their choice without limitations.

With the implementation of GESY, HIO is responsible for providing the catalogue of medicinal products available within the GESY and related protocols/guidelines (GESY, 2018e). The GESY compensates only for prescription medicinal products (medicinal products dispensed with a doctor's prescription according to the relevant law) (GESY, 2018e). These medicinal products are included in the Catalogue of Medicinal Products, which the HIO compiles following the relevant scientific committee's recommendations

(GESY, 2018e). Prescribing certain medicinal products is subjected to specific regulations such as protocols/guidelines, prescribed by specific specialists' categories, or pre-approval by the HIO (GESY, 2018e). HIO published a list introducing prescription restrictions for certain pharmaceutical products by physician speciality (HIO, 2019a, HIO, 2019b). Only a few national disease management guidelines were available in Cyprus, which were mainly developed before the GESY implementation. (PSMH, 2019b; PSMH, 2018, p.46-47).

Table 3.10 Anti-diabetic treatment covered by general healthcare system (GESY), provided by private pharmacies.

Oral Anti-diabetic Treatment	
Metformin hydrochloride 500mg[2]	Glimepiride 1mg, 2mg, 3mg, 4mg
Metformin hydrochloride 850mg[2]	Vildagliptin 50mg[1]
Gliclazide 60mg[2]	Sitagliptin 100mg[1]
Glibenclamide 5mg[2]	Sitagliptin 50mg
Saxagliptin 5mg	Linagliptin 5mg
Insulin	
Rapid – acting insulin	Intermediate-acting insulin
Insulin human, Rdna 100iu (penfill)[1]	Insulin isophane 100.00 iu
Insulin human, Rdna 100iu	Long-acting insulin
Insulin glulisine 100 u	Insulin detemir 100u[1]
Insulin lispro 3 ml2	Insulin glargine 100u
Insulin human 100iu	Insulin biphasic isophane 100iu
Insulin aspart (R-Dna) 100u	
Insulin Combination	
Insulin isophane human, biosynthetic 100IU	Insulin aspart (Rdna) (soluble insulin aspart 30% and insulin aspart crystallised with protamine 70%) 100U
Drug Combination	
Metformin hydrochloride 1000mg | vildagliptin 50mg	Linagliptin 2.50mg | metformin hydrochloride 1000mg
Metformin hydrochloride 850mg | vildagliptin 50mg	Linagliptin 2.5mg | metformin hydrochloride 850mg
Metformin hydrochloride 1000mg | sitagliptin phosphate monohydrate 50mg	Saxagliptin 2.5mg | metformin hydrochloride 1000mg
Metformin hydrochloride 850mg | sitagliptin phosphate monohydrate 50mg	Metformin hydrochloride 850mg | saxagliptin 2.5mg
Other	
Dulaglutide 0.75 mg[3]	Exenatide 5.00 mcg[3]
Dulaglutide 1.50 mg[3]	Liraglutide 6.00 mg[3]
Exenatide 10.00 mcg[3]	Lixisenatide 10.00 µg | lixisenatide 20.00 µg[3]
[1]only one brand was available; beneficiaries must pay a personal contribution (II). [2] beneficiaries have the choice of different brands with the same active substance. In the case that they choose a more expensive pharmaceutical product than the one covered by the GESY must pay a personal contribution (II). [3]exceptions of Medication - Dispense at Hospital Pharmacies for Outpatients,	
Source: Adapted from PSMH, 2019c	

Table 3.11 Anti–diabetic drug treatment only offered in the private sector.

Drugs	Drug combinations
Repaglinide	Dapagliflozin
Nateglinide	Linagliptin / Empagliflozin
Canagliflozin	Metformin hydrochloride / Canagliflozin hemihydrate.
Source: Adapted from PSMH, 2019c	

3.8. Pathways for the treatment and management of diabetes

According to the laws and regulations and the services provided by the Ministry of Health in Cyprus, the pathway of an outpatient with diabetes in GESY and the private sector is displayed in Figure 3.1 (HIO, 2022; HIO, 2019a, HIO, 2019b, HIO, 2019c; GESY, 2018c; GESY, 2018d; GESY, 2018i; Azina et al., 2016).

MOHRC, in collaboration with the HIO, developed a presentation slide for the "Clinical pathways and guidelines of type 2 diabetes disease" (MOHRC, 2013). The national guidelines were based on National Institute for Health and Care Excellence (NICE) guidelines published in May 2009 (translated into Greek), Cypriot epidemiological data, and the contribution of competent scientific persons. The national guidelines aimed to be used as a supporting tool for HCPs in their daily tasks. The national guidelines included the management and treatment of type 2 diabetes mellitus (T2DM) disease, treatment for managing glycated haemoglobin (HbA1c), lipids, hypertension (HTN), and detection and management of diabetes complications (MOHRC, 2013).

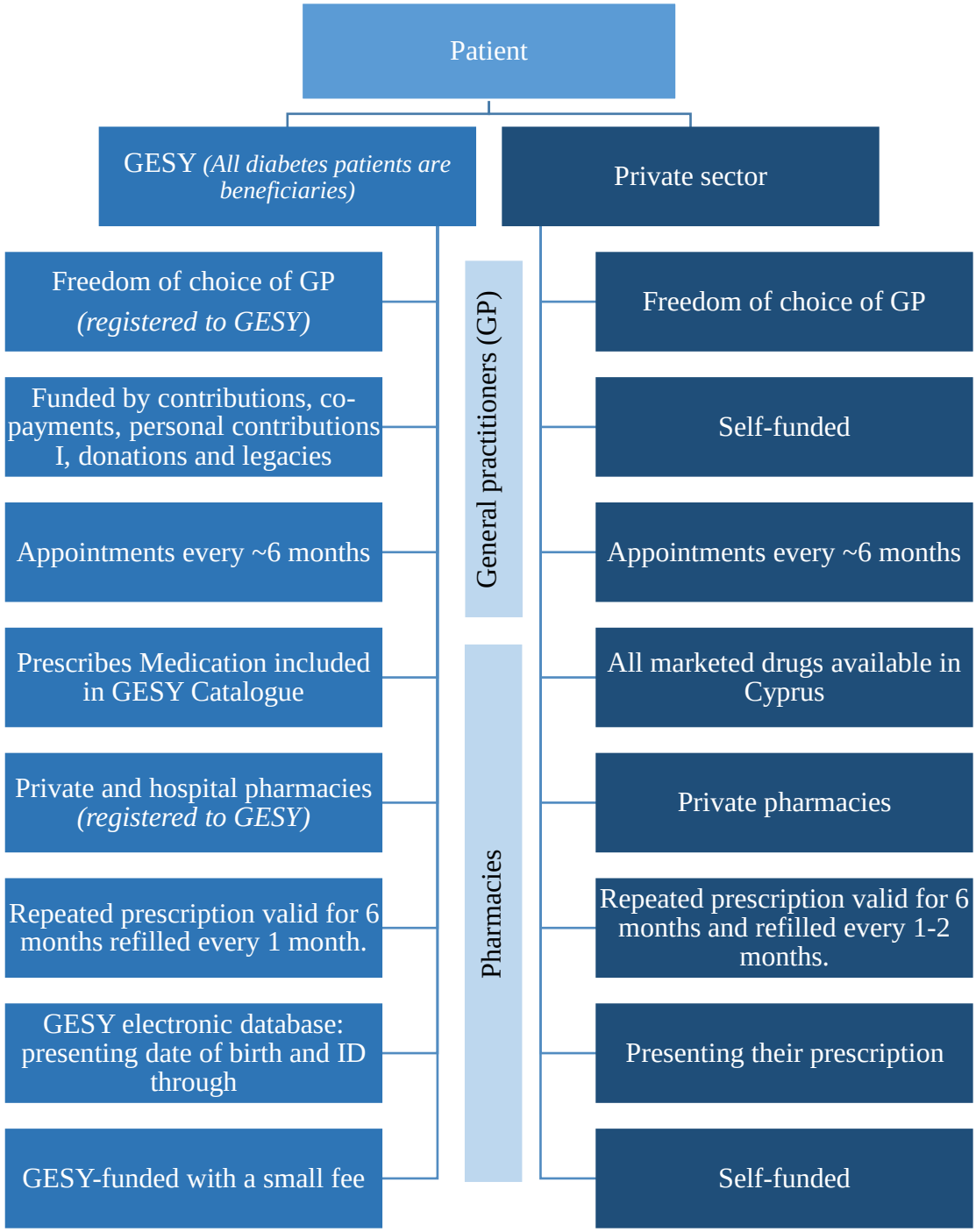


Figure 3.1 Pathway of outpatient with diabetes follows in the private and public sector (HIO, 2022; HIO, 2019a, HIO, 2019b, HIO, 2019c; GESY, 2018c; GESY, 2018d; GESY, 2018i; Azina et al., 2016).

3.9. Diabetes control centre and diabetes clinics in the governmental sector and data recording for diabetes mellitus

The diabetes control centre (DCC) and DCs were developed with the aim to improve the management of diabetes, and support and empower diabetes patients to achieve self-treatment through education (Azina et al., 2016). All diabetes patients (and their families)

using DC and DCC are registered in an educational program depending on their type of diabetes, age, personal treatment, etc. (Azina et al., 2016). Self-care diabetes education checklist and educational leaflets were created/identified to assist diabetes nurses in the provision and track of patient education, see Appendix 3.1 and Appendix 3.2Appendix 3.2. However, structured educational programs and services supporting self-management of diabetes according to standards and guidelines are lacking in the diabetes management services offered in Cyprus.

Healthcare professionals' role in diabetes control centres and diabetes clinics

Diabetes control centres (DCCs) and diabetes clinics (DCs) consist of an endocrinologist or diabetologist, or GP interested in diabetes and a diabetes nurse, where the GP is in collaboration and constant communication with the diabetes nurse. However, it was found that there was no holistic approach to managing diabetes within GESY services and that also a shortage of endocrinologists and diabetologists. To address this, there are specialist nurses and GPs trained to offer diabetes management and treatment services. The title of the GP attending diabetes short courses is "GP interested in diabetes." Diabetes nurses also undertake specialist diabetes mellitus courses. The course duration is one year, with twice a week a theoretical part and a practical part of 20 days (Azina et al., 2016; Nursing Services of Ministry of Health, 2014, p.32).

Diabetes nurses' role in diabetes control centres and diabetes clinics

Prior to their routine appointment with the GP, patients visit the diabetes nurse, who conducts the following:

- Measures weight and height.
- Demonstrates how to administer insulin injections.
- Checks the patient's adherence to treatment and BG monitor.
- Keeps record – data collection (where applicable).
- Provides information/education about diabetes.
- Orders laboratory tests.

Referral to diabetes control centre and diabetes clinic

According to Cyprus pathways in diabetes, patients who struggle to manage diabetes were referred to DC by their GPs or other specialist physicians. Those referrals include a larger number of visits than regular referrals, from 3 to 12 visits, and are valid for longer periods of up to 12 months, and then a new referral is needed (GESY, 2018g; Azina et al., 2016; Nursing Services of Ministry of Health, 2014, p.32). The referrals among physicians are conducted through the information system of GESY. Figure 3.2 demonstrates the pathways of an outpatient from the referral by their physician to DCC.

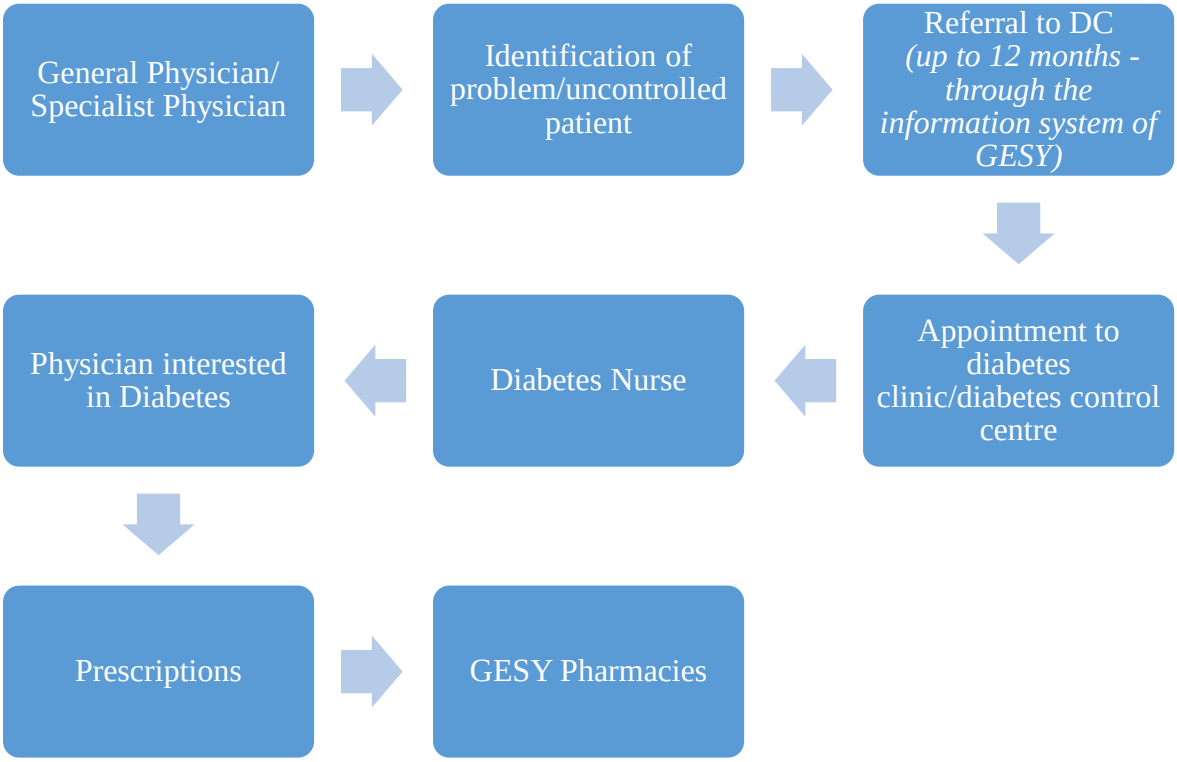


Figure 3.2 Pathways from a referral by a physician to diabetes control centres (DCCs) and diabetes clinics (DCs) services.

3.10. Data recording for diabetes - European Best Information through Regional Outcomes in Diabetes

There is no diabetes national archive. The governmental sector had previously recognised this and, specifically, an endocrinologist and a diabetes nurse initiated the European Best Information through Regional Outcomes in Diabetes (EUBIROD). However, due to changes during the implementation of GESY, EUBIROD operation is currently paused/stopped, but the scenario of re-opening in the future is still open.

EUBIROD system was collecting diabetes patients' data for epidemiological and statistical purposes. The EUBIROD system was the only system solely used at DCC and

DC in Cyprus for the recruitment and data recording for diabetes in contexts with a European Program. EUBIROD started at Larnaca General Hospital and then expanded to Old Larnaca Hospital and Kofinou medical centre with expectations to cover the whole island's needs (Azina et al., 2016).

Diabetes patient health records of Nicosia General Hospital

General physicians (GPs) and diabetes nurses have access to the hardcopy patients' files and information system of the Nicosia General Hospital. However, laboratory results conducted at other facilities, apart from the Laboratory of the Nicosia General Hospital, require access from the centralized information system of GESY. Pharmacists have access to patients' pharmacotherapy, dispensed at the Nicosia General Hospital. However, they need to contact the patient's GP or diabetes nurse to access other information, such as the diagnosis, laboratory results, and medical history.

Diabetes nurse record keeping at the diabetes clinic of the Nicosia General Hospital

The diabetes nurse at the DC of the Nicosia General Hospital created her own patient record-keeping for the DC, which included the name and surname of the patient, date of the appointment, gender, diabetes type, age, GP visiting, BG, weight, height, and HbA1c, if available. The diabetes nurse has the printed appointment list, which includes patients' names, surnames, phone numbers, and ID, provided one day before patients' appointments.

3.11. Association and non-profit organisations diabetes in Cyprus

Two diabetes associations exist in Cyprus: Cyprus Diabetes Association (CDA) and Cyprus Diabetes Association in Limassol (CDAL). The former is the leading and oldest diabetes association with offices across Cyprus; the latter is smaller, mainly operating in Limassol.

Cyprus Diabetes Association – Pan-Cyprian diabetes association

Founded in 1979 the Cyprus Diabetes Association (CDA) champions the rights of patients with diabetes (all types of diabetes) in Cyprus. CDA aims to support people with diabetes and their families and to inform, prevent and educate about diabetes. CDA collaborates with the Cyprus Ministry of Health and Education, Cyprus Diabetes Society, Endocrine Society, Podiatry Association, and Cyprus Dietetic and Nutrition Association. CDA operates offices in all provinces serving over 10,000 members. The CDA collaborates

with internationally recognized organisations, such as International Diabetes Federation (IDF), translating available, evidence-based educational leaflets and material into Greek. These are available to the public and recognised by the Ministry of Health (see Appendix 3.2).

Cyprus Diabetes Association in Limassol

Cyprus Diabetes Association in Limassol (CDAL) is the second diabetes association in Cyprus. Founded in 2000, its activities are based on volunteering, and through its members offers support to diabetes patients and their families. CDAL collaborates with Social Wellbeing Services and the Cyprus Ministry of Health.

3.12. Perceptions regarding the intervention

The setting of the intervention

In order to identify the optimal setting for this intervention, discussions with HCPs working in different settings of GESY, diabetes patients, and the board of directors of the CDA were conducted.

Because the diabetes population in Cyprus is registered with the CDA, this was explored as a possible setting for the intervention. Discussion identified the CDA records which included basic information about their diabetes members (gender, years since diabetes diagnosis). In addition, each member could visit different GPs on the whole island. Thus, using this setting for the proposed intervention was not operable.

Primary settings in Cyprus offering diabetes management services were searched, and particularly DCs/DCCs were investigated. Hence, communication with HCPs working in different settings of GESY, specifically DC/DCC, was conducted. Kofinou medical centre was a potential setting as a DC was operating once a week using the EUROBIROD system and was staffed with a pharmacist, a diabetes nurse, and a GP interested in diabetes. A number of discussions and communication were made. HCPs working at the Kofinou medical centre were willing to participate in this research, offered valuable information about diabetes management in Cyprus, referred the researcher to essential stakeholders (such as the diabetes nurse and GP who initiated the EUROBIROD system in Cyprus), and commented in the operation of the intervention. However, due to GESY implementation, the DC of the Kofinou medical centre, Larnaca General Hospital, and Old Larnaca Hospital closed. The HCPs suggested the DC of the Nicosia General

Hospital. The DC of the Nicosia General Hospital was further explored as the intervention setting and discussions were held with HCPs about the operational aspects of the intervention. The DC of the Nicosia General Hospital operated with one diabetes nurse and three GPs interested in diabetes and used a different patient system record from EUROBIROD. Consequently, the DC of the Nicosia General Hospital was further investigated as the setting of the intervention, and discussions about operational aspects of the intervention were also discussed with the HCPs working there.

Potential study population

The potential study population were discussed with the HCPs at the DCs of the Kofinou medical centre and the Nicosia General Hospital.

All HCPs mentioned that they mainly work with T2DM patients and hence expressed that it would be feasible to identify and recruit T2DM patients. The diabetes nurse at the DC of the Nicosia General Hospital explained that most T2DM patients visiting the DC were on a combination of insulin and oral therapy. As identified during the preliminary fieldwork 113/201 were on a combination of insulin and oral therapy. HCPs could not provide any information about the patients' diabetes and comorbidities (such as uncontrolled diabetes and years of diabetes) as these were not recorded.

Services of the intervention delivered by a pharmacist

Discussions regarding the services provided in the proposed DHI were conducted with HCPs working at the DCs (Kofinou medical centre and Nicosia General Hospital). All services were feasible to implement in the proposed setting. Pharmacist online advice to patient queries, tracking and uploading self-monitoring of blood glucose (SMBG) readings, graphical reports, reminders, and education could potentially be integrated with the DC workflow. All HCPs had positive views about the services. They believed it was a challenging intervention offering several services but would benefit the patient if implemented and successfully used by the patients. They particularly mentioned the gap in research regarding diabetes management and the need for more action. The HCPs from the Kofinou medical centre mentioned the benefits of the EUROBIROD system. Explaining the system helped them monitor their patients' needs and provided valuable information and annual reports on patients' status (such as HbA1c, drug therapy, smoking status, etc.).

Diabetes nurses expressed the need for pharmacist involvement in diabetes management (especially in providing medication information) and the lack of pharmacy service in Cyprus. Education and provision of information to individuals with diabetes were mainly responsibilities of diabetes nurses, including on issues relevant to medication. This led to an increase in the burden of their workload. Diabetes nurses expressed their worries about patients not properly managing their medication and specifically stated the need for an expert to augment patients' education about their medication.

HCPs reacted positively to the proposal that the intervention would include "review of patients' medications," discussing any problems which might occur in patients' pharmacotherapy. Moreover, HCPs were all willing to discuss with the pharmacist regarding her recommendations for participants' diabetes management. They stated they are happy to support and assist in implementing this intervention once ethical approvals were obtained. HCPs were also asked about national guidelines in Cyprus for the management of diabetes. They all stated that only one comprehensive diabetes management protocol existed, and they usually search for guidelines and protocols from international sources, such as NICE and UpToDate.

Perceptions and usability of digital health interventions

Further investigation was conducted about the perceptions and usability of DHIs interventions, specifically apps. Diabetes patients having their appointment at the DC and CDA members (who attended an event for World Diabetes Day in 2018) willing to participate in informal interviews were asked about their thoughts. Mixed thoughts were expressed.

Most diabetes patients and/or their relatives (from the CDA and DCs) expressed that they already used simple apps (such as WhatsApp) to communicate with their HCP. Some of them mentioned using diabetes apps to manage their disease. They explained that apps augment communication with their HCP and mainly use it to exchange information (e.g., patients' BG readings and feedback). They seemed enthusiastic about how diabetes apps could assist them in the daily management of their diabetes. Moreover, they were using apps in the English language, as they stated they were not aware of any available apps in the Greek language.

Other stakeholders, such as GPs and nurses, were also asked about DHI. One issue raised and discussed was the high prevalence of elderly patients with diabetes and whether they are familiar with the technology. Two HCPs expressed that their patients were unaware of how to use their smartphones, apart from making and receiving phone calls. The other two HCPs were curious to see how patients react to an DHI. Whereas one GP was convinced that diabetes patients are already using apps for communication with him, sending him their BG readings and, in general, for diabetes management. Nonetheless, they all agreed that DHIs could assist in managing diabetes.

Consequently, from the informal interviews, it was shown that although some HCPs had concerns regarding the use of the apps by older patients, both HCPs and patients agreed that DHIs could support the management of diabetes.

Information about digital health intervention

None of the main stakeholders from GESY and CDA knew of any DHIs implemented in Cyprus. However, the CDA member referred the researcher to a dietician who was currently developing an app for the diabetes population with a dietician PhD student. After contacting the PhD candidate, the researcher discovered that the app was only focusing on type 1 diabetes (included information about diet, exercise, and medication) and was not yet finalized. Thereupon, a google search was conducted to identify apps in Greek about diabetes management or DHIs established in Cyprus.

The research yielded two DHIs established in Cyprus, but none were about diabetes management, and few diabetes apps were available in Greek. Few apps were identified developed in foreign countries but available in Greek. Their services were then screened, and most were about BG tracking and upload, and hence not further evaluated. One app for diabetes management was identified in Greece with similar services to the proposed intervention. The researcher contacted the project coordinator of the app for potential collaboration. Although the project coordinator of the app was willing to collaborate, this was terminated due to concerns about protecting patients' data.

3.13. Conclusion

The fieldwork conducted has informed the study in different aspects. Reviewing official websites, attending public engagement events, and facilitating discussions with key stakeholders identified on issues pertinent to the present study. It showed that

interventions aiming at improving diabetes management and holistic diabetes management pathways were lacking in Cyprus. Interviewees expressed a gap in pharmacist contribution to diabetes management and a lack of diabetes patients' data records in Cyprus. They highlighted the benefits of actions/interventions aiming to improve diabetes management. Nonetheless, diabetes patients have access to diabetes mellitus pharmacotherapy, including medical supplies, through their community pharmacy.

The challenges in diabetes management pathways discussed indicated that further improvements are needed. More structured organization, and educational programs are required. Although educational leaflets exist in Cyprus, a written curriculum with a mission statement and goals for diabetes education is not in place. One crucial point highlighted by the HCPs working at DCs was the insufficient data records for diabetes patients in Cyprus. However, the only DC operating kept data that might potentially augment the feasibility of this intervention, as the necessary information can be retrieved through those records, and a multidisciplinary team is working there.

In Cyprus, pharmacists' responsibilities and duties remain in their traditional role of dispensing, and there is a lack of a clinical pharmacy service. Thus, expanding pharmacists' responsibilities and taking advantage of their skills and knowledge would be beneficial for the diabetes population in Cyprus. Considering the workload of diabetes nurses and GPs, it was apparent that pharmacists' involvement in diabetes management could lead to successful results. This was supported during the interview with diabetes nurses in different settings in Cyprus. Therefore, it became evident that an intervention led by pharmacists would be beneficial. DHIs in Cyprus were in the very early stages. Nevertheless, promising results were yielded from the discussions with diabetes patients and HCPs who supported expanding research about DHIs.

Consequently, preliminary fieldwork highlighted the necessity of developing and testing interventions optimizing diabetes management in Cyprus and the rationale for implementing the proposed intervention. In addition, it guided the structure and operational aspects of the intervention and informed the objectives of the proposed study, which are further described in the methodology chapter.

End of Chapter Three

Overview of the previously discussed chapters

The previous three chapters serve as a valid base of information to design a study. Chapter One confirmed the need for further research regarding the management of diabetes. This chapter demonstrated that diabetes is a chronic disease affecting people worldwide, is one of the top ten causes of death globally and imposes a significant economic impact on all regions worldwide, including Cyprus. The burden from this disease and its complications are still escalating and expected to rise more in the future unless proper strategies for managing diabetes and its complications are addressed.

A fundamental requirement for managing diabetes is patients' ability to self-manage their disease. However, evidence indicates low adherence rates are an ever-present and complex problem. Policies to meliorate diabetes self-management include a multifactor intervention, compromising patients' education, reminders, follow-up appointments, and regular review of patients and medication counselling through a multidisciplinary team. RPS states pharmacists should be part of a multidisciplinary team (RPS, 2016). In addition, a new approach to achieve the goals mentioned above is DHI, which is currently characterized as one of the most critical strategies in ameliorating healthcare delivery. Consequently, interventions led by pharmacists and other HCPs using DHIs were searched through scoping literature review described in Chapter Two.

Chapter Two reviewed previous evidence and examined DHIs led by pharmacists and other HCPs, through a scoping literature review of 24 studies. The review suggested that DHIs could serve as an effective strategy to improve diabetes management, but more evidence is needed. Moreover, from the studies retrieved, only five were led by pharmacists. This indicates the need for further research regarding pharmacist-led interventions. Hence, it became apparent that a study assessing the feasibility of implementing a DHI led by a pharmacist aiming to tackle adherence and support self-management of diabetes would be pertinent to healthcare needs.

Acknowledging and examining current practice and content to integrate and deliver a DHI delivered by a pharmacist in the existing diabetes management pathway in Cyprus were researched in Chapter Three. Initially, it was essential to review the Cyprus healthcare system, diabetes management pathways, digital health services in Cyprus, and

the pharmacist's role. After that, the potential integration of the proposed intervention into existing diabetes services was examined. Beliefs and thoughts of patients and HCPs regarding pharmacists and DHI were also investigated and considered in the development and evaluation of the proposed intervention. Therefore, it became apparent that improving diabetes management through a DHI would be the subject to be studied. Also, the primary outcome would be to investigate its feasibility in the Cyprus setting and, subsequently, evaluate participants' medication adherence and self-care activity.

Research question, aim and objectives

Research question: Is it feasible to establish an intervention delivered by a pharmacist employing digital health in existing diabetes management pathways in Cyprus?

Aim

This study aimed to design and implement a digital health intervention (DHI) delivered by a pharmacist, which aimed to improve the self-management of type 2 diabetes patients through improving patients' knowledge, adherence, and patient self-care activity and to evaluate its feasibility and participants' acceptability and potential value from the perspective of stakeholders.

Specific objectives:

- To design an intervention based on the literature and through discussion with stakeholders in Cyprus.
- To identify the feasibility of the intervention from the perspective of participants and healthcare professionals.
- To investigate the application and workability of instruments to assess potential clinical outcomes (adherence and self-care activities).
- To examine workability, time spent to deliver the intervention, and cost estimation for the delivery of the intervention.
- To examine possible integration of the intervention into the current pathways and recommendations for modifications to the intervention and/or future service provision.

Chapter Four

Development of the intervention

4.1 Introduction

The purpose of this research study was to design and implement an intervention to be delivered by a pharmacist and employ technology to improve diabetes self-management. This chapter describes the intervention's development and delivery and addresses the research study's first objective. The iterative development process of the intervention followed these steps; development of the first draft intervention, presentation of the intervention to the pertinent healthcare professionals (HCPs), refinement of the intervention, piloting, further refining, and final design. This chapter is divided into the following subsections:

- Theoretical approach to the intervention development process.
- Theoretical framework underpinning the intervention.
- Development of the first draft intervention.
- Refinement of the first draft intervention by the HCPs.
- Pilot.
- Final design of the intervention.
- Delivery of the intervention.

4.2 The theoretical approach to the intervention development process

The theoretical approach to the intervention development process was according to the latest Medical Research Council (MRC) framework (Craig et al., 2008a; Craig et al., 2008b). The MRC framework was originally published in 2000, updated in 2008, enriched in 2018, and revised in 2021 in collaboration with the National Institute for Health Research (Skivington et al., 2021; Bleijenberg et al., 2018; Craig et al., 2008a; Craig et al., 2008b).

In the latest MRC guidance, the first steps for developing a complex intervention are identifying contextual factors and available evidence (Skivington et al., 2021; Bleijenberg et al., 2018; Craig et al., 2008a; Craig et al., 2008b). These steps were largely addressed and presented in chapters 1, 2, and 3. Based on the MRC framework, the next step is identifying or developing an appropriate theory (Skivington et al., 2021; Bleijenberg et al., 2018; Craig et al., 2008a; Craig et al., 2008b). Chapter 1 described the identification of appropriate theories to address the research aims in improving the self-management of diabetes. In this chapter, how these theories shaped the proposed intervention is described.

The next step was to combine the evidence and information identified through the previously mentioned steps and develop the first draft intervention. According to the latest MRC guidance, before the final version of the intervention, refinements and tests are required (Skivington et al., 2021; Bleijenberg et al., 2018; Craig et al., 2008a; Craig et al., 2008b).

The Table 4.1 summarizes the steps followed to develop the proposed intervention based on the latest MRC guidance (Skivington et al., 2021; Bleijenberg et al., 2018; Craig et al., 2008a; Craig et al., 2008b). This chapter describes how all identified evidence shaped the proposed intervention.

Table 4.1 The development process of the proposed intervention based on the latest Medical Research Council (MRC) guidance.

The development process of the intervention	Description of the steps followed	Chapter described	
• Identification and definition of the problem[1]. • Determine the patients' needs[1].	• Epidemiology of diabetes mellitus (focused on type 2) and its management. • Evidence based on treatment adherence (including adherence to medication), empowerment and self-management. • Evidence of non-adherence to treatment and ways to improve it.	Chapter 1	First draft intervention
• Identification of evidence by reviewing published and existing systematic reviews.	• Evidence of interventions led by pharmacists and digital health interventions before conducting scoping literature review. • Scoping Literature Review focusing on digital health intervention and self-management of diabetes.	Chapters 1 and 2	
• Examine current practice and context[1].	• Preliminary fieldwork: meetings and interviews with important stakeholders, identification of national guidelines and diabetes management pathways and problems/gaps in the existing system which hinder the provision of optimal care.	Chapter 3	
• Identifying/developing of appropriate theory.	• Evidence of already existing theories were identified. • Empowerment framework and principles of motivational interviewing.	Chapter 1	

Table 4.1 The development process of the proposed intervention based on the latest Medical Research Council (MRC) guidance.

The development process of the intervention	Description of the steps followed	Chapter described	
• First draft intervention, refined by the healthcare professionals' staff, piloted and further refined until final version	• Cumulative evidence and information identified from the previous steps • Develop first draft intervention, refine by healthcare professionals' staff comments, piloted, and further refined • Engage stakeholders throughout the process	Chapter 4	Second draft intervention
• Pilot period	• Identify final changes that would shape the intervention's final version.	Chapter 4	Final intervention

[1] added to updated and enriched Medical Research Council (MRC) framework Skivington et al., 2021; Bleijenberg et al., 2018

Source: Skivington et al., 2021; Bleijenberg et al., 2018; Craig et al., 2008a; Craig et al., 2008b.

4.3 The theoretical framework of the intervention

The proposed intervention aimed to improve type 2 diabetes mellitus (T2DM) self-management by improving knowledge, adherence, and empowerment. Consequently, the appropriate theoretical framework chosen to underpin the design of the proposed intervention was the philosophy of empowerment and motivational interview (MI) (Salimi et al., 2016; Anderson and Funnell, 2000; Funnell et al., 1991). Details of how each theory shaped the intervention are described below. Both concepts were developed to address the non-adherence problem, especially in chronic diseases such as diabetes, and they are employed to improve self-management and ownership of patients' disease, as described in chapter 1 (Salimi et al., 2016; Anderson and Funnell, 2000; Funnell et al., 1991). The empowerment framework encompasses the concept that to accomplish effective self-management, patients must be well-informed and active partners or collaborators in their own care (Funnell and Anderson, 2004; Funnell et al., 1991). MI aims to empower patients, achieve positive, long-lasting change, and evoke them to be part of the management of their disease (described in chapter 1) (Salimi et al., 2016).

4.4 The development of the first draft intervention

The first objective of the proposed research study was to base the intervention on robust evidence identified through literature and discussions with stakeholders in Cyprus.

Consequently, based on the knowledge gained through available evidence (chapter 1), literature review (chapter 2), and informal discussions with stakeholders in Cyprus (chapter 3), the first draft intervention was developed. The first draft intervention included an idea of what the intervention would look like including the concept of the intervention based on the theoretical framework underpinning the intervention, the services and operational aspects of the services, and the media used to facilitate the intervention. Each subcategory is described below.

Concept of the proposed intervention based on the theoretical framework

This intervention aimed to create active patient making informed decisions regarding their self-management with the optimal aim to improve self-management and provoke long-lasting behaviour change. To achieve these goals, MI techniques guide each intervention step, including the conversations between the pharmacist and the patients (Sabeeh, 2015; Steinberg and Miller, 2015; Ogedegbe et al., 2007). The four core motivational interviewing skills are open questions, affirmations, reflections, and Summaries, abbreviated OARS (Sabeeh, 2015; Steinberg and Miller, 2015; Ogedegbe et al., 2007). OARS is a skills-based model of interactive techniques adapted from a patient-centred approach using motivational interviewing principles (Sabeeh, 2015; Steinberg and Miller, 2015; Ogedegbe et al., 2007).

Mainly, principles of MI and OARS were employed to understand patients' needs and values. Concurrently the pharmacist engages with patients to create a diabetes self-management plan. (Salimi et al., 2016; Sabeeh, 2015; Steinberg and Miller, 2015; Ogedegbe et al., 2007). The proposed intervention was planned to allow patients to guide the consultations by choosing those issues they believed most relevant or essential for them to, and hence design their self-management plan. Their opinions would be required before the pharmacist offered the "solution" to their problem. Guidance was developed to assist the pharmacist in delivering the intervention to base all patient conversations on OARS and MI techniques. This guidance included examples of questions identified by the Sabeeh, 2015, Ogedegbe et al., 2007 and Steinberg and Miller, 2015 studies and is presented in Appendix 4.1 (Sabeeh, 2015; Steinberg and Miller, 2015; Ogedegbe et al., 2007)

Concurrently, the philosophy of empowerment was used in the proposed intervention. Specifically, the notion that HCPs provide the knowledge, education, appropriate care, recommendations, expert advice, and support and that the patients bring the expertise on their life and what suits them the best was used to underpin the design of the proposed intervention (Funnell and Anderson, 2004; Funnell et al., 1991).

Patients set personal goals and develop personal plans

Based on the philosophy of empowerment and MI, the proposed intervention was individually driven (Salimi et al., 2016; Funnell and Anderson, 2004; Funnell et al., 1991). These were grounded in a literature review of similar interventions (chapter 2), informed by the available evidence (chapter 1) and relevant studies employing MI techniques (Sabeeh, 2015; Steinberg and Miller, 2015; Ogedegbe et al., 2007; Welch et al., 2006).

Evaluate the patient's self-management activities

The first step required to develop an individual plan based on similar studies identified through the literature was to evaluate the patient's self-management behaviour, knowledge, empowerment, and/or other related diabetes information (McLeod et al., 2020; de Vasconcelos et al., 2018; Hawes et al., 2018; Threatt and Ward, 2017; Tang et al., 2013; Chen et al., 2013; Bond et al., 2007). Thus, a tool to facilitate this was required. From the evidence identified (in chapter 1), the Diabetes Self-Care Activity Questionnaire – Greek version (DSCAQ – Greek version) was the optimal tool (Intas et al., 2012). Initially, because it measures the frequency of self-care activity in the last seven days for five aspects of the diabetes regimen, thus it serves our purpose of identifying patients' self-management behaviours. Secondary, because it was available in the Greek language and its use was validated in the Greek population (Intas et al., 2012).

This tool will assist the pharmacist in understanding patients' behaviour regarding their self-management in five domains: medication taking, self-monitoring of blood glucose (SMBG), healthy eating, physical activity, and foot care (Intas et al., 2012). It is essential to highlight that the intervention's primary focus is medication adherence; hence, the DSCAQ – Greek version was adapted to address that. In particular, because of the importance of adherence, the flow of the DSCAQ – Greek questions was changed to ask the topics about medication first and then the rest. The permission to use the DSCAQ –

Greek version, primary questionnaire and the adapted questionnaire, in Greek and English versions are presented in Appendix 4.2, Appendix 4.3, and Appendix 4.4, respectively.

The next step was correctly interpreting patients' responses to the adapted DSCAQ – Greek version. This was required to support patients' set self-care goals and develop a personal plan. The interpretation of the Diabetes Self-Care Activities Questionnaire was identified and adopted by Toobert et al., 2000. However, Toobert et al., 2000 study did not address the cut-off point for adherence. The researcher did not identify other studies interpreting the adherence threshold of the DSCAQ. Consequently, final cut-off points were sought from other studies evaluating medication or other diabetes activities adherence. The Baumgartner et al., 2018 systematic review of medication adherence concluded that the 80% threshold was clearly questioned as a general standard. The systematic review suggested setting an adherence threshold relative to clinical relevance. A retrospective analysis for adherence threshold for T2DM patients concluded that optimal adherence cut-off appeared to be slightly higher than the conventional value of 80% and may vary depending on the length of assessment period and outcome definition (Lim et al., 2021). Concerning the clinical relevance that the research study aimed to achieve, a cut-off points of 80% was considered reasonable for assessing patient adherence. Therefore, a good adherence level will be considered 80% for each diabetes activity, between 60%-80% will be considered average adherence, and below 60% will represent low adherence levels (see Figure 4.1 for instructions for estimating patients' adherence levels and Appendix 4.5 for instructions on scoring scales and adherence cut-off points).

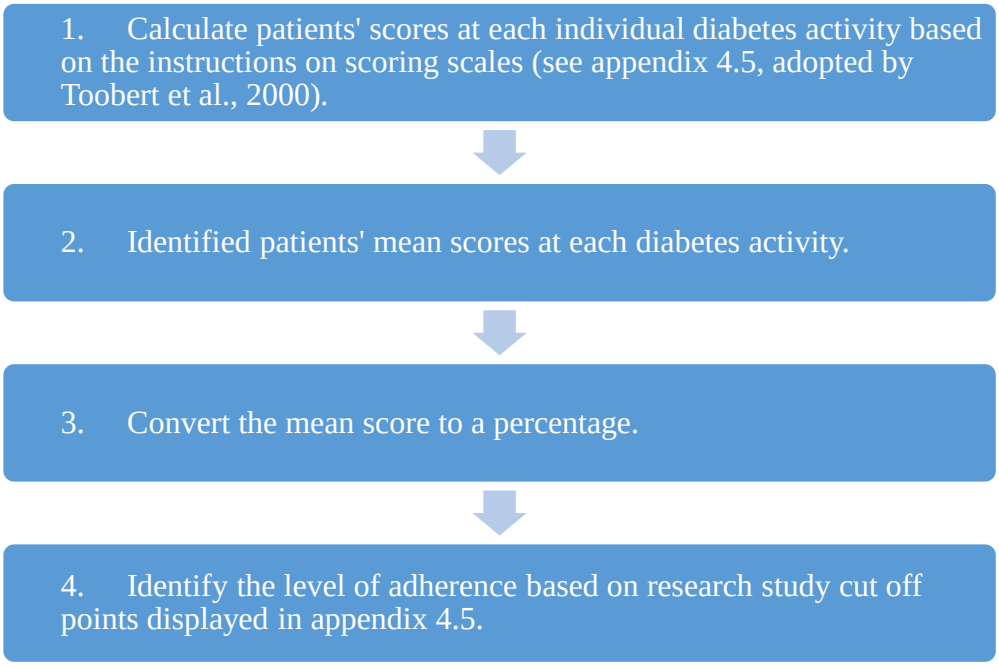


Figure 4.1 Estimating patients' adherence level based on the responses to the adapted Diabetes Self-Care Activity Questionnaire – Greek version (DSCAQ - Greek version) (adopted by Baumgartner et al., 2018 and Toobert et al., 2000).

Employing motivational techniques to support patients in setting self-care goals

This intervention aims to encourage patients to optimize their self-care. Thus, to support them in setting one or more self-care goals, MI techniques were employed (Salimi et al., 2016; Steinberg and Miller, 2015). Available examples to guide the consultation appointments and elicit patients' preferences, needs, and values and evoke patients to create a diabetes self-management plan were required. In the literature review, examples identified patients being encouraged to set one or more self-care goals and formulate an agreed care plan through a discussion with their HCP (McLeod et al., 2020; de Vasconcelos et al., 2018; Hawes et al., 2018; Threatt and Ward, 2017; Tang et al., 2013; Chen et al., 2013; Bond et al., 2007). Only two of the identified studies employed MI, but none described how this was implemented (McLeod et al., 2020; Tang et al., 2013). Consequently, MI techniques were identified and adapted from Sabeeh, 2015 and Ogedegbe et al., 2007 studies (Sabeeh, 2015; Ogedegbe et al., 2007). The consultation appointments were changed to ask topics about medication first and then the rest of the topics (in case the patient chose medication as a topic from the agenda-setting). A summary of the core elements followed during the consultation appointments based on MI techniques is described in Figure 4.2. A detailed explanation of the steps followed during the consultation appointments is presented in Appendix 4.6 and Appendix 4.7.

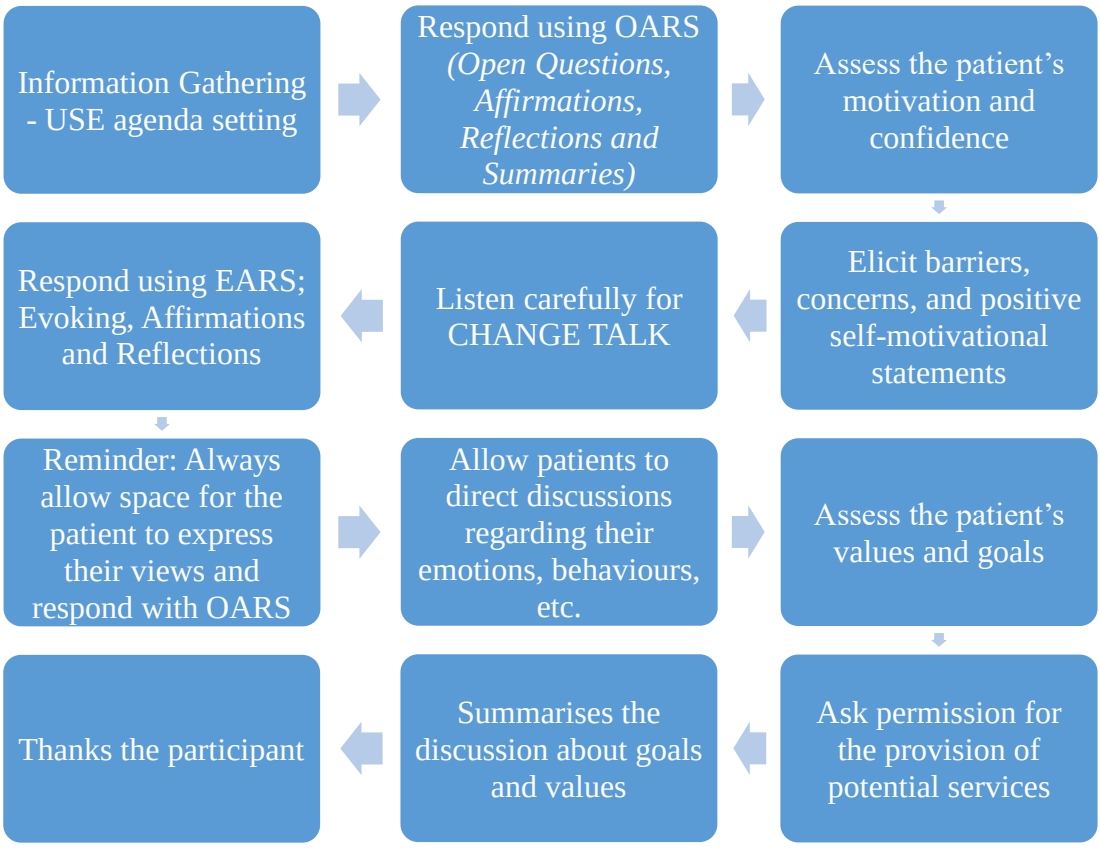


Figure 4.2 A summary of the core elements followed during the consultation appointments based on MI techniques (Adapted by Sabeeh, 2015; Ogedegbe et al., 2007).

Based on the MI principles, HCPs offering the MI should use an agenda-setting, like a simple chart, to elicit patients' preferences regarding the focus of the consultation (Steinberg and Miller, 2015; Welch et al., 2006). The agenda-setting developed was adopted by Steinberg and Miller, 2015, Welch et al., 2006 and Powell et al., 2014 studies which employed MI techniques (Steinberg and Miller, 2015; Welch et al., 2006; Powell et al., 2014). The agenda-setting presented to patients was based on the adapted DSCAQ – Greek version and can be found in 0. The questionnaire evaluates treatment adherence in respect of five domains: medication taking, SMBG, healthy eating, physical activity, and foot care. Furthermore, foot care was incorporated into the knowledge, as participants might choose knowledge for different aspects of diabetes. Hence, the topics for the agenda settings were classified as medication taking, SMBG, healthy eating, physical activity, and knowledge about diabetes.

Similar studies identified that setting personal goals and developing a personal plan was performed during recruitment of participants (McLeod et al., 2020; de Vasconcelos et al.,

2018; Hawes et al., 2018; Threatt and Ward, 2017; Tang et al., 2013; Chen et al., 2013; Bond et al., 2007). Thus, it was reasonable to set personal goals and develop a personal plan at the first appointment with the patients. Moreover, based on evidence, an agreed and continually updated care plan tailored to individual needs and lifestyle is essential in improving health outcomes (WHO, 2016a; IDF, 2017a; NICE, 2015b). Thus, patients' personal plans and goals will be continually updated throughout the intervention (IDF, 2017a; WHO, 2016a; NICE, 2015b). For these purposes, a flowchart was developed to assist the pharmacist in providing initial and subsequent consultation appointments with the patients. Moreover, the flowchart was designed to increase consistency between the appointments offered by the pharmacist. The flowchart is displayed in Figure 4.3.

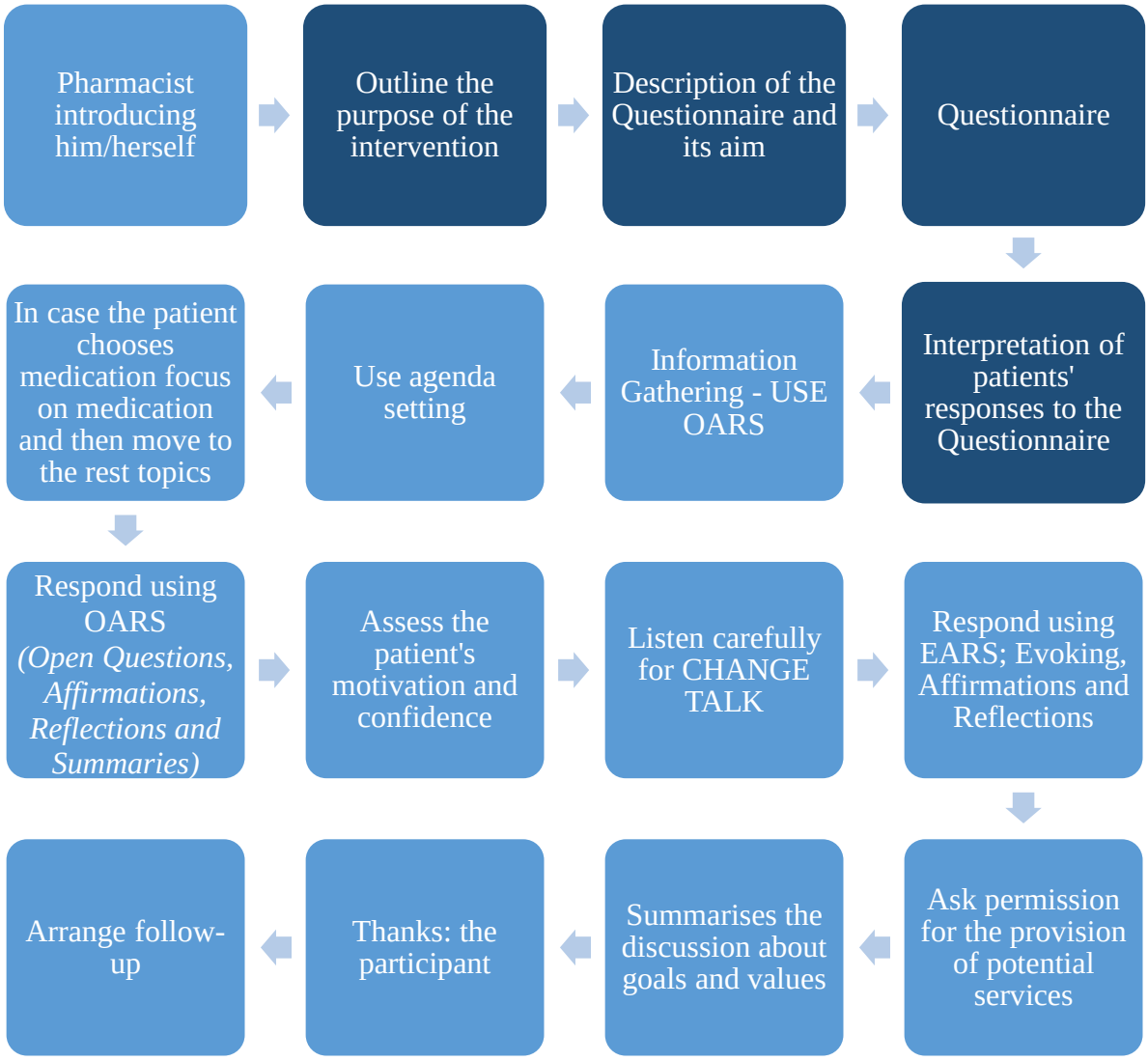


Figure 4.3 Flowcharts of initial and follow-up consultation appointments (steps in dark blue are employed in the initial consultation, and steps in blue are repeated at each consultation with the participant).

Potential services to patients' diabetes problems

The services planned to be part of the intervention were pharmacist online advice to patient queries, provision of education, review of patients' medications, reminders for SMBG, reminders for medication taking, reminders for medication refill and reminders for appointments, and tracking of blood glucose (BG) and graphical reports (see Table 4.2). The category of potential services for patients with diabetes problems is presented, and each service is explained in this section.

The pharmacist must be prepared to respond to different patients' diabetes problems. To improve consistency and cover different aspects of diabetes management, the potential services were based on the adapted DSCAQ – Greek version (see Table 4.2). According to the concept of the intervention, each service should be offered after obtaining patients' approval to learn the "solution" and after patients set personal goals to improve this aspect of diabetes management (e.g., improving medication taking or healthy eating) (Salimi, et al., 2016). Different services were developed, to address each problem based on patients' needs and lifestyle (Funnell and Anderson, 2004; Funnell et al., 1991).

Table 4.2 The potential services provided in the intervention based on patients' diabetes problems.

Adherence problems on	Medication	Blood glucose	Healthy eating	Physical activity	Knowledge/ Foot care
Potential adherence solutions for each adherence problem	Education[1]				
	Pharmacist online advice to patient queries[2]				
	Reminder				
	Tracking of blood glucose and graphic reports				

[1]Individually driven education was based on the information identified in chapter 3 (educational leaflets and the PSMH's drug database) and on ADA/ AADE guidelines (Mensing et al., 2000).
[2] Answering questions to patients' concerns in a certain timeframe.

Provision of education

The rationale for including the provision of education was to empower and support individuals with diabetes to manage their disease, consistent with the concept and aim of the proposed intervention (Funnell and Anderson, 2004). Also, it is well established that patient education is one of the key priorities for managing diabetes (NICE, 2015b; NICE, 2008). Based on the preliminary fieldwork, the educational leaflet distributed to diabetes patients in Cyprus and the drug database of the PSMH were the most appropriate sources

to educate patients about the proper management of diabetes. An advantage of using the existing leaflets, already distributed in Cyprus, is that this might increase consistency and integrate the proposed study into the available diabetes management pathways because all HCPs will be more likely to offer the same educational leaflets.

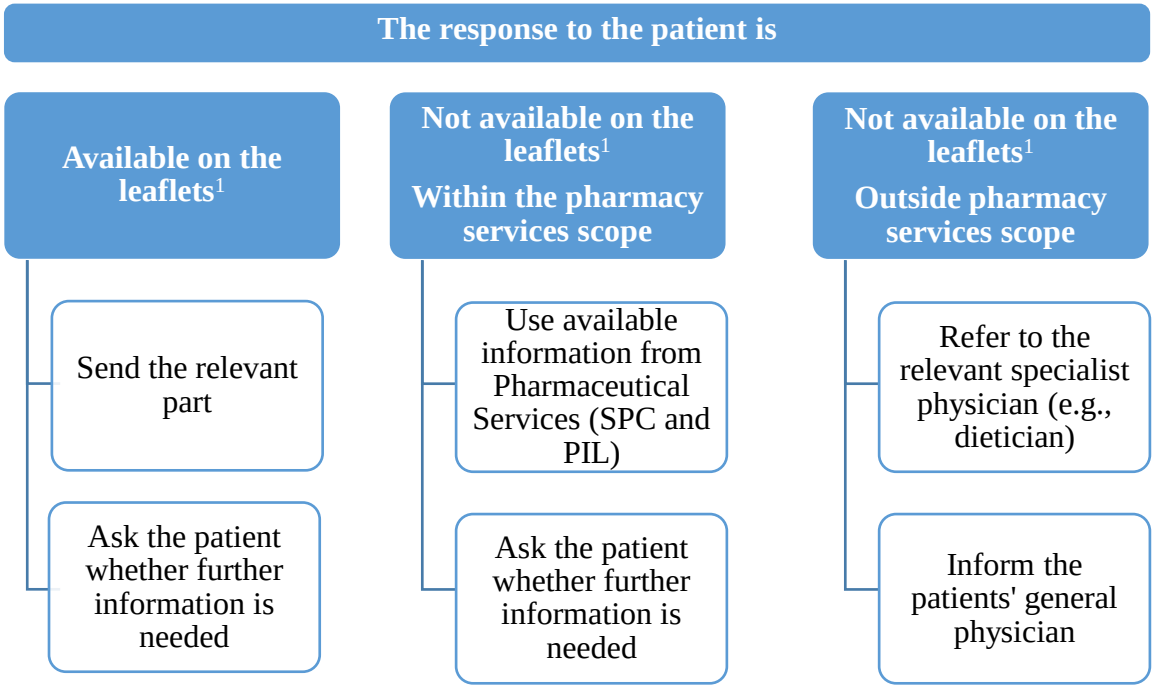
Consequently, the education provision was individually driven, and the education curriculum was based on the information identified in chapter 3 (educational leaflets and the PSMH's drug database) and based on ADA/ AADE guidelines (Mensing et al., 2000). The ADA/AADE curriculum and available leaflets at diabetes clinic (DC) are presented in Appendix 4.8. Examples of educational leaflets employed are presented in Appendix 4.9.

How the education would be provided was planned to be conducted by discussing or sending personalized educational information to patients. Previous studies identified provided education through calls, messages with text or videos, or access to an electronic library. The only ways not feasible to implement in the current situation were the videos and access to an electronic library. Creating the videos would require considerable time, and there was no library on diabetes, either electronic or handwritten, in Cyprus, thus it was not feasible to implement in the current situation. Therefore, discussing or sending personalized educational information to patients was feasible.

Pharmacist online advice to patient queries

The feasibility and practicability of the service "pharmacist online advice to patient queries" was considered. Different ways of delivering this service were identified through the literature (chapter 2) and were: immediate response to patients' diabetes related data, creating motivational messages and medication adjustments. Medication adjustments could not be implemented in the current context, as regulations in Cyprus do not allow pharmacists to modify patients' treatment independently (PSMH, 2018, p.46-47; PSMH, 2019b). Answering questions to patients' concerns in a certain timeframe was considered accomplishable and potentially effective. From the studies which facilitated online messages/ responses to participants' questions, only one stated the response time, which was 48 hours (Lau et al., 2014). This timeframe, 48 hours, was thought manageable when taking account, the study's sample size (feasibility study) and that only one pharmacist will provide the service.

Moreover, to ensure consistency and validity a flowchart for the pharmacist online advice to patient queries is presented in Figure 4.4. Three categories of questions and responses to those questions were developed, as shown in Figure 4.4. For example, if a patient has a question about hypoglycaemia, which is covered in the leaflets available, then the pharmacist should follow the instructions in the leaflet and also ask the patient if they would like more information. Similarly, questions within the pharmacy services scope can be addressed with SPC and PIL information and outside the pharmacy scope by referring to the relevant specialist physician.



[1]Leaflets refer to the educational leaflets employed for the provision of education.

Figure 4.4 Flowchart for the service "pharmacist online advice to patient queries".

To increase consistency and remind the pharmacist offering the intervention to follow MI techniques, a template of message conversation between the pharmacist and patients was developed (see Appendix 4.10).

Review of patients' medications

The preliminary fieldwork showed the need for a clinical pharmacy, including review of patients' medications service. Thus, adding this service to the proposed intervention would be beneficial. Review of patients' medications refers to the pharmacist reviewing participants' regimens and improving their treatment according to their individual status

(e.g., age, comorbidities, drug interaction, etc.). Based on Cyprus regulations, pharmacists cannot independently adjust patients' pharmacotherapy. Nevertheless, they must make recommendations to GP about medication when needed (PSMH, 2019b; PSMH, 2018, p.46-47). Hence, in the proposed study, a review of patients' medications was initially planned to be implemented by the pharmacist making recommendations to the GPs.

Guidelines and protocols were needed to support the pharmacist's recommendations to the GPs. All recommendations must follow national regulations and rules (PSMH, 2019c; HIO, 2019d). However, only one national protocol was identified through preliminary fieldwork (MOHRC, 2013). Hence, further discussions with the HCPs working at the DC were required to determine what other sources could be used. Moreover, a communication template on pharmacist recommendations was developed. The reason for this was to ensure consistency in the communications. The template is displayed in Appendix 4.11.

Reminders for self-monitoring of blood glucose, medication taking, medication refill, and appointment

Evidence showed promising results in increasing diabetes medication adherence with reminders (WHO, 2011; Hanauer DA et al., 2009; Quinn et al., 2009; Franklin et al., 2008; Cocosila et al., 2004) and has shown that appointment reminders may increase attendance (Vermeire et al., 2005; WHO, 2003). Thus, it was planned to include this service in the proposed intervention.

Operational aspects of this service were adopted by similar studies identified through scoping review (Nundy et al., 2014a; Nundy et al., 2014b). Instructions for the pharmacist to follow to develop individual patients' reminder message programs were developed at this point to enhance consistency. In addition, responses from the patient on whether they have taken their medication were requested. This was to monitor patients' medication adherence. Individual patients' reminder message programs and examples of messages in Greek and English language are presented in Appendix 4.12.

The feasibility of implementing this service was also considered. The time and day the text messages were sent can be scheduled in advance on all mobile phones. Thus, it only

requires one person to organise those text messages and prepare them in advance. For example, every week, which is considered feasible for the pharmacist's workload.

Tracking of blood glucose and graphical reports

This service was to be part of the intervention based on the evidence that sharing patient's related data with HCPs' feedback can enhance decision support in healthcare settings, integrated care, education, and empowering patients in their own self-care (WHO, 2017; World Health Assembly, 71, 2018a).

According to preliminary fieldwork, some patients already sent their SMBG readings through the Viber application (app) to their GP. Viber app is a simple, commonly used app in Cyprus, available in Greek, enabling free communication among people through an internet connection (similar to WhatsApp) (Viber, 2019). All Viber calls and chats are protected by built-in end-to-end encryption to secure all conversations (Viber, 2019). In addition, the SMBG device, currently offered to diabetes patients, enables uploading and transmitting patients' SMBG readings. Consequently, tracking of SMBG could be integrated into the current practices. Similar studies, identified through the literature (chapter 2), were reviewed regarding the timeframe for providing graphical reports (Baron et al., 2017; Lau et al., 2014; McWhorter et al., 2015; McWhorter et al., 2014; Tang et al., 2013; Chen et al., 2013; Orsama et al., 2013). The timeframe considered feasible to implement in the proposed study was every 2-4 weeks. Due to the concept of the intervention being individually driven, the timeframe depended on patient needs and preferences. The Excel program will be employed for the creation of graphical reports.

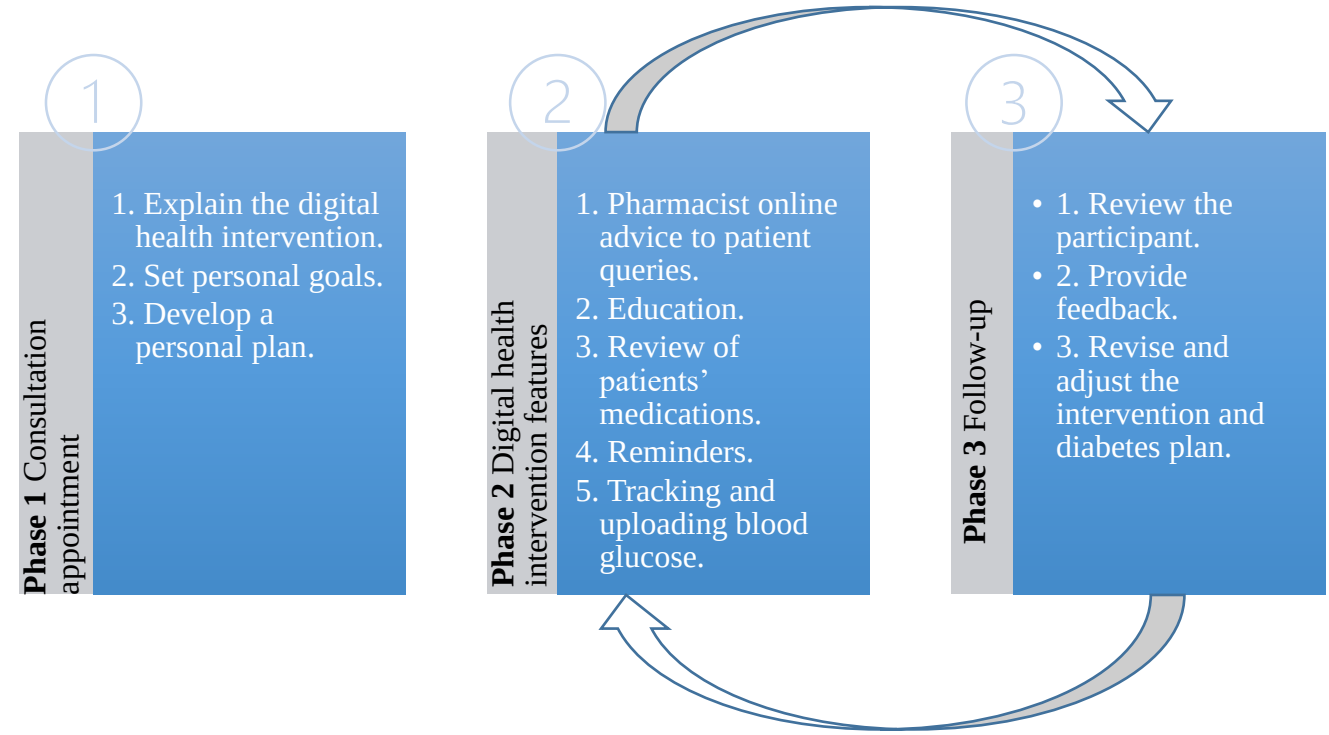
Follow-up appointments

Follow-up appointments between the pharmacist and the patients were included in the intervention. Evidence indicating that follow-up appointments and regular review of patients are some of the components of optimal interventions in improving adherence to treatment and health outcomes. (WHO, 2016a; Vermeire et al., 2005; Renders et al., 2000). The purpose of patients' follow-up appointments would be to review the patient (assess the progress of self-care adherence), provide feedback or address any questions/concerns. Based on that, the intervention and diabetes individual plan were revised and adjusted. The developed plan for each patient must be constantly updated,

based on patients' responses, at each follow-up appointment (IDF, 2017a; WHO, 2016a; NICE, 2015b).

Since the intervention developed is individually driven, patients could choose how they want to be contacted and the frequency. Thus, follow-up appointments were scheduled on frequency, time, and day convenient to the patient. However, this was also informed by the scoping review to have a plan of how this will be facilitated. Patients were regularly reviewed at 1-2 or 3-week, 2–3-month intervals by text and phone calls (Sun et al., 2019; de Vasconcelos et al., 2018; Threatt and Ward, 2017; Klug et al., 2011; Bond et al., 2006). Three months was considered a long period based on the nature of the study (feasibility study). Hence, intervals between 1 week and up to 8 weeks were considered manageable. Text messages and phone calls were feasible based on patients' preferences in the proposed setting.

Furthermore, the theoretical framework underpinning the intervention and the nature of the study guided how many follow-up appointments were facilitated. The flowchart detailing the structure of the intervention and activities carried out at each appointment is presented in Figure 4.5. The intervention aims to be individually driven. Thus, if the patient is adherent and feels that he/she does not need further support, she/he will be able to continue using the services of the intervention until the next appointment. After that, if the patient continues to adhere to diabetes management and feels that he/she gained the benefits of the intervention, the pharmacist should encourage and acknowledge the patient's efforts, and no additional appointments will be required. In cases where the patient is not adherent and feels that he/she needs further support, follow-up appointments with the pharmacist will be scheduled.



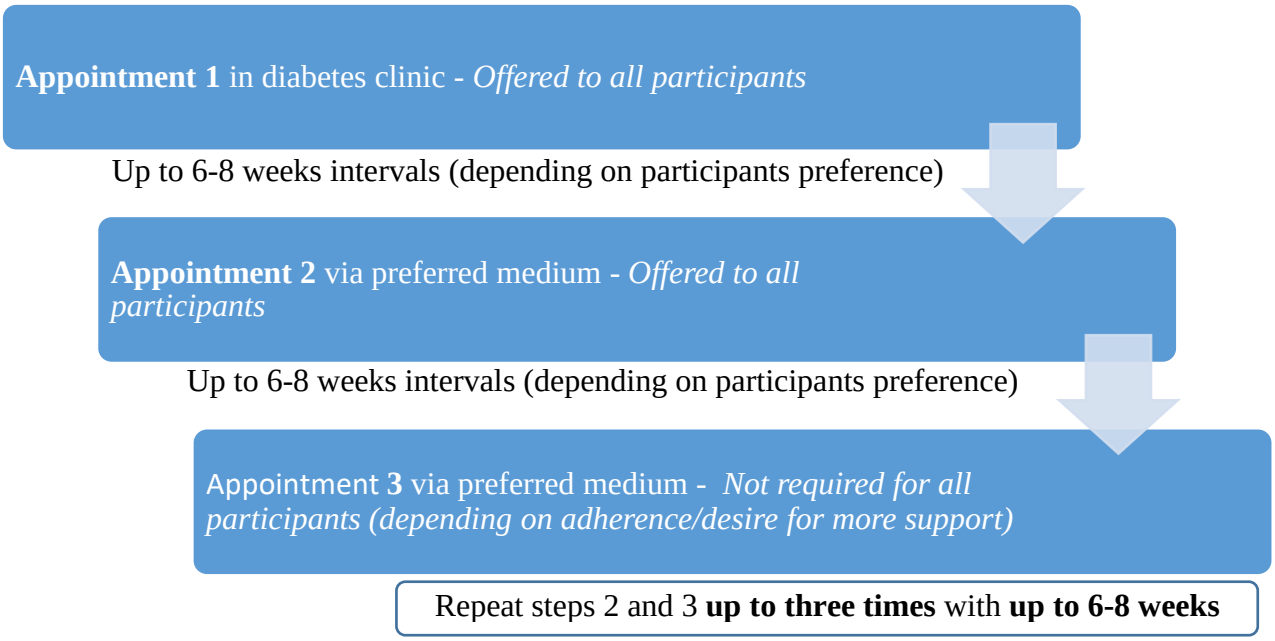


Figure 4.5 Flowchart detailing the structure of the intervention and activities carried out at each appointment.

Reasons for communicating with the patient earlier than scheduled procedures were adopted from the studies of McWhorter et al., 2015 and McWhorter et al., 2014, and are outlined in Table 4.3.

Table 4.3 Reasons for communicating with the patient earlier than scheduled procedures (adopted by the McWhorter et al., 2015 and McWhorter et al., 2014 studies).

Reasons for communicating with the patient earlier than scheduled procedures
• If the participant stops using the intervention (stops responding/contacting the pharmacist).
• Pharmacist's judgement that a severe problem has arisen which needs to be assessed (recommendation to make an appointment with general physician when appropriate).

Translation of Greek to English and vice versa

The consultation appointments were identified in English language and, after that, translated into the Greek language (the official language of Cyprus). The DSCAQ – Greek version was identified in Greek and English. Hence, the intervention was provided in English or Greek based on the patients' spoken language. To ensure the validity of the translation, published guidelines on the thorough translation process of the instruments were followed, and one independent researcher also reviewed the translation and ensured it was correct and the meaning was not altered, as explained in chapter 4, section 4.4 (Translation of Greek to English and vice versa) (Hilton and Skrutkowski, 2002).

The media for the delivery of the intervention

Based on the MRC framework, reviewing the literature, preliminary fieldwork and economic considerations should guide the choice of the media used in the proposed intervention (Skivington et al., 2021; Bleijenberg et al., 2018; Craig et al., 2008a; Craig et al., 2008b). The results obtained through the scoping review (chapter 2) were inconclusive. Thus, based on the preliminary fieldwork and economic consideration, a simple app like Viber was the optimal choice for the proposed intervention. It was also rational to demonstrate the Viber app to the patients since almost all studies included in the scoping review provided a demonstration of the media employed (Ladner et al., 2022; Lee et al., 2020; Sun et al., 2019; Baron et al., 2017; Fortmann et al., 2017; McWhorter et al., 2015; McWhorter et al., 2014; Chen et al., 2013; Orsama et al., 2013; Tang et al., 2013; Klug et al., 2011; Bond et al., 2007).

4.5 Training for the pharmacist to deliver this type of intervention

The competency of pharmacists to deliver such an intervention was assessed. The pharmacist's training included training about diabetes management, MI techniques, and operational aspects of the intervention (structure to follow, use of technology, keeping records, etc.). In this feasibility study, one pharmacist with clinical training was responsible for the delivery of the intervention. However, a future study would involve more pharmacists and these roles would be independent. Thus, professional skills and potential training issues are addressed below.

Education and training required for a pharmacist to undertake this intervention should include diabetes management, medication adherence and MI techniques. In addition to that, for the provision of review of patients' medications, education on how to review diabetes pharmacotherapy is required. The pharmacist delivering the intervention must have a clinical background in diabetes, as the intervention aims to improve diabetes management. Improving medication adherence includes one of study aims. Thus, the pharmacist delivering the intervention needs to understand the theory and reasons underpinning non-adherence and be aware of the practical solutions to support patients in increasing their medication adherence. An example of an evidence-based document describing this can be retrieved through National Institute for Health and Care Excellence (NICE) recommendations (NICE; 2009). To compensate for these, the pharmacist delivering the intervention attended an MI course and had a clinical background in diabetes disease and review of patients' medications (see Appendix 4.13 for the pharmacist's training for the provision of this intervention).

No additional training about the intervention's operational aspects (data forms and procedures) was required because the pharmacist delivering the intervention was also the researcher.

4.6 Setting of the intervention

The setting of the intervention was examined in the preliminary fieldwork in chapter 3. It was concluded that the most suitable setting to identify T2DM patients and enhance the collaboration between HCPs was a diabetes clinic (DC) within the general healthcare system (GESY) services. The only DC operating during the development of the intervention was established in the Nicosia General Hospital. The DC of the Nicosia

General Hospital offers outpatient services to diabetes patients who are in need and referred by their GP or other specialist physicians (Azina et al., 2016; Nursing Services of Ministry of Health, 2014, p.32).

4.7 Study population

The study population was selected based on the study's aims, similar studies identified through scoping review, discussions with pertinent HCPs, and the pilot period. Also, different media were employed to deliver the proposed intervention. Thus, the study population initially targeted patients with T2DM who were using technology. Moreover, due to the study's design, patients under 18 years old and pregnant patients were excluded as the intervention is not designed to fit their requirements.

Nevertheless, patients with T2DM may be on oral medication or insulin treatment, or a combination of those, uncontrolled or controlled, and have had diabetes for years or have recently been diagnosed. Thus, it was logical to discuss with the HCPs whether setting additional criteria to identify the study population who will benefit the proposed intervention based on current practices.

4.8 The refinement of the first draft intervention by the HCPs

Despite initial and general questions sought through preliminary fieldwork (chapter 3), it was essential to have a detailed plan involving solely the HCPs working at the DC to develop a meaningful intervention integrated into current practices. The reasoning for this was to facilitate operational aspects, integrate the proposed intervention based on current practices and pertinent HCPs, ensure the suitability of the intervention, and concurrently gain their support for the delivery of the intervention and their approval to be part of this intervention. Informal discussions with the HCPs working at the DC were conducted during the intervention's development in January 2019 and continued before the intervention's pilot in May 2020. These informal discussions ensured we did not spend time designing an intervention that HCPs would not support. Also, they were conducted for stakeholder involvement throughout the development process and to enhance the integration of the proposed intervention into current practices (Skivington et al., 2021; Bleijenberg et al., 2018; Craig et al., 2008a; Craig et al., 2008b).

The DC of the Nicosia General Hospital is staffed with two GPs interested in diabetes and one diabetes nurse. The manager of the DC was one of the GPs who staffed the DC. Oral discussions were conducted with the manager of the DC and the GPs at least 2-3 times to present the intervention, and the diabetes nurse working at the DC was contacted several times to discuss the intervention procedures. The researcher initially spoke with the DC's manager and informed her that this intervention was planned to be implemented at the DC. After that, the researcher presented to the nurse the first draft intervention. Then, the researcher met the GPs. Due to Covid-19 restrictions, the researcher spoke with the diabetes nurse and one GP each time. It was explained to them that at this stage of the development process, the first draft intervention was developed, and their assistance was critical to address the operational and feasibility aspects of the intervention. The conversations concerned the intervention services, operational aspects, and study population. Specific questions aimed at defining the details of each aspect of the intervention were addressed. An iterative procedure was conducted, where the researcher, after each discussion, made amendments to the intervention based on the HCPs' comments and then re-scheduled another meeting with them to obtain all GPs' opinions and present the revised intervention.

At the final point, where the researcher spoke with every GP working at the DC and collected enough information to shape the intervention, she returned to present the final intervention. The final intervention presented to the HCPs included all data forms, procedures, and flowcharts, which guided the pharmacist in delivering the intervention. Again, she contacted each GP individually due to Covid-19 restrictions. The diabetes nurse was present at all meetings with the GPs. The meetings with the GPs lasted 6-7 minutes, whereas the meetings with the diabetes nurse lasted up to 20-30 minutes each time. During this period, the researcher attended the DC three times to observe the workflow and common practices and stayed for a half day each time. Table 4.4 summarizes the first draft intervention, the following steps, and a list of planning questions.

Table 4.4 The first draft intervention characteristics, the following steps with the diabetes clinic, and a list of planning questions.

Characteristics of the first draft intervention		Following steps	List of planning questions
Setting	Diabetes clinic of the Nicosia General Hospital	Observe specific setting workflow and gain approval by the hospital for the intervention to be carried out	• Observe the flow of the specific clinic. • Procedure required to gain approval by the hospital for the intervention to be carried out. • Approval for the pharmacist located in the diabetes clinic.
Study population	Adults with type 2 diabetes mellitus and patients using technology	Define study population	• Define study population-based patients' characteristics and knowledge of technology?
Concept	Individually driven – Setting personal goals (Based on the philosophy of empowerment and principles of motivational interview)	Operational aspects and healthcare professionals' staff views	• Any views or advice from healthcare professionals' staff?
Mobile health	Viber application and phone device	Healthcare professionals' staff view and how to facilitate this service?	• Do they use Viber at the clinic? • Do they use any other technology? • What other technology can I use?
Services	**Pharmacist online advice to patient queries** Answering questions to patients' worries Timeframe to respond: 48 hours	Engage stakeholders throughout the process	• Do they communicate with their patients, if yes how is this facilitated? • Do they have any other comments regarding this service and how to implement this?
	Provision of education A structured and written curriculum with clear goals to be achieved. Patient-centred approach	Healthcare professionals' staff view and how to facilitate this service?	• How this will be conducted – media used? • Is there any curriculum used or guideline to follow at the diabetes clinic, which was not previously identified, do they follow a specific to the clinic procedure?

Table 4.4 The first draft intervention characteristics, the following steps with the diabetes clinic, and a list of planning questions.

Characteristics of the first draft intervention		Following steps	List of planning questions
			• Do they have other educational leaflets in addition to that identified in the preliminary fieldwork?
	Review of patients' medications Making recommendations to general physicians	Healthcare professionals' staff view, assistance, and permission	• Do they have local guidelines (not previously identified), what guidelines do the healthcare professionals' staff follow? • Examine their support in sending them recommendations and how this would be facilitated. • How can we increase intervention integration to current practices? • How can we increase feasibility of the intervention?
	Reminders for self-monitoring of blood glucose, medication taking, medication refill and appointment The pharmacist organising and preparing the reminders in advance	Engage stakeholders throughout the process	• Do they have anything similar at the clinic? • How can we increase intervention integration to current practices?
	Tracking of blood glucose Patients sending their self-monitoring of blood glucose readings through Viber app to the pharmacist.	Engage stakeholders throughout the process	• Do they have anything similar at the clinic? • Is it possible to collaborate with the healthcare professionals' staff to identify each participant blood glucose plan and also share this information with them. • How can we increase intervention integration to current practices? • How can we increase feasibility of the intervention?
	Graphical reports of blood glucose readings The timeframe was every 2-4 weeks depended on patient needs and preference		

4.9 Results of the healthcare professionals' perceptions and observations of the diabetes clinic

The researcher's observation of the DC and the discussions with the HCPs staff informed operational aspects, the intervention's study population, and the suitability of the intervention. HCPs' comments regarding the study population are described below. Moreover, HCPs supported the intervention's concept, services, and reasoning for implementing this intervention. It was decided to include all services presented to the HCPs in the proposed intervention. The main refinements concerned the service "provision of education" and "review of patients' medications."

Healthcare professionals' comments on implementing such intervention at the diabetes clinic

The HCPs were happy to implement the proposed intervention at the DC. They offered guidance to the researcher to gain approval from the hospital for the intervention to be carried out. Moreover, it was explained to them that this intervention is designed to be a multifaceted professional intervention, and their support is required for this purpose. The patients' individual diabetes plans needed to be shared with them to establish a referral system among a multidisciplinary HCP team. They all agreed to be part of the intervention, and each HCP chose their preferred medium to facilitate communication with the pharmacist.

Healthcare professionals' comments regarding the concept of the intervention

The approach and theoretical framework underpinning the intervention were explained to the HCPs. The HCPs were informed that the pharmacist delivering the intervention would support and assist patients in setting their personal goals and diabetes plan. Patients' choices will dynamically tailor the intervention. The HCPs expressed that they cannot recall any intervention implemented in the clinic based on this concept. They generally liked the idea and supported the implementation of the intervention. Consequently, operational aspects of the intervention needed to be further informed and refined.

Refinement of the services of the intervention by the nurse and general physicians

Healthcare professionals' comments regarding the services of the intervention are explained below. They were in favour of implementing this intervention and the services included. The services were considered workable and beneficial.

Refinement of the service "pharmacist online advice to patient queries" by the nurse and general physicians

Regarding the service "pharmacist online advice to patient queries," the HCPs' expressed that it looks like a good idea and plan. Notably, the diabetes nurse stated that the timeframe was appropriate. The researcher asked how the HCPs communicate with their patients. The diabetes nurse reported that she has informal communication with patients through phone calls or text messages. This communication is usually conducted after changes in patients' pharmacotherapy, as expressed by the diabetes nurse. No other comments or advice on how to implement this service were added. However, the rationale for including this service was provided. Patients were already communicating with the diabetes nurse through text messages and phone calls, as also supported in preliminary fieldwork with other HCPs. Thus, the proposed intervention could facilitate pharmacist online advice to patient queries through phone calls and text messages.

Refinement of the service "reminders for self-monitoring of blood glucose, medication taking, medication refill and appointment" by the nurse and general physicians

Healthcare professionals stated they do not have similar services regarding the service "reminders for self-monitoring of BG, medication taking, medication refill, and appointment." The common practice followed, as observed by the researcher, and discussed with the diabetes nurse, was to remind patients about their appointment early in the morning.

Refinement of the service "tracking of blood glucose and graphical reports" by the nurse and general physicians

The researcher observed the standard practice followed at the DC, which can address the questions sought regarding the service "tracking of BG and graphical reports." The responsibility of the diabetes nurse was to identify patients' BG readings, then record them, measure the BG reading of the patient at the time of their appointment, and then provide all patients' BG measurements to the GP. The diabetes nurse asked the patients during their appointment whether they had recorded their BG readings. Diabetes patients attending the DC provide their BG readings mostly handwritten in the calendar (provided by the Ministry of Health) or electronically on their BG devices. Moreover, as observed by the researcher, some patients forgot to provide their calendars or device. Using the patients' BG automatically instead of manually would increase their accuracy. The diabetes nurse expressed that this would be a good idea if feasible. Consequently, this

enhances the reasoning and suitability to include these services and informed operational aspects of the intervention, as both the calendar and BG device can be used.

Refinement of the provision of education by the nurse and general physicians

The provision of education was discussed with the HCPs at the DC. Moreover, educational leaflets and curriculum employed at the DC were sought to finalize the education provided. There is no written curriculum with a mission statement, goals, or specific guidelines used in the DC for diabetes education. The diabetes nurse showed the researcher the educational leaflets employed at the DC and stated that although it is usually her responsibility to provide the educational leaflets (based on each patient's needs), there is usually not enough time to discuss with the patient due to her increased workload. Consequently, in collaboration with the HCPs working at DC, it was decided to use only the educational leaflets already administered at the DC and categorise them into the ADA/AADE curriculum.

It was agreed with the diabetes nurse and the Cyprus Diabetes Association (CDA) to provide new educational leaflets. The pharmacist concurrently sought new education leaflets to cover patients' needs not identified through the educational leaflets already identified. Thus, educational leaflets were proactively sought, throughout the provision of the intervention, with the CDA and the diabetes nurse's assistance. Enough information was included in the leaflets of the governmental sector (provided by CDA and the Ministry of Health) about hypoglycaemia, hyperglycaemia, monitoring of diabetes, and diabetes comorbidities (see Appendix 3.2).

Refinement of the review of patients' medications (recommendations) by the nurse and general physicians

Permission was required to send recommendations to HCPs and to agree on the protocols and guidelines to be used to base the pharmacist's recommendations. This was discussed with the HCPs working at the DC. GPs usually search for international guidelines and protocols, such as the UpToDate and NICE. The pharmacist also asked the HCPs if it was possible to use the International Diabetes Federation (IDF) education and Pharmaceutical Services Database (SPC and PIL) as a source of information. Consensus was reached, and all sources were agreed to be employed. Consequently, in addition to the one national guideline for T2DM management, the following sources were used to support pharmacist recommendations; NICE guidelines, UpToDate guidelines, IDF education and PSMH's

drug database (SPCs and PIL) (IDF, 2022; PSMH, 2022; NICE, 2015b; NICE, 2012; MOHRC, 2013).

HCPs agreed to receive recommendations from the pharmacist and be informed about the patients' treatment plans. In addition, permission to notify them about patients' updates/changes due to the proposed intervention was also provided by them. Each HCP chose a different medium for communication with the pharmacist. Thus, the pharmacist contacted two GPs through email and messages, the other GP through phone calls, and the diabetes nurse through the Viber app.

Healthcare professionals' staff comments regarding the media for intervention delivery

Some HCPs insisted that some patients might struggle to use the Viber app, as expressed in preliminary fieldwork. Thus, other media which could be employed and are available at the DC were discussed. The medium used at the DC to communicate with their patients was traditional phone calls. In addition, all HCPs have business emails, a fax machine at their disposal, and also use the post for official documents. Thus, based on the current setting and the intervention's aims to be individually driven, all the above-mentioned media were used for the intervention's delivery.

Healthcare professionals' staff comments regarding study population

The HCPs at the DC expressed that the study population should not be restricted by patients' diabetes characteristics or knowledge of smartphone use. Based on the preliminary fieldwork, patients' records only include the type of diabetes and pharmacotherapy (insulin, oral medication, or both). Thus, the only achievable distinction was the type of diabetes and the type of patient's pharmacotherapy. The diabetes nurse expressed that setting additional criteria for the study population would not benefit the intervention and would probably cause more complications. Notably, the diabetes nurse stated that identifying patients based on their type of pharmacotherapy, in addition to their type of diabetes, will demand extra time, and it is not easy. Thus, based on the aims of the intervention to support patients with T2DM and HCPs' views, the study population was defined to include patients with T2DM, irrespective of the type of pharmacotherapy.

Moreover, HCP working at the DC supported that patients might not have a smartphone but their caregivers may have or have a phoneline at home. Thus, they stated that the eligibility criteria for having a smartphone do not adequately describe all patients

observed at the DC. Particularly, patients or caregivers were interested in participating in such intervention and were willing to use their phones or contact the pharmacist through their caregiver. Thus, based on the intervention design, which allows patients to choose their preferred medium, and HCPs' views, the study population was further refined to include patients or their family caregivers who own/have access a/to a phone device/smartphone. This serves the aims of the intervention and also facilitates the delivery of the intervention.

4.10 Approval by the hospital for the intervention to be carried out

It is required to contact the clinic's and/or hospital's manager for approval to conduct research within GESY services. The manager of the DC provided her verbal approval and the hospital manager the approval of the hospital, which was obtained in December 2019 (see Appendix 4.14). The only restriction stated was to not use medical files outside the hospital premises.

The location of the pharmacist in the diabetes clinic

The pharmacist delivering the intervention gained access to the same area as the other HCPs working in the DC. The diabetes nurse identified a private office adjacent to her practice that was used by the pharmacist to implement the intervention in the hospital.

4.11 The delivery of the intervention

The delivery of the intervention is described in the following subheadings; study location of the intervention, population receiving the intervention, concept of the intervention, language of the intervention, the media for intervention delivery, and operational aspects of the final intervention. In addition, to improve the completeness of intervention's report and replicability the Template for Intervention Description and Replication (TIDieR) checklist and guide was employed and presented in Appendix 4.15 (Hoffmann et al., 2014).

Study location of the intervention

This study was carried out in Nicosia, the capital of Cyprus, in the DC of the biggest governmental hospital, the Nicosia General Hospital (now offering its services under GESY regulations).

Study population

The population receiving the intervention includes all adults with T2DM (communication could be facilitate by a carer), who have been prescribed medication for their diabetes and own/have access a/to a phone device/smartphone and receiving care at the DC of the Nicosia General Hospital.

Concept of the intervention

It is also crucial to state that all communications with the pharmacist were based on MI techniques and OARS (Sabeeh, 2015; Steinberg and Miller, 2015; Ogedegbe et al., 2007). For example, when a participant is asking whether to take their medication, and he/she is hesitating, the pharmacist should provide the information asked and should follow OARS (Open Questions, Affirmations, Reflections, and Summaries) without pressing the participant to take the medication (Sabeeh, 2015; Steinberg and Miller, 2015; Ogedegbe et al., 2007).

Multifaceted professional interventions

Continual communication with HCPs and the pharmacist was facilitated. Participants' diabetes treatment plan was shared with the pertinent HCPs to establish a referral system among a multidisciplinary HCP team.

Language of the intervention

The intervention was offered in two languages based on the spoken language of the participants, namely English and Greek.

The media for intervention delivery

The participants chose the media used to deliver each intervention service. The Viber app (similar to WhatsApp) and traditional ways of communication, namely, text messages and phone calls for communication, emails, fax, and post to provide educational leaflets, were available for intervention delivery (Viber, 2019).

Operational aspects of the intervention

The intervention was split into three stages. The first stage was the face-to-face consultation appointment with the patient, which was conducted at the DC. The second stage comprised the digital health intervention (DHI) services, and the third stage was the patients' follow-up appointments, with up to three telephone follow-up appointments for

each patient. The flowchart followed by the pharmacist can be found in Figure 4.5. The completion form for the pharmacist to use for each appointment with the participant is presented in Appendix 4.16.

Appointment 1 - Consultation appointment

The first consultation between the pharmacist and the participant was held in the DC in a private office. In the first consultation, the pharmacist introduced herself, explained the DHI, demonstrated the Viber app use to the participants, and, when required, assisted patients in downloading the Viber app. The flowchart summarizing the steps followed by the pharmacist for the delivery of the initial appointment is presented in Figure 4.3. The detailed procedure followed for the consultation appointment is displayed in Appendix 4.6.

The pharmacist, along with the participants, developed a personal plan for managing their diabetes disease. Patients' personal plans were based on their needs and lifestyle, as elicited from principles of MI, the adapted DSCAQ – Greek version, and their selection of potential services (Sabeeh, 2015; Steinberg and Miller, 2015; Intas et al., 2012; Ogedegbe et al., 2007). The adapted DSCAQ – Greek version was primarily used to measure participants' treatment adherence and therefore employed to design an individual plan based on their needs (Intas et al., 2012). The pharmacist described the questionnaire and its objective as it is necessary for the participants to know what will happen step by step and the reasons for carrying out each step of the intervention (UCL, 2022, WHO, 2022c).

Qualtrics XM® was used as the tool to build the adapted DSCAQ – Greek version (Intas et al., 2012). Qualtrics XM® charts provided a quick assessment of each patient's response. The adapted DSCAQ – Greek version is presented in Appendix 4.4. The questionnaire's interpretation instructions are explained in Figure 4.1 and Appendix 4.5, respectively.

An agenda-setting based on the MI techniques was developed and employed to elicit participants' preferences regarding the focus of the consultation (Sabeeh, 2015; Steinberg and Miller, 2015; Ogedegbe et al., 2007). The agenda-setting presented to the participants is displayed in Appendix 4.6. The participants were asked for one topic most important to them, but they were allowed to identify more than one topic if, for example, they were

interested in two or more topics. In case the patient chose medication as a topic from the agenda setting, this was discussed first, and then other patient-preferred topics.

After that, a patient's personal plan was developed and agreed upon between the pharmacist and the patient. The patients could choose their preferred potential adherence service(s) offered in the intervention. The potential adherence services, categorized by the adherence problem, are displayed in Table 4.2. The pharmacist discussed with each participant their preferred services depending on their personal plan. There was no limitation on how many services each participant could select; hence, each participant was free to select from zero to all services.

For example, when a participant has problems with non-adherence to medication (and chose this topic from the agenda-setting), the pharmacist could offer four different services to support him/her. One service was pharmacist online advice to patient queries, as it was shown that good communication between patients and healthcare providers and social support had been related to improving adherence (WHO, 2003). Therefore, the pharmacist could discuss potential participants' worries regarding the medication. Another service was to send an educational leaflet about the medication, as the increase in knowledge was shown to improve patients' empowerment and thus patients' adherence (NICE, 2015b). For example, a section of the PIL explaining how to take/store the medicine could be sent to the participant when relevant queries were discussed with the pharmacist. Similarly, graphical reports can be provided to the participant to explain how the medication works (World Health Assembly, 71, 2018a; WHO, 2017; WHO, 2016b; WHO, 2011). Finally, reminders were another potential service if non-adherence was unintentional, e.g., due to patients' forgetfulness (Clark et al., 2020; McLeod et al., 2020; Dixon et al., 2019; Sun et al., 2019; Fortmann et al., 2017; McWhorter et al., 2015; McWhorter et al., 2014; Nundy et al., 2014a; Nundy et al., 2014b; Klug et al., 2011; NICE, 2009).

Follow-up appointments were scheduled at the end of the appointment. The subsequent appointments were scheduled on frequency, time, and day convenient to the patient.

Appointment 2 – Digital health intervention services

The proposed DHI provided several services tailored to each participant's needs. The services of the proposed intervention are displayed in Table 4.5 and further described below.

Table 4.5 The services of the proposed intervention.

The services of the intervention
• Pharmacist online advice to patient queries • Education (healthy lifestyle and diabetes). • Review of patients' medications. • Reminders for self-monitoring of blood glucose, medication taking, medication refill and appointment. • Tracking of blood glucose and graphical reports.

Pharmacist online advice to patient queries

Text messages, the Viber app, and emails facilitated pharmacist online advice to patient queries. The patients sent their queries to the pharmacist, who had 48 hours to respond. A flowchart and templates of text messages were developed and assisted the pharmacist in responding to each participants' queries. The flowchart and templates of text messages can be retrieved in Figure 4.4 and Appendix 4.10, accordingly.

Provision of education

The pharmacist provided education based on the ADA/AADE curriculum and available leaflets at DC (Mensing et al., 2000). The ADA/AADE curriculum and available leaflets at DC are presented in Appendix 4.8. The pharmacist scanned the educational leaflet and sent the relevant part to the participants. Depending on the preferred medium of the participant, the educational leaflets were sent through emails, the Viber app, post, and fax. Moreover, the pharmacist was in constant communication with the diabetes nurse and the CDA in case new educational leaflets were available to provide to the participants. An example of a part of a PIL employed as an educational leaflet is presented in Appendix 4.9. In addition to that, a message template informing participants that the pharmacist sent the educational leaflets can be found in Appendix 4.10.

Review of patients' medications (recommendations)

The pharmacist reviewed patients' pharmacotherapy and diabetes management plan to make recommendations to the HCPs working at the DC. The pharmacist sent the recommendations through email/text, depending on the preferred medium of the HCPs.

The pharmacist's clinical recommendations were based on national and international guidance identified and agreed upon between the HPCs. Table 4.6 illustrates the national/international guidance used to underpin the clinical recommendations made in this intervention. A template used for the communication between the pharmacist and the GP regarding a recommendation is displayed in Appendix 4.10.

Table 4.6 The national and international guidance used to underpin the clinical recommendations made in this intervention.

National guidance	International guidance
• National guidelines for diabetes type 2 management: the "Clinical pathways and guidelines of type 2 diabetes disease".	• International Diabetes Federation education.
• Pharmaceutical Services Database (Summary of Product Characteristics and Patient Information Leaflet).	• National Institute for Health and Care Excellence guidelines. *(for exampe: Type 2 diabetes in adults: management, Preventing type 2 diabetes overview, Type 2 diabetes in adults overview)*
	• UpToDate guidelines.

Source: UpToDate, 2022; IDF, 2022; PSMH, 2022; NICE, 2015b; MOHRC, 2013; NICE, 2012.

Reminders for self-monitoring of blood glucose (BG), medication taking, medication refill, and appointment

Patients' individual reminder messages program was tailored based on patients' medication and BG monitoring regimens, baseline self-management activities, and text message timing preferences. The pharmacist programmed the reminder messages in advance by scheduling the sending time with the intervention's smartphone. Instructions followed to accomplish this are explained in Appendix 4.12.

Tracking of blood glucose (BG) and graphical reports

The participants provided their BG readings differently depending on their preferred medium. The pharmacist received participants' BG readings and created graphical reports through the Excel program. The pharmacist then elaborated on the meanings of the graphic reports with the participants and further discussions took place regarding the participants' BG readings. The timeframe of the provision of graphical reports was set every 2-4 weeks depending on patient needs and preferences.

Appointment 3 - Follow-up appointments

Telephone follow-ups were conducted in the proposed intervention, with a maximum of three telephone appointments at a maximum of 6-8 weeks intervals (see Figure 4.5). The subsequent appointments were scheduled on frequency, time, and day convenient to the patient. The flowchart and detailed procedure for the follow-up appointments are presented in Appendix 4.7. Reasons for communicating with the patient earlier than scheduled procedures are presented in Table 4.3.

The subsequent appointments with patients were to review the patient (assess progress of self-care adherence), provide feedback, and address any questions/concerns. Based on that, the intervention and diabetes individual plan were revised and adjusted. Thus, their plan was constantly updated based on patients' responses at each appointment. In addition, the pharmacist considered whether patients needed assistance using the Viber app and other media used to deliver the intervention.

Duration of the intervention

The duration of the intervention was up to 12-16 weeks (maximum of three telephone appointments with a maximum of 6-8 weeks intervals).

4.12 The pilot period and the final design of the intervention.

The intervention was piloted for two weeks (04 May 2020 until 15 May 2020) before the commencement of the intervention. The pilot period included recruitment, first consultation and follow-up appointments of two patients. This was conducted to determine the final changes that would shape the intervention's final version. The pharmacist went to the DC and started recruiting patients according to the protocol for delivering the intervention. No refinements were identified, and thus no changes were adopted after the piloting period. Observations during the pilot phase are described below.

Two patients identified on the first day of the pilot phase requested to receive the educational leaflets through email. In addition, a family caregiver requested to participate in the study and facilitated the intervention’s services through her. Consequently, HCPs’ comments were justified during the pilot phase regarding the media employed for the intervention’s delivery.

Similarly, the refined study population by the HCPs working at the DC was justified during the pilot phase. In the first few days of the pilot phase, it was observed that setting the study's population criteria based on the patient's pharmacotherapy would make the intervention's implementation more confusing and complicated. For example, there were cases where patients with T2DM were not taking insulin before their appointment with the GP (hence eligible). However, their pharmacotherapy was changed after their appointment, and insulin was added. Opposite cases were also observed; for example, a T2DM patient was taking a combination of insulin and oral pharmacotherapy. After his/her appointment, the GP removed insulin from his/her therapy. Consequently, including patients with T2DM, irrespectively of whether they are on insulin treatment, was more efficient in recruiting patients to the study and would address the study's aims.

4.13 Reliability and validity of the intervention

The intervention development was based on evidence after the screening, reviewing of the literature, and conducting preliminary fieldwork. Each step of the intervention, including the services and components of the intervention, was informed by previous research from the literature review and preliminary fieldwork to ensure validity and reliability. All information sent to the patient was retrieved from already available validated sources and followed the laws and regulations of the Health Insurance Organization (HIO) and GESY (PSMH, 2019c; HIO, 2019d). Pharmacist recommendations were according to laws and regulations by the HIO and GESY, and NICE guidelines, IDF education, and PSMH's drug database (SPC and PIL) (IDF, 2022; PSMH, 2022; NICE, 2012; NICE, 2015b; MOHRC, 2013). In addition, if the pharmacist could not respond to the patient's needs, the patient was advised to seek further help from the relevant specialist (e.g., a dietician). Data forms, procedures, and flowcharts to guide the pharmacist to deliver the intervention were designed and agreed upon beforehand and strictly followed to increase consistency, secure clear structure, and, after that, the reliability of the study. The intervention was presented to the HCPs working at the DC to assess suitability and clarity. The supervisors and other professionals with relevant experience also reviewed the study.

End of Chapter four

Chapter Five

Evaluation of the intervention

5.1 Introduction

After developing the intervention, the next step was to decide on the methods of evaluating the intervention. Based on the Medical Research Council (MRC) guidelines, the design of this study was a feasibility study (Skivington et al., 2021; Bleijenberg et al., 2018; Craig et al., 2008a; Craig et al., 2008b). In addition, participants' medication adherence and self-care activity were potential outcome measures in case of a full intervention evaluation. Feasibility was evaluated through participants' recruitment, non-response rates, retention and engagement, healthcare professionals' (HCPs) actions on recruitment and the pharmacist's recommendations to the GPs about participants' pharmacotherapy, tasks of the pharmacist delivering the intervention, time, cost to deliver the intervention and participants' and HCPs' acceptability through the interview at the study end. Triangulation methods were employed to address the research study's objectives (Bowling, 2014; Guest and Namey, 2014; Smith, 2010; Creswell and Plano Clark, 2007). Moreover, the World Health Organization (WHO) guidelines on reporting digital health interventions (DHIs) were used to report and assess the proposed intervention (Agarwal et al., 2016). This chapter describes the methodology for the evaluation of the intervention under the remaining five research objectives of the research study and is divided into the following subheadings: the study design, the ethical consideration, patients' and HCPs recruitment, data collection forms and instruments, and data analyses.

5.2 Study design

Medical Research Council framework

The theoretical approach to the intervention evaluation process was according to the latest MRC framework which is widely employed to ensure robust evaluation of complex interventions (Skivington et al., 2021; Bleijenberg et al., 2018; Craig et al., 2008a; Craig et al., 2008b). The "gold standard" for evaluating an intervention is a large, blinded, randomized controlled trial and, after that, a non-randomised, matched experimental and control groups study, as they limit threats to the study and increase internal validity (Bowling, 2014; Smith, 2010). However, while considered the gold standard, it is not always efficient and optimal to conduct a full trial evaluation before evaluating the feasibility of the intervention. Full trial evaluation of the intervention requires additional costs, effort, and time. According to the updated MRC framework, the next step after the intervention's development was assessing its feasibility (Skivington et al., 2021; Craig et

al., 2008a; Craig et al., 2008b). Therefore, the primary purpose of this study was to evaluate the feasibility of the developed intervention.

Feasibility study

Feasibility assessment gained information about the intervention's likely practicality, suitability, efficacy, and acceptability from the stakeholders' perspective. Those elements were pivotal to proceeding to a definitive study in the future (Orsmond and Cohn, 2015; Smith, 2010). Stakeholders' acceptability was crucial when designing, evaluating, and implementing the healthcare intervention. It could change the outcome of the service and provide valuable information in identifying potential future changes to the intervention design (Donovan et al., 2022; Sekhon et al., 2017; Moore, 2015; Smith, 2010). The key stakeholders in this study were participants as end users, pharmacists as intervention providers, and other HCPs as important collaborators and part of the intervention delivery. Quantitative procedures were employed for all study phases, apart from evaluating stakeholders' perceptions of intervention (patients and HCPs), where a qualitative approach was used. The data collected provided information on recruitment of participants, non-response rates, retention and engagement, healthcare staff actions on recruitment, and the pharmacist's recommendations to the GPs, on intervention's workability, time spent to deliver the intervention, and cost estimation for the delivery of the intervention. In addition, the theoretical framework of acceptability (TFA) was employed to evaluate the intervention's acceptability by participants and HCPs. Table 5.1 outlines the steps followed for the feasibility evaluation of the intervention based on the latest MRC framework (Skivington et al., 2021; Craig et al., 2008a; Craig et al., 2008b).

Table 5.1 Steps followed for the evaluation of the proposed intervention, based on the latest Medical Research Council (MRC) framework.

Steps for the evaluation of the intervention (based on the enriched MRC framework)		Description of each step followed for the evaluation of the proposed intervention
Feasibility	Assessing feasibility and acceptability of intervention and evaluation of design to make decisions about progression to the next stage of evaluation:	• Determine sample size: data from studies identified in the literature were used to inform the sample size decision. • Estimating recruitment of participants, non-response rates, retention, and engagement. • Testing procedures for acceptability: acceptability by important stakeholders (participants and healthcare professionals). • Healthcare staff actions on recruitment and the pharmacist's recommendations on participants pharmacotherapy. • The task the pharmacist needed to accomplish during the intervention, then the time spent on each task. • Cost estimation: costs for the delivery of the intervention were recorded. • Implementation issues, refinement of data collection procedures, and outcome measures.
Evaluation	Assessing an intervention using the most appropriate method to address research questions	**Assessing participants' medication adherence and self-care activity** • Evaluation of medication adherence and self-care activity changes prior to and after the intervention.

Source: Skivington et al., 2021; Bleijenberg et al., 2018; Craig et al., 2008a; Craig et al., 2008b

Triangulation method

In the proposed study, the triangulation method was employed. The triangulation method refers to using multiple sources, methods, or perspectives to support findings (Namey, 2014). It involves comparing data obtained from various sources in different ways and thus enhancing the study's validity and minimizes the risk of a partial or inaccurate interpretation (Bowling, 2014; Guest and Namey, 2014; Smith, 2010; Creswell and Plano Clark, 2007). For these reasons, the triangulation method is ideal for this study, as only one data set will not adequately explore the research objectives. It was employed to get an in-depth understanding of the feasibility of the proposed intervention and increase the study's validity.

There are different types of triangulation methods, mainly differentiated by when and how the triangulation occurs (Namey, 2014; Creswell and Plano Clark, 2007). In the

proposed study, qualitative and quantitative datasets were analysed separately and then compared during the interpretation phase of the analysis to address the five research objectives. For each research objective, quantitative and qualitative data sets were collected, analysed, and compared. For example, quantitative and qualitative analyses were conducted to comprehensively evaluate the acceptability of the intervention from the perspective of the participants and HCPs involved in the study. The qualitative method complements the quantitative data and aims to understand the participants' and HCPs' perspectives and address the reasons for their choices and actions. The final stage was to compare all data sets to deduce valid future intervention recommendations. Table 5.2 presents an overview of the methods, data collection forms, and data processing and analysis employed in the different data sets.

Table 5.2 Overview of the study design methods.

Research objectives	Study design and methods	Period of the data collected
1a. To identify the feasibility of the intervention from the perspective of participants.	• Pre-designed data collection forms to obtain data on recruitment of participants, non-response rates, retention, and engagement. • Semi-structured interviews based on theoretical framework of acceptability to obtain information on participants' perspectives.	• During the recruitment and delivery of the intervention • After the completion of the intervention
1b. To identify the feasibility of the intervention from the perspective of health professionals.	• Pre-designed data collection forms to obtain data on healthcare professionals' actions on recruitment and the pharmacist's recommendations. • Semi-structured interviews based on theoretical framework of acceptability to obtain information on healthcare professionals' perspectives.	• Preliminary fieldwork and during development of the intervention (chapters 3 and 4) • During the recruitment and delivery of the intervention • After the completion of the intervention
2. To investigate whether the application and workability of instruments to assess potential clinical	Examination of the tools employed and their ability to obtain the data required.	• Throughout the intervention • Baseline and after the end of the intervention

Table 5.2 Overview of the study design methods.

Research objectives	Study design and methods	Period of the data collected
outcomes (adherence and self-care activities).		
3. To examine workability, time spent to deliver the intervention, and cost estimation for the delivery of the intervention.	• Pre-designed data collection forms to obtain data on pharmacist's workload, time, and cost estimation for the delivery of the intervention.	• Throughout intervention delivery
4. To examine possible integration of the intervention into the current pathways and recommendations for modifications to the intervention and/or future service provision.	• Comparison of all above datasets and data sets obtained through interviews at study end.	• Throughout intervention delivery

World Health Organization guidelines on reporting digital health interventions

There is a lack of adequate, systematic, and useful reporting of DHIs and associated research studies, which is essential to appreciate the potential impact of a DHI (Agarwal et al., 2016). Resulting in WHO guidelines on reporting DHIs including the m-Health Evidence Reporting and Assessment (mERA) (Agarwal et al., 2016). The checklist includes information about the intervention's components, delivery, and evaluation and was employed to report the proposed intervention (see Appendix 5.1).

5.3 Ethical consideration

Ethical approval from Cyprus National Bioethics Committee, Cyprus Ethics Committee, and the UCL Research Ethics Committee were required. The Cyprus National Bioethics Committee reviews all scientific research conducted in Cyprus, whereas Cyprus Ethics Committee reviews all research conducted in the general healthcare system (GESY) services. For this purpose, the developed intervention and the study's evaluation process were submitted to both committees for review.

The ethical approval from the Cyprus National Bioethics Committee and the Cyprus Ethics Committee was received on November 27th, 2019 (study reference number ΕΕΒΚ ΕΠ 2019.01.202) and on April 5th, 2020 (study reference number 01/20), respectively. The approval from the UCL Research Ethics Committee was received on 28/04/2020

(study reference number Z6364106/2020/04/129). The ethics committees requested no amendments. The ethical approvals are displayed in Appendix 5.2.

The study complied with the Data Protection Act, which requires data to be anonymised as soon as it is practical. The participants were identified only by a participant identification (ID) number on any electronic document used. All electronic documents were stored securely, were password protected and only accessible to the research team. A specific mobile phone was used only for the intervention's delivery which was also password protected. Viber app was chosen as all calls and chats are protected by built-in end-to-end encryption to secure all conversations (Viber, 2019). Each participant number was saved with participant ID on the mobile phone catalogue. The pharmacist ensured confidentiality when speaking with the participants or when writing and replying to their messages. Concurrently, patients were informed that the pharmacist had 48 hours to respond to their questions and that the pharmacist's working hours were the usual hours of a community pharmacist in Cyprus. All paper records, including the consent forms, were locked in the cabinet diabetes clinic (DC) of the Nicosia General Hospital. Patients were informed in the consent form and verbally that their participation was voluntary, that they could withdraw from the study at any time they chose without an explanation, and about how their data would be used and analysed. Confidentiality and anonymity were maintained in publications by excluding the names of the respondents or any information that could be linked to a participant. All audio recordings were deleted after the end of the study evaluation, and participants were given the opportunity to receive the study findings after the study was completed.

5.4 Patients' recruitment

Eligibility criteria of the intervention

Patients' eligibility criteria for the intervention have been described in chapter 4 in section 4.7. Table 5.3 present the inclusion and exclusion criteria.

Table 5.3 Eligibility criteria for patients' recruitment for the intervention.

Inclusion Criteria	Exclusion Criteria
• Adults (over 18 years old) with type 2 diabetes (communication could be facilitate by a carer). • Receiving care at the Diabetes clinic of the Nicosia General Hospital. • Prescribed medication for their diabetes. • Own/have access a/to phone device / smartphone (required for study operation).	• Pregnant. • Not owning/having access to a mobile device/smartphone

The sample size of the intervention

Due to the nature of the study (feasibility study), a sample size calculation could not be based on the anticipated change in a specific outcome measure. The recruitment target has been based on the number of patient appointments at the DC, the number of eligible patients, potential attrition of the sample (informed by the studies in the scoping review), and the workload of the pharmacist delivering the intervention. On average, 200 patients visit the DC monthly, around half of patients are expected to be eligible (based on the scoping review, chapter 3), and only one pharmacist delivers the intervention and recruitment process and thus not it might not be possible to approach all eligible patients. Klug et al., 2011, feasibility study was used as an example to inform the sample size. It is a similar feasibility study offered DHI by a pharmacist, where 45 patients consented to participate, and 28 enrolled. It can be assumed that around one-third might withdraw from the study Consequently, the target for patient recruitment was determined as 30-35 patients, which was considered sufficient to achieve the feasibility study objectives.

Recruitment period

The agreed period to start the recruitment was 18 May 2020 until the completion of the study. It was determined in advance, based on the discussions with all HCPs included in the study, their availability and the workload of the pharmacist who undertook the recruitment.

Development of information leaflet, patients' expression of interest reply slip, and consent form

The consent form was essential to ensure that participants understood and consented to the study's procedures. The information leaflet aimed to outline the service and include the contact details of the pharmacist. The patients' expression of interest reply slip was a simple paper attached to the information leaflet, without any logo. The patients' expression of interest reply slip was essential to obtain the contact details (name, telephone number, and preferred call times) of patients interested in participating in the intervention. Information to return the slip to the diabetes nurse was also written on the patients' expression of interest.

To develop the information leaflets, patients' expressions of interest, and consent forms, similar information leaflets were identified. There was no standard template in Cyprus or

the hospital that the researcher should follow. Thus, examples of information leaflets and consent forms from the UCL and WHO (Research Ethics Review Committee) websites guided the development of the information leaflet, patients' expression of interest reply slip, and consent form for the proposed intervention (UCL, 2022, WHO, 2022c). An example of the UCL template for the participant information sheet is presented in Appendix 5.3. Essential information retrieved through these examples were; the information written should be simple and easy to follow, with general information about what the study involves, an explanation of the purposes of the research, a description of the procedures to be followed, and that their participation is voluntary and choosing not to participate would not disadvantage them in any way, were all included (UCL, 2022, WHO, 2022c). In addition, amendments were made to reflect the content of the proposed intervention.

After the wording of the information leaflet and patients' expression of interest reply slip was decided, the formatting and design were chosen. A graphic designer created the information leaflet based on the researcher's instructions. The graphic designer presented different design styles of the information leaflet to the researcher and transferred all the wording into the final agreed design.

Translation of information leaflet, patients' expression of interest reply slip, and consent form from English to Greek

The information leaflet, patients' expression of interest reply slip, and consent form were developed in English and translated into Greek (the official language of Cyprus). Hence, based on the spoken language of the patients, the English or Greek information leaflet/patients' expression of interest reply slip was provided. To ensure the validity of the translation, published guidelines on the thorough translation process of the instruments were followed, and one independent researcher also reviewed the translation and ensured it was correct and the meaning was not altered, as explained in chapter 4, section 4.4 (Translation of Greek to English and vice versa) (Hilton and Skrutkowski, 2002).

Review and approval process of information leaflet, patients' expression of interest reply slip, and consent form

The information leaflet, patients' expression of interest reply slip, and consent form were developed by the researcher and reviewed by both supervisors and HCPs involved in the

intervention in Cyprus before finalizing and distributing to the patients. It was updated following the review and ensured that the information included was coherent and intelligible. Most of the amendments were about clarifying the information to be as comprehensive, understandable, and clear to readers as possible. A copy of the information leaflet, with the patients' expression of interest reply slip and consent form are available in Appendix 5.4 of this document.

The development of the recruitment process

To augment response rates, recruitment was conducted in different ways. The recruitment process was initially designed to include invitation and reminder text messages and an information leaflet incorporating the patients' expression of interest reply slip. The recruitment procedures must be informed by relevant stakeholders and developed and decided in advance before the actual delivery of the intervention to ensure consistency (UCL, 2022, WHO, 2022c; Bowling, 2014; Smith, 2010). Hence, discussions with the HCPs and available guidelines informed the development of the recruitment procedures well in advance. Collaboration with the general physicians GPs and the diabetes nurse was needed in the recruitment phase. Their role was to remind patients that an intervention was being conducted in the DC, distribute the information leaflets incorporating patients' expression of interest reply slips, and for the diabetes nurse to have the consent forms at her disposal. In addition to that, their assistance was required to enable invitations and reminder text messages to be sent, determine an office in which the pharmacist would be located within the DC and also agree on the pathway the pharmacist would use to recruit patients between their DC appointments.

The interviewer's approach and personal contact with patients may help promote a reasonable response rate (Bowling, 2014; Smith, 2010). Hence, the pharmacist would be in the intervention setting during the recruitment. This would also enable the pharmacist to respond to potential patients' questions and distribute information leaflets. Moreover, the pharmacist's presence is required to ensure that the patients understand the information provided in the information leaflet and consent form and, after that, review patients' consent (UCL, 2022, WHO, 2022c).

Refinement of the recruitment procedures by the nurse and general physicians

All HCPs agreed to all methods developed, apart from sending the invitation and reminder text messages to the patients. The managers of the hospital rejected invitation text

messages and reminder text messages. The researcher was advised to remove this from the recruitment procedure. The reason for this, as they explained, was to protect the patient's data based on the General Data Protection Regulation (GDPR) (GDPR, 2023). Consequently, the recruitment process was amended to the information leaflet distributed by the diabetes nurse, GPs, and pharmacist, HCPs reminding patients that an intervention was conducted in the DC and the pharmacist was at the DC.

The diabetes nurse and GPs were willing and agreed to distribute information leaflets to patients. The diabetes nurse agreed to display the information leaflet of the intervention at the stand and on the notice board, outside her office which included the DC news announcement and educational leaflets for diabetes patients. The diabetes nurse also agreed to collect and store the consent forms and expression of interest response slips in the locked cabinet (for data protection) and informed the pharmacist when a new patient filled them out. All HCPs expressed that reminding eligible patients about the study during their regular appointment might not be feasible due to their increased workload. However, they agreed to inform the patients that a study was being undertaken at the DC and, if they were interested in participating, then to contact the pharmacist. The diabetes nurse identified a private office next to her office, which was available during the implementation of the intervention. Moreover, it was agreed that the pharmacist should identify the gap between the patients' appointments before the diabetes nurse or between the diabetes nurse and the GP. This would not interfere with the regular workflow of the DC, and it could be adjusted during the implementation of the recruitment.

Final recruitment procedures

The recruitment procedures include the information leaflet, patients' expression of interest reply slip, and consent form, distributed mainly by the pharmacist, diabetes nurse, and GPs (see Figure 5.1).

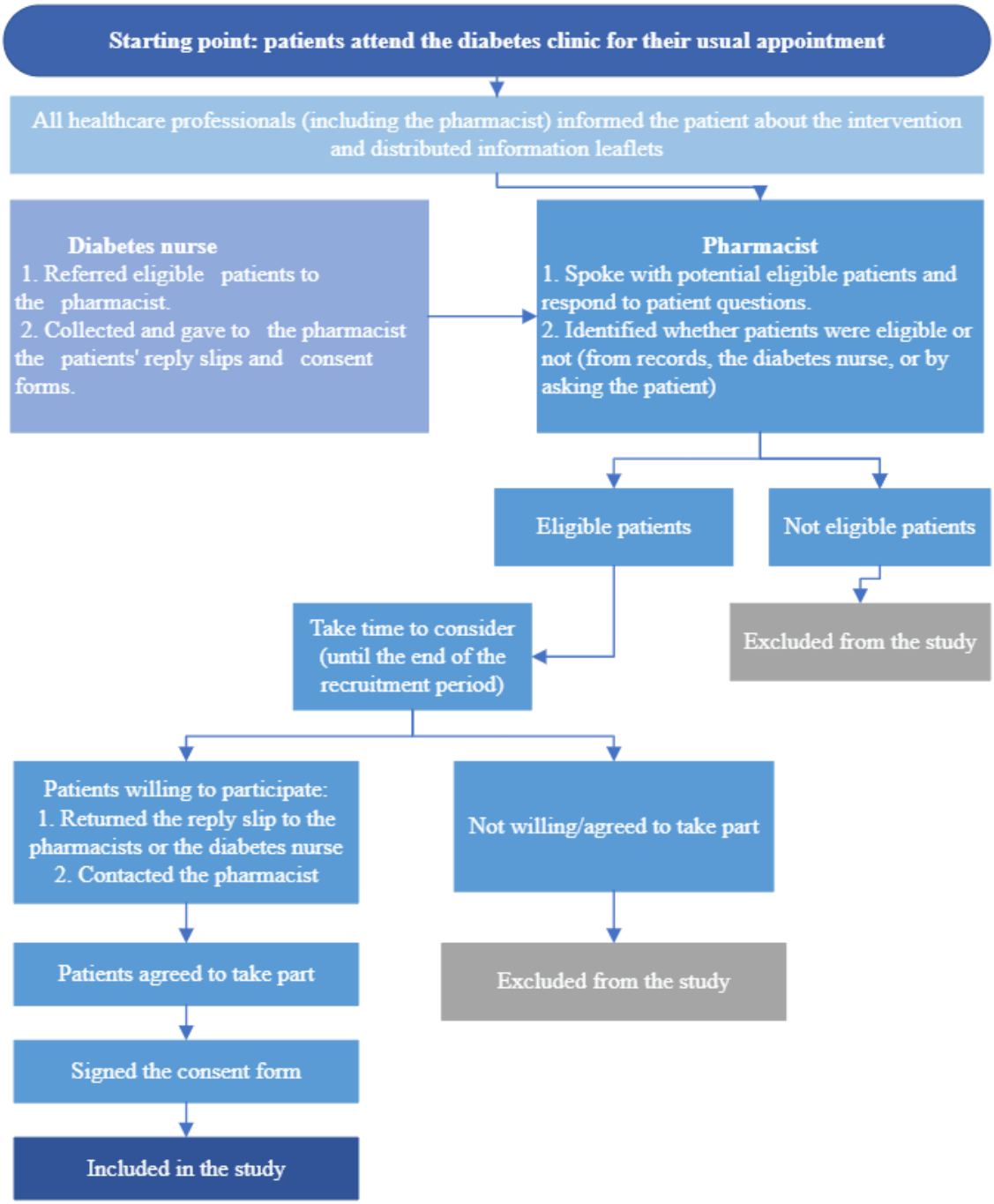


Figure 5.1 Recruitment procedure for the proposed intervention.

The pharmacist operated within the DC setting during the recruitment period (18 May 2020 until 31 July 2020). The days she was present at the DC each week depended on the Covid-19 restrictions and operation of the DC. The pharmacist was responsible for ensuring patients understood the information provided in the information leaflet and consent form and, after that, reviewing patients' consent (UCL, 2022, WHO, 2022c). Patients who were confident to participate and did not need further information could collect and filled the consent form and return it to the diabetes nurse or pharmacist. The pharmacist collected their consent forms that were fully completed, and signed before the

intervention's commencement, as described in Figure 5.1. Alternatively, the participants could call the pharmacist (the pharmacist's phone number was in the information leaflet) or return the patients' expression of interest reply slip or the consent form to the pharmacist or diabetes nurse. Thereupon, the pharmacist contacted the participant and booked an appointment as soon as possible, even on the same day if feasible (during the usual working hours of the DC), for their primary intervention consultation.

Patients' recruitment for interviews at the intervention end

Based on the sample size, it was feasible to interview all participants to obtain a more comprehensive data set. Thus, all participants were verbally informed at the initial meeting and on the consent form that they would be invited for a final interview at the intervention end.

5.5 Recruitment of healthcare professionals

On account of the few HCPs involved in the proposed study, all of them were recruited, as described in chapter 4, section 4.8. HCPs' actions were evaluated throughout the intervention delivery, and they were approached via phone for discussion about the intervention at the end of the intervention. The telephone interview was scheduled at a time convenient for them. Acceptability of the pharmacist delivering the intervention (who was the same as the researcher developing and evaluating the intervention), was evaluated through filling a developed form concerning her views in different stages of the intervention (from the initial appointment till the end of the intervention).

5.6 Data collection forms and instruments

An overview of the study data collection forms is presented in Table 5.4.

Table 5.4 Data collection forms and instruments employed in the proposed intervention.

Variable	Data collection forms
Participants	**Data collection forms** • Recruitment and retention • Non-response rates • Engagement (Appendix 5.5) **Instrument** • Semi structured interview schedule (Appendix 5.11)
Healthcare professionals	**Data collection forms** • Healthcare professionals' actions on recruitment (Appendix 5.6)

Table 5.4 Data collection forms and instruments employed in the proposed intervention.

Variable	Data collection forms
	• Healthcare professionals' actions on the pharmacist's recommendations (Appendix 5.10) • Pharmacist's experience (Appendix 5.15) **Instrument** • Semi structured interview schedule (Appendix 5.12)
Adherence	**Data collection forms** • Participants' responses to reminders. (Appendix 5.9) Completeness of instrument, loss to follow-up and data missing. (Appendix 5.5, Appendix 5.6, Appendix 5.7, Appendix 5.8) • Time required to fill the instrument. (Appendix 5.16) **Instruments** • The adapted Diabetes Self-Care Activity Questionnaire – Greek version (DSCAQ – Greek version) (Appendix 4.4) • Semi structured interview schedule (Section 2: Burden) (Appendix 5.11)
Workload and cost	**Data collection forms** • Pharmacist's workload and time (Appendix 5.16) • Cost estimation for the delivery of the intervention (Appendix 5.17)

Development and piloting of the recruitment of participants, non-response rates and retention

Three data collection forms were needed to enable the collection of data regarding the recruitment of patients, non-response rates and retention in a systematic way. Namely participants' characteristics, recruitment and retention, and non-response rates data collection forms. The final versions of the relevant sociodemographic characteristics, recruitment and retention data collection form, and the non-response rate form are shown in Appendix 5.5 and Appendix 5.8 respectively.

The researcher kept a record of the study's process. During the recruitment, a field note calendar was used to track the days the pharmacist attended the clinic and the discussions with patients. Afterward, the researcher abstracted the information from the field note diary into the data collection forms at the end of each day. The data collection forms included information such as; the number of eligible patients, the number of patients recruited each day and when (before patients' appointment with the diabetes nurse or with GPs), patient attendance at the DC, and the recruitment method and who informed patients to participate in the intervention (information leaflet, pharmacist, GPs, diabetes nurse). A daily log of whom the researcher called and the result of the phone calls, as

advised by Burke and Miller, 2001 (e.g., rescheduling the appointment, did not respond, or conducted the appointment) was recorded (Burke and Miller, 2001). Also, the sociodemographic characteristics of participants and the source of this information were also monitored. This information was needed to ensure the diversity of the sample.

The data collection forms were updated during the pilot phase (04 May 2020 until 15 May 2020), with new information such as how many patients the pharmacist spoke to, their type of diabetes, etc. It has also been reviewed to make it more user-friendly and assist the pharmacist in keeping reliable collected data records. Data collection regarding the recruitment of patients, non-response rates and retention commences from the recruitment period until the final interviews at the end of the study.

Development and piloting of the data collection form for the participants' engagement

Four data collection forms for the participants' engagement were developed. The final versions of the data collection forms for the participants' engagement are displayed in Appendix 5.8. Data collection regarding the participants' engagement commenced from the initial appointment with the participant until the final appointment.

The participants' engagement from studies identified through the literature was measured in different ways. In the proposed intervention, the researcher retrospectively reviewed the text messages, exchanged phone calls between the pharmacist and the participants, and manually transferred them into excel. Participants' engagement refers to the use of the proposed intervention. Usability of each service of the intervention during the study comprises; participants' choice regarding the services, how many times each service was chosen (whether it was the same during the study), number of text messages sent to and received by the pharmacist, number of educational leaflets sent by category, number of phone calls and follow-up calls and by whom (participant or pharmacist). In addition, areas where the patients needed further support (e.g., medication, healthy eating), the type of questions made to the pharmacist, and their frequency. Data selected were to evaluate participants' engagement was to keep track of all participants' choices regarding all services and operational aspects of the intervention.

The forms developed allowed for collecting information about each aspect of using the intervention and details of their preferences. Initially, the forms included the services provided in the intervention, the goals agreed upon at the initial appointment with the

participants, and the topic and number of the educational leaflet sent to the participants. During the piloting phase (04 May 2020 until 15 May 2020), the form was expanded to include topics discussed between the pharmacist and participants. Due to the large amount of information obtained, two separate records were created. One for the topics discussed between the pharmacist and each participant and one to track the number of phone calls, text messages, and emails exchanged between the pharmacist and the participant.

Data collection form for the participants' medication adherence and self-care activity

The participants' diabetes self-care activities and medication adherence were measured through the participants' responses to reminders and the adapted DSCAQ – Greek version (Intas et al., 2012). Thus, a data collection form for participants' responses to reminders was developed, and the adapted DSCAQ – Greek version, was employed (see Appendix 5.9). Qualtrics XM® was used to build and analyse responses from the adapted DSCAQ – Greek version in both English and Greek (Qualtrics XM®, 2023). The researcher refined, piloted, and tested the questionnaire before starting the intervention.

Two different ways were planned to be used to evaluate medication taking to minimize the limitation of each method and increase the validity of the results (as described in chapter 1). In this research design, the advantages of using the self-reported adapted DSCAQ – Greek version were superior to using other expensive and complicated methods for the proposed intervention. Also, the reply to text messages from participants about whether they have taken their medication (during the intervention) was identified by two studies from the literature (McWhorter et al., 2015; McWhorter et al., 2014) and thought to be an easy and feasible way to evaluate medication adherence.

Diabetes Self-Care Activity Questionnaire – Greek version instrument overview

The researcher contacted the author of the DSCAQ – Greek to ask for permission to use the DSCAQ – Greek and receive it by email. The author kindly replied, approved the instrument's use in the present study, and attached it to the email. Permission to use the DSCAQ – Greek version and the final version of the questionnaire (after the adaptation to the proposed study) are presented in appendix 4.2 and 4.4, respectively. According to Intas et al., 2012 study, the average time required for completion is 8 minutes (standard deviation ±4.2 minutes) (Intas et al., 2012).

The questionnaire was adjusted, specific questions were removed and the flow of the questions was changed to fall under the objectives asked in the proposed interventions. This minimized the time required to conduct the questionnaire and also provided the opportunity to discuss other relevant issues with the participants. Three areas, namely diabetes risk factors and physical and mental health questions were excluded from the final questionnaire used, as they do not serve the research aims. Sociodemographic information was adjusted to ensure that the participants recruited represented a range of personal and diabetes characteristics. Thus, information about participants' marital status, whether participants live alone, educational level, monthly income, and insurance status, were replaced by; where the participant lived, diabetes characteristics about participants' baseline BG (mg/dL), glycated haemoglobin (HbA1c) (%), pharmacotherapy for diabetes, and other morbidities. Moreover, the parts HCPs' recommendations on participants' self-care and smoking were not repeated at the end of the intervention, because the intervention did not evaluate those activities. The adapted DSCAQ – Greek version was piloted during the pilot phase (04 May 2020 until 15 May 2020). No changes were required. The final version of the questionnaire (after the adaptation to the proposed study) is presented in Appendix 4.4.

The adapted DSCAQ –Greek version was conducted on two occasions, once at the initial meeting and once at the final appointment with the participant. The method of conducting the adapted DSCAQ – Greek version was flexible to the participant's lifestyle. This was decided as the researcher did not want to cause further stress to participants and as the intervention is individually driven. The initial appointment could be conducted by phone or face-to-face at the DC, and the final appointments could be conducted via telephone, with the arrangement for completion via the participants' preferred medium (e.g., text message, Viber, telephone). This was decided to avoid participants' inconvenience attending the DC for this reason only.

Development and piloting of the data collection form of the healthcare staff actions on the intervention

Healthcare staff actions on the intervention were evaluated and consisted of their recruitment assistance and responses to the pharmacist's recommendations. Before the commencement of the intervention, two data collection forms were developed to collect and analyse the data obtained regarding the HCPs' actions on recruitment and the pharmacist's recommendations to participants' pharmacotherapy. The data collection

form regarding HCPs' actions on recruitment was incorporated in the data collection form for recruitment and retention and is presented in Appendix 5.6. The data collection form of the healthcare staffs actions on the pharmacist's recommendations to the GPs is displayed in Appendix 5.10.

The two data collection forms were piloted (during the pilot phase from 04 May 2020 until 15 May 2020) to ensure that all relevant data were recorded. The data collection form regarding HCPs' actions on recruitment, included how many patients they recruited and how they assisted in the recruitment. The data collection form on HCPs' actions on the pharmacist's recommendations was enriched during the pilot phase. The final form consisted of the number of recommendations made, how each issue emerged, the nature of the issue, the need for further actions by the pharmacist, details of the problem, contacts made, whether healthcare staff responded to the pharmacists or not, the number of those accepted by the healthcare staff, changes to participants' pharmacotherapy, and the outcome.

Data source employed to identify participants' pharmacotherapy and diabetes management

Information on participants' pharmacotherapy was gathered from several sources. These sources included GPs and diabetes nurse notes, participants' medical files, laboratory results, medication records, dispensing data, the participants, and appointment lists at the DC. The data collection form for participants' characteristics was used to record the source used to identify participants' pharmacotherapy (Appendix 5.5).

Interview schedules for the evaluation of participants' and healthcare professionals' (HCPs) staff acceptability

Two interview schedules were developed to evaluate the intervention's acceptability, one from the participants' perspective and one from the standpoint of the HCPs. The final interview schedules are presented in Appendix 5.11 and Appendix 5.12. The form of a semi-structured interview was chosen as it does not constrain the interview interaction, the researcher has more control of the sequence of questions than in unstructured interviews, and at the same time, provides greater freedom than structured interviews, allowing for probing and clarification (Mann, 2016). Also, it provides room for discussion and expansion of the interviewee's responses (Mann, 2016).

To develop the interview schedule, the researcher had to identify theories and evidence to accurately and effectively measure the underlying determinants of the attitude investigated (in this case, acceptability) (Stuckey, 2018; Taylor et al., 2016; Bowling, 2014; Smith, 2010; Burke and Miller, 2001). Although it is increasingly acknowledged that "acceptability" is an essential factor, the published literature offers little guidance on defining or assessing it (Sekhon et al., 2017). The TFA aimed to fill this gap, developed in Sekhon et al.'s 2017 study and was employed to measure the participants' and HCPs' acceptability regarding the intervention. The seven component constructs of the TFA and their definitions are presented in Appendix 5.13(Sekhon et al., 2017, page 12, Additional file 6).

An introduction explaining to the participants and the HCPs the reason for this interview and emphasized the importance of their participation was necessary. Interviewees responses may be affected and may be more sympathetic towards the pharmacist because she is a PhD pharmacy student and because all HCPs were involved from the development of the intervention till the end of the study. They may feel obliged to provide positive experiences (Smith, 2010). Thus, the pharmacist explained that this research aims was not to obtain positive results but to genuinely understand their perceptions and experience of the intervention, the needs of diabetes participants and gain information on how to fulfil those needs through pharmacy services and the use of technology. It also informed the interviewees that the interview is audio recorded for data recording accuracy, but confidentiality will be maintained, and provided an estimate of the interview's length. The researcher prepared a script with all this essential information to ensure consistency and that all details were explained to all interviewees (Taylor et al., 2016; Burke and Miller, 2001).

In multiple-informant studies like this, an interview guide ensures that all essential topics are explored (Mann, 2016; Taylor et al., 2016). The TFA, along with the critical areas of the intervention, served as an interview guide to ensure all topics were covered (general views, burden, effectiveness, and future changes). Under each component of the TFA and critical areas of the intervention, specific questions were developed. A critical area of the intervention was the motivational interview (MI) technique. Direct questions regarding MI were not included in the interview schedule developed, to refrain from directing the participant to respond positively to questions on MI but to truly understand and capture their experience (Mann, 2016; Taylor et al., 2016). Thus, the questions included in the

semi-structured interview were devised to obtain this information indirectly. For example, questions underpinning MI theory, such as self-management, motivation, and confidence, were employed to indicate whether the intervention achieved its aims of improving participants' adherence, self-management, and empowerment.

The general strategy of qualitative interviewing was applied as follows: the researcher asked open-ended questions, and descriptive questions about general topics, waited for participants or HCPs to talk about meaningful experiences, and probed for details and specific descriptions of their experiences and perspectives (Taylor et al., 2016). Probing questions were used to ensure all relevant views and experiences were captured (Taylor et al., 2016; Bowling, 2014; Smith, 2010). Consequently, probing questions were developed to follow open questions, where necessary, to gather more detail on participants' or HCPs' associated experiences and views and to obtain information on other aspects of the intervention (see Appendix 5.14)

After the development of the interview guide, questionnaires used in other studies identified through the literature were reviewed as an example (Ladner et al., 2022; Sun et al., 2019; Hawes et al., 2018; Fortmann et al., 2017; Nundy et al., 2014a; Nundy et al., 2014b; McWhorter et al., 2014; Orsama et al., 2013; Tang et al., 2013; Klug et al., 2011). The researcher refined the interview questions to be understandable and easy to follow by the participants and HCPs (Taylor et al., 2016; Smith, 2010). Moreover, to cover each HCPs role, different questions were included. For example, the diabetes nurse's recruiting role differed from the GPs. Thus, a new section regarding recruitment was developed, and relevant questions were included. The questions developed were constantly reviewed and updated accordingly. This was conducted to ensure the questions were intelligible and to increase the validity of the interview scheduled.

Translation from English to Greek of the semi-structured interviews

The semi-structured interviews could be conducted in Greek and English language. To ensure the validity of the translation, published guidelines on the thorough translation process of the instruments were followed, and one independent researcher also reviewed the translation and ensured it was correct and the meaning was not altered, as explained in chapter 4, section 4.4 (Translation of Greek to English and vice versa) (Hilton and Skrutkowski, 2002).

Piloting the semi-structured interviews

The semi-structured interview schedule was piloted prior to commencement of the study and then employed at the intervention's end. The researcher tested the interview schedule with a Greek-spoken HCP working at a private DC with a clinical background in diabetes to identify wording issues that need to be addressed and enhance the integrity and clarity of the data. Moreover, the pre-test provided an estimation of the time required to conduct the interview, estimated to be around 10 minutes. This information is essential as the researcher needs to state the amount of time required in advance, which is one of the most common questions asked (Burke and Miller, 2001). No changes were needed. The final interview schedules are presented in Appendix 5.11 and Appendix 5.12.

Method for conducting the acceptability interviews

Telephone interviews were chosen as the most suitable method instead of face-to-face interviews. This was chosen mainly because of the constantly updating Covid-19 restrictions. Albeit behavior and body language through phone calls interviews could not be observed, they are more flexible compared to scheduling an in-person meeting (Mann, 2016). Based on Bowling, 2014, up to three call-backs to a non-responder and three re-schedules of the interview could be conducted when necessary to increase the response rates (Bowling, 2014).

Audio-recording of the semi-structured interviews

All interviews were audio-recorded using the Olympus DM-670/650 digital voice recorder. This enabled the interviewer to listen and focus on conducting the interview rather than writing, ensuring that additional details and clarification were addressed for all relevant issues (Taylor et al., 2016; Smith, 2010). In addition, the data analysis was based on what the respondents actually said rather than on an interviewer's summaries or paraphrasing. Furthermore, the researcher tested the audio recorded and mobile phone before use to ensure they were working correctly and that her voice was clearly heard. This reduced the possibility of losing essential data (Taylor et al., 2016; Burke and Miller, 2001).

Data collection form for pharmacist's perception with operating and applying motivational interview approaches in the interview

One data collection form was developed to record the pharmacist's views on delivering the intervention. This form included the pharmacist's experience throughout intervention

delivery (preparation for participant appointments, appointments with the participants, discussions with participants), in terms of additional time/workload required, impact on pharmacist's work (positive or negative), impact by participants, burden and other comments. The data collection form is presented in Appendix 5.15.

Development of data collection form for the pharmacist's workload, delivery time, and cost of the intervention

Two data collection forms were developed; one data collection form recorded the pharmacist's tasks and the time required to deliver them, and one data collection form for cost estimation was developed. The data collection forms were piloted during the pilot phase (04 May 2020 until 15 May 2020). No changes were required, and the final versions of the forms are presented in Appendix 5.16 and Appendix 5.17. A record of all pharmacist's tasks, time, and costs due to the provision of the intervention was kept throughout intervention delivery.

The pharmacist's workload was measured by identifying the tasks the pharmacist needed to accomplish during the intervention and the time spent on each task. The pharmacist's workload included familiarizing with the intervention's procedures, preparing before each appointment by identifying and reviewing participants' information (medical history, pharmacotherapy, etc.), and contacting the participants and HCPs. The time spent for each pharmacist's tasks was recorded from the Qualtrics XM® for the adapted DSCAQ – Greek version, phone call durations, the recordings, which also recorded the time taken to finish the interviews and appointments, and a timer the pharmacist used to calculate the time spent for each activity (such as reviewing participants' pharmacotherapy, making recommendations, etc.). All tasks and time spent were recorded and calculated to determine the pharmacist's workload and time required to deliver the intervention.

Estimation of costs

The costs included in this estimation for the delivery of the intervention consists of the resources required, the pharmacist's training to deliver the intervention, and the pharmacist's hours. All resources (and access to those resources) required to provide the intervention were recorded. All estimates are in Euro, based on the exchange rate of 1 EURO = 0.88 pounds (exchange rates from 29/03/2023 to 29/03/2023). These included mobile phones, computers, educational leaflets, fax, stationery, etc. The pharmacist's

salary cost was calculated based on the pharmacist's workload (hours invested for the intervention's delivery. Based on the Treasury of the Republic of Cyprus, the gross monthly salary of a pharmacist working at the hospital pharmacy at the Nicosia General Hospital (where the DC is located) is 2475 (equivalent to 15 euros per hour, based on the working hours per month) (Treasury of the Republic of Cyprus, 2023).

Building services (e.g., office, heating, lighting, and cleaning), stationery, and resources were offered by the DC and thus were not calculated. In addition, services integrated into the DC could use these services free of charge. For the mobile phone device and contract, three main telephone companies in Cyprus were contacted and the cheapest one was chosen. The computer was already provided by the DC because each office is equipped with a computer and the pharmacist was allowed to use it. Other devices used were Viber and e-mail available free of charge and fax provided by the DC. Educational leaflets, copies of them and a printer machine were available by the DC and Cyprus Diabetes Association (CDA). MI training cost was included in the costs of the intervention and based on the pharmacist's training (see Appendix 4.13). Also, costs related to promotion were also estimated (for example information leaflets and documentation for recruitment period).

5.7 Data analysis

Triangulation methods were employed to fulfil research objectives, as described in Table 5.5. Thus, data analysis was divided into three steps; data analyses for data obtained through the quantitative process and qualitative approach and triangulation of the findings of each data set after analyses.

Table 5.5 Overview of the study data collection forms, data processing and analyses

Data collection forms	Data processing and analyses
• Recruitment and retention • Non-response rates • Engagement (Appendix 5.5) • Semi structured interview schedule (Appendix 5.11)	• Excel and IBM SPSS Statistics 26. • Analysed and reported using basic descriptive frequencies. • NVivo 12 for further organization of the data. • Thematic framework analysis was employed

Table 5.5 Overview of the study data collection forms, data processing and analyses

Data collection forms	Data processing and analyses
• Healthcare professionals' actions on recruitment (Appendix 5.6) • Healthcare professionals' actions on the pharmacist's recommendations (Appendix 5.10) • Pharmacist's experience (Appendix 5.15) • Semi structured interview schedule (Appendix 5.12)	• IBM SPSS Statistics 26 • Analysed and reported using basic descriptive frequencies. • NVivo 12 for further organization of the data. • Thematic framework analysis was employed
• Participants' responses to reminders. (Appendix 5.9) Completeness of instrument, loss to follow-up and data missing. (Appendix 5.5, Appendix 5.6, Appendix 5.7, Appendix 5.8) • Time required to fill the instrument. (Appendix 5.16) • The adapted Diabetes Self-Care Activity Questionnaire – Greek version (DSCAQ – Greek version) (Appendix 4.4) • Semi structured interview schedule (Section 2: Burden) (Appendix 5.11)	• Exported from Qualtrics and entered in IBM SPSS Statistics 26. • Analysed and reported using basic descriptive frequencies. • NVivo 12 for further organization of the data. • Thematic framework analysis was employed
• Pharmacist's workload and time (Appendix 5.16) • Cost estimation for the delivery of the intervention (Appendix 5.17)	• IBM SPSS Statistics 26 • Analysed and reported using basic descriptive frequencies.

Data processing and analyses for data obtained structured data collection forms

The data sets, regarding recruitment of participants, engagement and self-care activity, healthcare staff actions, pharmacist's workload, time, and cost of the intervention were initially collected from data collection forms. Data from the completed forms were entered manually into to Excel and then where needed transferred and analysed using the Statistical Package for the Social Sciences (IBM SPSS Statistics 26). Data regarding recruitment (nonresponse rates), healthcare staff actions, and cost estimation were analysed in Excel, as only minimal statistics were required (sum, frequency, and percentages).

Each variable, about the participants' characteristics and engagement, was coded by assigning numerical value to each response, e.g., choose for education=1 and choose for

review of patients' medications=2. Data collection variables for participants' characteristics and engagement are presented in Appendix 5.18. After the data entry, the data set was cleaned by double-checking that the data transferred were correct, checking randomly for coding errors such as duplicates or skipped entries. Any confirmed missing data were coded 999 to ensure correct output in the analysis. These were conducted to ensure the quality assurance of the data and eliminate data migration errors. After that, participants' characteristics and engagement were analysed in SPSS by calculating the frequency and percentage of each variable. Participants' age, the number of education leaflets sent, the duration of phone calls made between the pharmacist and participants and the number of phone calls and messages sent throughout the intervention by medium per participant were transferred from Excel to SPSS to calculate the minimum, maximum, sum, mean and SD %. Similarly, the duration of the pharmacist's tasks was estimated in the same manner (recorded in Excel and transferred to SPSS for analysis of minimum, maximum, sum, mean and SD %).

Qualtrics XM® was also employed to record participants' responses to Diabetes Self-Care Activities Questionnaire. The Qualtrics XM® charts showed a quick real-time evaluation of each participant's response. However, for statistical analysis, those data were transferred to the IBM SPSS Statistics 26. At the end of the study, the data obtained from Qualtrics XM® were exported to SPSS Statistics 26. The researcher ensured the accuracy of data exported from Qualtrics XM® to SPSS by reviewing the participant's ID and the total number of participants' responses. After that, the number and percentage of participants who responded to each question were calculated to estimate participants' adherence level.

Data processing and analyses for data obtained through interviews

A combination of thematic inductive and deductive analysis was employed. The former allowed flexibility in themes, ideas, and explanations to emerge naturally from the data. The latter approach meant specific interrogation for the predefined categories derived from the semi-structured interview guide (Ritchie et al., 2014; Gale et al., 2013). The NVivo 12 software was chosen to help manage data and code data obtained from the final interviews. Before being transferred to NVivo 12, transcripts were re-read alongside listening to the audio recording to ensure accuracy. This was also done, so the researcher familiarised themselves with the data. The interviews were transcribed verbatim, processed, and analysed in Greek, and then the codes, themes, and results were translated

into English. An independent researcher reviewed the translation of each interview. This ensured the translation was correct and the meaning was not altered, as explained in chapter 4, section 4.3 (Translation of Greek to English and vice versa) (Smith, 2010; Hilton and Skrutkowski, 2002).

The semi-structured interview guide served as a priori framework during the initial analysis stage and deductive codes were created. After that, an inductive approach was followed, and the codes were further refined based on the actual responses made (new ideas emerged from the data). Analysis was an iterative process, and codes were further modified and refined by adding new codes, dividing previous ones, and providing better descriptions of codes for clarity. Constant comparison techniques were used, where all data items were assigned a particular code and, after that, were appraised for similarities and divergences from those already coded (Bowling, 2014; Smith, 2010). Based on the relationship between the primary categories, they were then clustered into secondary categories. Brief or missing data were also coded and distinguished based on the reason, e.g., due to legitimate reason (e.g., not applicable) or responders who did not know the answer or were unwilling to reply (Smith, 2010). For example, not all prompts were applicable for all participants since all participants did not use all intervention services (e.g., emails). Furthermore, brief responses were also received and hence were coded and analysed. This enabled the development and update of the ongoing data collection and informed analysis. The next step involved the identification of themes and interpretation to make meaning out of data. In the thesis's results section, the researcher describes the key findings/themes that emerged and supports them with quotes.

The coding frame was independently reviewed by both supervisors to ensure the reliability of before commencing with line-by-line coding in NVivo 12 (Smith, 2010). The researcher sent one coded and one uncoded transcript with the coding frame to the supervisors for independent review and comparison. It was updated accordingly following the review. Each new coding frame was then discussed between the researcher and supervisors and updated with minor suggestions (e.g., the theme from “important for self-management.” to “enablement of self-management”). The researcher reviewed the coded transcripts with the updated coding frame to ensure they were coded accordingly. The researcher continued the indexing process by systematically applying the updated coding frame to all the data sets, and the codes were refined continuously. A coding frame

was developed, and examples of transcripts' extracts and relevant codes are presented in Appendix 5.19.

Triangulation of data sets

Once all the data sets were obtained and analysed individually, the last analysis stage was to compare the different findings obtained to fulfil research objectives. This was conducted to obtain broader information and to confirm the findings obtained by different methods.

Data regarding recruitment, engagement and attrition, and perspectives of participants expressed in final interviews were combined to provide a more comprehensive picture of acceptability to patients. Similarly, for the feasibility evaluation of the intervention from the perspective of HCPs, triangulation was employed to compare whether HCPs' actions were in accordance with their verbal responses to the interviews at the study end. Moreover, to answer whether the instrument employed for the intervention's delivery, in this case, the adapted DSCAQ – Greek version, was workable and indicated the extent to which clinical outcomes were likely to be achieved, the different results obtained from through the completeness of the instrument, loss to follow-up, data missing, the time required to fill the instrument, and semi-structured interview schedules (section 2: burden), were compared. Different findings obtained from different data sets were compared to answer the research objective regarding the workability of the intervention. Those were the pharmacist's task, the time spent to deliver the intervention, and the cost estimation for the delivery of the intervention. Finally, future recommendations were made based on the results obtained from comparing all findings collected in the study.

5.8 Reflexivity

The definition of reflexivity was identified by the Francisco et al., 2023 study as *"a set of continuous, collaborative, and multifaceted practices through which researchers self-consciously critique, appraise, and evaluate how their subjectivity and context influence the research processes"* (Francisco et al., 2023, page 242). Researchers need to critically evaluate their own biases, values, and experiences about the phenomenon under investigation and how those may influence the study's outcome impact (Mann, 2016; Creswell, 2013). Each researcher brings their own cultural, social, gender, class, and personal agendas that may affect how the researcher interprets the data and/or the

participants and sites under study throughout the study (Francisco et al., 2023; Mann, 2016; Creswell, 2013).

In the same manner, the pharmacist/researcher's own agenda influenced the proposed study. Her background experience, education and workplace likely greatly affected the choice of the study and the setting of the intervention in the first place. Initially, from a pharmacist's perspective, she was aware of the various pharmacy services provided worldwide, including interventions supporting diabetes. She also had the skills and knowledge on how to develop an intervention led by a pharmacist due to her project during her MSc studies, which potentially influenced the idea of developing an intervention. Her preference to work on non-communicable diseases could probably influence her diabetes research. The choice of type 2 diabetes patients (T2DM) was also influenced by the HCPs' views and the way the pharmacist viewed the information they provided. HCPs working in DCs stated that there is a greater need to support T2DM patients and they provided specific data to support this.

In addition, from the perspective of a community pharmacist working in a medical centre that included a DC, the pharmacist experienced firsthand the needs and gaps in the DC and the needs and reasons to develop an intervention to support diabetes patients. Therefore, preliminary fieldwork was initiated from the DC where the pharmacist worked. HCPs working at that DC referred her to other relevant stakeholders. Thus, her experience and involvement in the governmental sector potentially influenced the stakeholders who were approached. For example, HCPs in the private sector were not involved in the intervention's development. In addition, the choice of methods and especially, informal discussions may be affected by her employment status. Stakeholders may be more willing to support a friend/colleague referred by HCPs who are familiar with or to support a pharmacist working within the same sector (government) as them. Also, the pharmacist's background studies may affect the way other HCPs viewed this intervention. The fact that this intervention was developed for PhD studies at this University, which is highly viewed by other HCPs may also affect and increase their engagement and collaboration. They may be more willing to support this intervention and help a colleague, provide more positive feedback on the pharmacist's ideas about the proposed intervention and positively respond to the final interventions on the perception of the intervention.

Following the preliminary fieldwork, the studies identified and critically appraised in the scoping review were affected by the pharmacist's education and profession. Pharmacy-led services were one of the eligibility criteria in the scoping review. In addition, services aimed to improve patients' knowledge, adherence, and self-care activity were chosen. These are components that pharmacists are trained to provide to patients to improve their diabetes management. In the same way, the framework chosen probably was influenced by the profession of the pharmacist. Patient-centred intervention, principles of MI and the philosophy of empowerment are frameworks which pharmacists are familiar with and employed in improving medication adherence. Similarly, the intervention developed, the services chosen, their frequency and the procedure followed potentially were influenced by the pharmacist's working status and experience. She may feel more confident in supporting patients in improving their adherence and discussing medication than any other interventions available to support diabetes patients. For example, a GP or psychologist would probably set different eligibility criteria for the scoping review and may choose and appraise differently the studies identified. Moreover, digital health interventions were also a choice of the pharmacist and her personal preference in learning about this rapidly evolving area.

Because of the researcher's dual role (responsible clinician to receiving follow-up calls from patients and ensuring patients' safety and care), the pharmacist may be more eager to support and address patients' problems based on her ambition to achieve patients' behaviour changes and to receive more positive feedback at the end of the intervention. The approach to analysis was also potentially influenced by the pharmacist's ambition to identify more positive feedback than presenting negative results. How the findings were reported was influenced by the pharmacist/researcher's background. For example, patients' responses on medication adherence were also viewed by the pharmacist perspective and wish to improve adherence and provide solutions to the problem. In contrast, a researcher (different from the pharmacist) may question the reasons for non-adherence instead of worrying and rushing to provide solutions.

Consequently, the components of the study and the study itself were highly influenced by the researcher's personal agenda and previous experience and education. Nevertheless, the pharmacist/researcher by identifying and acknowledging her personal influence on the study, aimed to identify methods to composite and minimize reflexivity bias. To this end, steps were taken to the methodology development to minimize potential bias. First,

background information and evidence supporting the rationale for developing the proposed intervention. Ethical issues of power and obligation were also considered, during preliminary fieldwork, recruitment and intervention delivery, because the pharmacist and the researcher were the same person. Participants and the other HCPs involved in the development of the intervention were more likely to support the intervention by taking part in the intervention, positively responding to the questionnaires, overestimating their behaviour changes, and providing more positive feedback at the final interviews (Smith, 2010). The Foster framework was employed to consider ethical issues during the preliminary fieldwork (Foster, 2001). Also, HCPs and patients working/visiting another setting, apart from the pharmacist's workplace, were identified and participated in the informal discussions. An introduction was developed that explained to participants (HCPs and patients) the purpose of each stage of the study. This was applied during the preliminary fieldwork, recruitment, and final interviews. An information leaflet was also developed during the recruitment.

Each step of the intervention was based on robust evidence and thoroughly described to provide justification. The MRC framework was employed to guide the intervention's development and evaluation. Theoretical frameworks with proven results in improving diabetes self-management were identified and employed. The MI technique was chosen as it has a specific structure which could be applied and followed to each discussion with the patients. The intervention was individually driven to allow flexibility of choice in services and frequency. Thus, really understand participants' needs and preferences. Documentation of all data including the intervention's procedure, data collection forms, piloting and describing the reasons for choosing each step was also another way to minimize reflexivity. The DSCAQ – Greek version was chosen due to its validity and the semi-structured interview was developed based on the TFA. The transcripts of the final interviews were re-read alongside listening to the audio recording to ensure accuracy, were analysed in both deductive and inductive ways and interviewees' quotes were presented in the results chapters. Robust evidence and available educational leaflets were employed to minimize the personal perceptions of the pharmacist and increase consistency. After that, triangulation of the method was the optimal way to address research objectives to allow the intervention, including the extent to which it was successful, to be appraised from all perspectives. In addition, the triangulation of the method and individualization of the intervention enabled a truer understanding the participants' perspective and acceptability of the intervention.

5.9 Validity and reliability of data

Validity refers to the extent to which the instruments used accurately measure what they are designed to measure; hence, the findings reflect the phenomena under study (Smith, 2010). The study employed different questionnaires and used principles of different methods to ensure that data were obtained in different ways and from differing perspectives. Triangulation was also used to complement each method employed and compare the findings from the different data sets. Thus, minimise bias and verify consistency (Bowling, 2014; Guest and Namey, 2014; Smith, 2010; Creswell and Plano Clark, 2007).

Reliability of the study refers to the repeatability of results using the same methods with freedom from random error (internal consistency) (Bowling, 2014; Smith, 2010). To ensure reliability, there must be uniformity in data collection and analyses. For example, ensuring consistency in interview schedules and questionnaires chosen/developed, maintaining records of non-responders, and gathering and coding data are essential (Smith, 2010). Limitation of the study was the fact that the pharmacist who developed, delivered, and evaluated the intervention was the same person. Notwithstanding, all procedures were agreed upon beforehand, piloted, and refined, and the final version was strictly followed (Smith, 2010). The most accurate and reliable scale for the proposed study population and intervention was implemented. Data were maintained throughout intervention delivery.

End of Chapter five

Chapter Six

Recruitment of participants, retention, engagement, and diabetes self-management

6.1 Introduction

This chapter presents the results of the recruitment of participants, nonresponse rates, retention, engagement, and participants' medication adherence and self-care activity, before and after the intervention.

6.2 Recruitment of participants

The recruitment period lasted 2.5 months, from 18th May 2020 until 31st July 2020. Due to Covid-19 restrictions, the operation of the clinic differed between the first month and a half (18th May until the end of June) and the last month of the recruitment (1st July until the end of July), where the clinic was in full operation (see Table 6.1). Four HCPs working at the diabetes clinic (DC) were involved in the study; three general physicians (GPs) and one diabetes nurse. One pharmacist undertook recruitment with the assistance of the HCPs working at the clinic. The pharmacist was present at the DC at least 1-2 and a maximum of 3 days per week, based on the Covid-19 restrictions.

Table 6.1 Operation of the diabetes clinic.

Operation of the diabetes clinic		**Days with covid restriction**	**Days of full operation**
Dates	From	18th of May	1st of July
	Until	30th of June	31st of July
Diabetes clinic working days per week		3	5
Capacity of patients' appointments per day		10	30
Number of general physicians	Minimum	1	2
	Maximum	2	3
Number of diabetes nurses		1	1

Results on recruitment rates of patients

The target sample size of 32 participants was achieved. The pharmacist approached 62 out of 107 eligible patients to participate in the study (62/107, 58%). Of the 62 who were approached, thirty-two patients (32/62, 52%) were interested in responding to the baseline adapted Diabetes Self-Care Activity Questionnaire – Greek version (DSCAQ – Greek version) and 27 participants (27/32, 84%) consented to participate (see Figure 6.1).

Of the 30 patients (30/62) who did not agree to participate, not all expressed their reasons for not participating in the study. However, 4/30 cited an extra burden to participate, 3/30 reported already being aware of diabetes, and 1/30 felt they had nothing to gain from the

study. Of the 32/62 (52%) who were interested in participating in the study, 5 (5/32, 16%) wished to respond to the questionnaire. Reasons for participants' interest in responding to the questionnaire and not proceeding to the study were; 4/32 were only curious about the content of the intervention and they did not need assistance managing their diabetes and one was excluded by the pharmacist due to memory loss problems after the diabetes nurse pointed it out during recruitment. Thus, the pharmacist informed the patient that she could no longer participate in the study.

Thereafter, 5 out of 32 participants withdrew from the study. Of those 5, two did not express the reason (with one of them withdrawing without completing the initial appointment and the other one at the 2nd appointment) and one due to communication difficulties (withdrew at the 2nd appointment). An attempt to solve the participant's inability to use technology was to facilitate communication through his daughter. However, the participant's daughter's workload limited the time available for communication, and hence, the participant withdrew from the intervention. The pharmacist excluded another two participants (at the 2nd appointment) because one was interested in cardiovascular information and not diabetes, and the other patient had a heart attack and wanted some time before participating in the study, which was not feasible due to the study's timeframe.

The remaining 22 patients (22/32) completed the study.

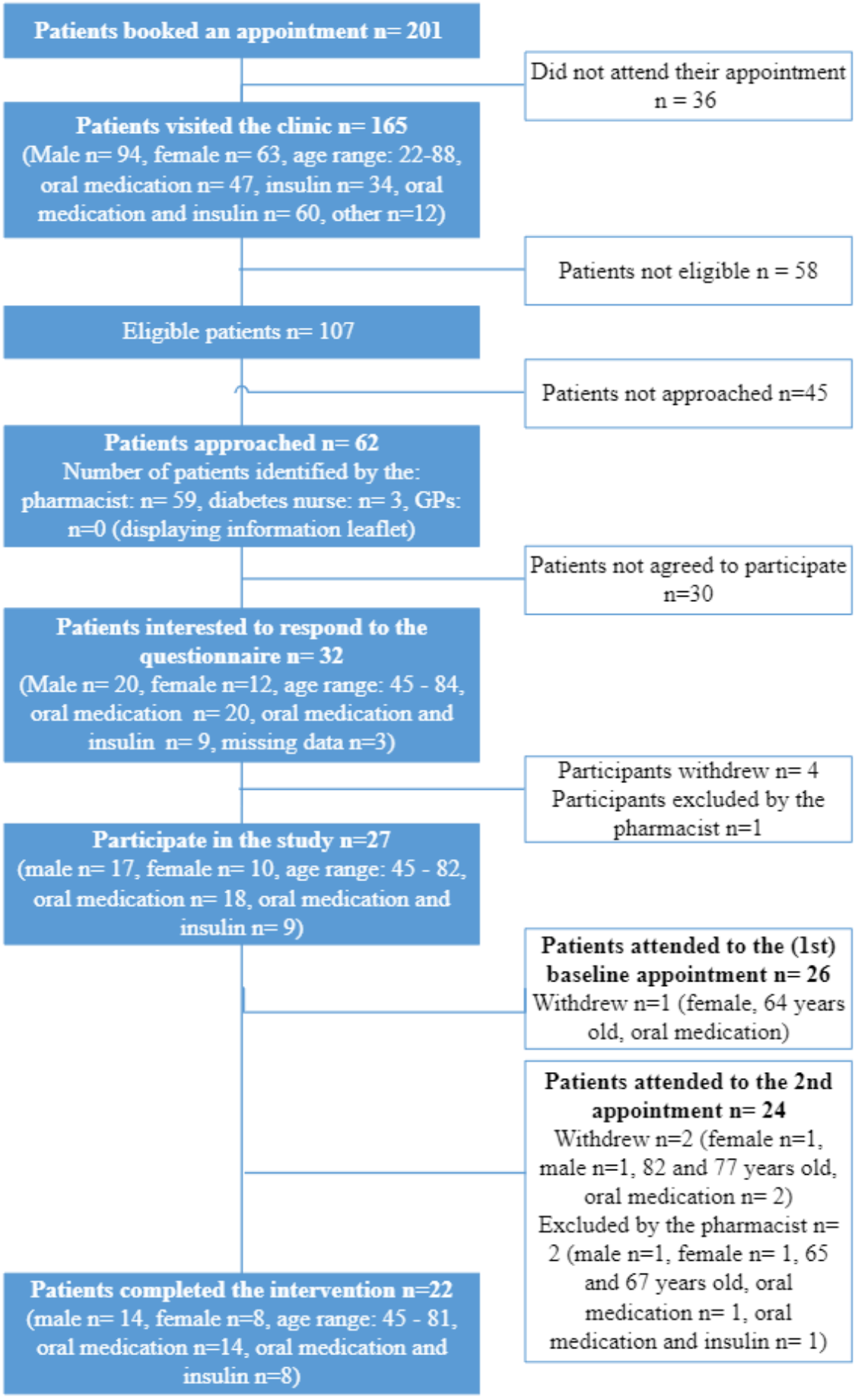


Figure 6.1 Results of the recruitment rates of study participants.

6.3 Participants' characteristics

Participants' characteristics were sought for all study participants who completed the study (n= 22 participants). Data retrieved concerned participants' age, gender, area, district, pharmacotherapy, baseline blood glucose (BG) and glycated haemoglobin (HbA1c). Participants' baseline clinical characteristics are displayed in Table 6.2

The participants included a range of personal and diabetes characteristics (such as gender, age, BG, HbA1c, and medication) (see Table 6.2). About a quarter of participants, who consented to participate in the study, had well-controlled diabetes HbA1c ≤7% (8/22, 36%) at the time of baseline clinical visit, 4/22 (18%) moderately controlled diabetes HbA1c 7% to 8%, and 6/22 (27%) poorly controlled diabetes HbA1c ≥8% (HbA1c normal ranges based on IDF, 2017b; MOHRC, 2013 recommendations). The study participants predominantly were taking only oral therapy 14/22 (64%), whereas 8/22 (36%) were on a combination oral and insulin regimen. A large proportion was taking medicines for other comorbidities 17/22 (77%).

A small proportion were smokers, 5 (23%). All 5 patients who smoke reported smoking during the past seven days including the day of the interview (see Table 6.3). Also, all 5 reported having received counselling and/or being offered referral to a stop-smoking program.

Table 6.2 Baseline characteristics of patients who completed the intervention (N=22).

Characteristic of participants		Patients completed the intervention N=22
Age, years, mean [SD]		69 [8.3]
Gender N (%)	Male	14 (64)
	Female	8 (36)
District N (%)	Nicosia	20 (91)
	Other	2 (9)
Area N (%)	Urban	15 (68)
	Rural	7 (32)
Baseline BG (mg/dL),	Mean [SD]	167 [68.4]
	Minimum - Maximum	70 - 350
	Data missing N (%)	2 (9)
Baseline HbA1c[1]	Mean [SD]	7.4 [1.3]
	Minimum - Maximum	5.8 - 10.3
	Less than <7% N (%)	8 (36)
	Between 7-8% N (%)	4 (18)
	Above than >8% N (%)	6 (27)
	Data missing N (%)	4 (18)
Baseline participants' antidiabetic pharmacotherapy N (%)	Oral medication only	14 (64)
	Oral medication and insulin	8 (36)
	Data missing	0 (0)
Antidiabetic drugs N (%)	Metformin	18 (82)
	Dipeptidyl peptidase-4 inhibitor (DPP-4)	9 (41)
	Sulfonamides	9 (41)
	Insulin glargine	7 (32)
	Fast-acting insulin	2 (9)
	Data missing	3 (14)
Baseline participants' pharmacotherapy for other morbidities N (%)	Participants taking other medication	17 (77)
	Data missing	5 (23)
Other medication N (%)	Cholesterol-lowering medications	8 (36)
	Cardiovascular medications	5 (23)
	Anticoagulants or antiplatelet medications	10 (45)
	Other conditions	4 (18)
	Data missing	5 (23)
Smoking N (%)	Yes	5 (23)
	No	17 (77)

[1]Participants were referred for an HbA1c test one to two weeks (a maximum of one month) before their diabetes clinic appointments. SD is the standard deviation. HbA1c is glycated haemoglobin.

Table 6.3 Participants' responses to the baseline adapted DSCAQ – Greek version, smoking (N=5 patients who smoke).

Questions of the Diabetes Self-Care Activity Questionnaire – Greek version regarding smoking	Number of participants' responses	
At your last doctor's visit, did anyone counsel you about stopping smoking or offer to refer you to a stop-smoking program?	Yes	5 (100)
	No	0
Have you smoked a cigarette—even one puff—during the past SEVEN DAYS?	No	0
	Yes	5 (100)
Number of cigarettes per day: N (mean) [SD]	Range	10-45
	Mean [SD]	26 [17]
When did you last smoke a cigarette?	Today	5 (100)

6.4 Participants' engagement

An evaluation of participants' engagement is presented in this section. Data regarding the 22 study participants, who completed the intervention, were evaluated. The participants' engagement was assessed in terms of service(s) chosen, frequency of contact and follow-up appointments, and the medium employed.

Participants' services use

The participants' choices regarding the services provided in the intervention by each appointment are displayed in Table 6.4. Participants' preferences regarding the services of the intervention changed throughout the intervention. For example, some participants chose education at the initial appointment, whereas others choose education at a subsequent appointment. In addition, each participant was eligible to choose more than one service. All participants used the pharmacist online advice to patient queries service, which was mandatory. No participants choose reminders (for medication taking, self-monitoring of blood glucose, and appointment attendance), tracking and uploading self-monitoring of blood glucose readings, and graphical reports of self-monitoring of blood glucose readings.

Table 6.4 Participants' choice regarding the services provided in the intervention by each appointment (N=22).

Services	Baseline appointment	First appointment	Second appointment	Third appointment
Education	18/22	6/22	6/22	3/22
Did not choose an additional service *(apart from pharmacist online advice to patient queries*	5/22	15/22	15/22	18/22

Table 6.4 Participants' choice regarding the services provided in the intervention by each appointment (N=22).

Services	Baseline appointment	First appointment	Second appointment	Third appointment
service, which was mandatory)				
Review of participants' medications	1/22	1/22	1/22	1/22

Although the adapted DSCAQ – Greek version provided basic information regarding each participant's knowledge and behaviour in diabetes management, it did not identify possible reasons for their actions. During the communication/discussions with the pharmacists, more details were obtained regarding these activities and revealed whether the participants were genuinely adhered. For example, all participants (22/22) appeared to be adhered to medication taking. However, during the discussions, many participants admitted that they were not taking their medication as prescribed and reasons for nonadherence as described below.

Communication/discussions with the pharmacist

Table 6.5 described the content and frequency of communication between the pharmacist and the participants. The study participants predominantly discussed concerns about medication 20/22 and foot care 16/22. Each participant discussed various topics with the pharmacist. For example, the same participant discussed with the pharmacist about medication and foot care, or different topics related to medication (e.g., correct dosage and vaccination).

Table 6.5 Communication between the pharmacist and participants by content and frequency (N=22).

Content discussed with the pharmacist		Number of participants
Category	**Topic discussed**	
Medication	Participants correct dosage scheme and worries about adverse medication events	10/22
	Medication-taking (including the role of each medication and why they are taking them)	5/22
	Vaccination	3/22
	Insulin (storage of insulin and areas of injection)	2/22
	Medication refill information	2/22
	Frequency of discussions about medication	20/22
Reasons for nonadherence	Afraid of side effects	4/22
	Afraid of insulin injections	1/22

Table 6.5 Communication between the pharmacist and participants by content and frequency (N=22).

Content discussed with the pharmacist		Number of participants
Category	**Topic discussed**	
	Unable to eat at the time told to take the medication	1/22
	Did not want to take the medication/injection in front of colleagues	1/22
	Frequency of discussions about reasons for nonadherence	7/22
Foot care	Foot aches and possible causes and solutions	14/22
	Foot care	3/22
	Frequency of discussions about foot care	16/22
Healthy eating	How food affects their BG and how they can maintain their BG within the range of dieting habits	9/22
	Information about each food category (e.g., carbohydrates),	3/22
	Alcohol and diabetes management	2/22
	Frequency of discussions about healthy eating	11/22
Self-monitoring of blood glucose (SMBG)	Blood glucose interpretation results	9/22
	When to measure their blood glucose	3/22
	Information about finger-picking problems	1/22
	Frequency of discussions about SMBG	11/22
Physical activity	Information about what type of exercise they could do	7/22
Other (Queries about the diabetes clinic pathways)	Rescheduling their appointment due to high BG	1/22
	Appointment booking	1/22
	Frequency of discussions about other topics	2/22

Education

A majority of participants chose education 18/22 from the services available throughout the study, and all of those agreed to receive educational leaflets about diabetes (18/22), as presented in Table 6.6Table 6.6. The education material by content identified at the diabetes clinic and sent to the participants is shown in Table 6.6. Thirty-six educational leaflets were sent to the 18 (18/22) participants throughout the intervention, and 10/18 participants requested more than one educational leaflet, as described in Table 6.7.

Table 6.6 Number of participants who chose education by the content of the education leaflet sent (N=18).

Content of the education leaflet sent		Number of participants
Category	**Education material identified at the diabetes clinic**	
Healthy eating	Food exchanges (handbook)	5/11
	General advice for a healthy program from the dietitian of the diabetes clinic (leaflet)	4/11
	Diet and exercise (included information about alcohol) (leaflet)	2/11
	Total education leaflets sent about healthy eating	11/18
Foot care	Diabetes foot care (leaflet)	7/9
	Diabetes and limb diseases (leaflet)	2/9
	Total education leaflets sent about foot care	9/18
Physical activity	Diet and exercise	6/8
	Foot exercise on diabetes patients	2/8
	Total education leaflets sent about physical activity	8/18
Diabetes management	General educational leaflet about diabetes management (book)	5/18
Medication	Insulin instructions (injection and storage information) (patient information leaflet (PIL))	2/18
Hypoglycaemia	Hypoglycaemia leaflet	1/18
	Food exchanges handbook (included hypoglycaemia instructions)	1/18
	Total education leaflets sent about hypoglycaemia	2/18
Diabetes and eyes	Diabetes and eyes (leaflet)	1/18

Table 6.7 Number of educational leaflets sent, minimum and maximum of educational leaflets requested per participant.

Educational leaflets sent to the participants	
Total number of educational leaflets sent	36
More than one educational leaflet was requested per participant	10/18
Mean number of educational leaflets requested per participant [SD]	2 [1.2]
Minimum of educational leaflets requested per participant	1
Maximum of educational leaflets requested per participant	5

Review of participants' medications

Only one participant out of 22 (1/22) chose a review of medications. This was a family caregiver assisting an elderly participant with all health care and daily tasks (medication taking, eating, cleaning, scheduling appointments with HCPs, etc.). The family caregiver was concerned about the dangers of polypharmacy, as the participant was recently discharged from the hospital with ST-Segment-Elevation Myocardial Infarction (STEMI) and was interested in learning more about the participant's pharmacotherapy.

Frequency of contact and follow-up appointments, and the media employed

All 22 participants responded to the first and second calls from the pharmacist. Third phone calls were made to 18 participants (18/22) (see Table 6.8). Further to that, additional calls were also conducted to arrange and agree on how the educational leaflets were sent and re-schedule the appointments. A small proportion of participants (9/22) initiated the phone call towards the pharmacist. Table 6.9 presents the duration of phone call contacts between the pharmacist and the participant. The duration of the first phone call was the longest compared to subsequent phone calls. However, the duration of the phone calls between the participants varied from 1-4 minutes to 21-79 minutes.

Table 6.8 Number of phone calls between the pharmacist and the participant, by participant and phone calls conducted.

Phone calls between the pharmacist and the participant		
Number of participants	Who attended the 1st call	22/22
	Who attended the 2nd call	22/22
	Who attended the 3rd call	18/22
	Who required additional phone calls for further instructions[1]	10/22
	Who initiated at least one phone call	9/22
	Who requested a re-scheduled phone call	3/22
Number of phone calls per participant	Mean [SD]	4 [2]
	Minimum	2
	Maximum	7
	Number of repeated calls to re-scheduled	1-2
Number of phone calls	For further instructions[1]	28/85
	Initiated by participants	11/85
	Total number of phone calls	85

[1] Re-schedule appointments, instructions for receiving educational leaflets, further instructions after discussing with other HCPs at the diabetes clinic.

Table 6.9 Duration of phone calls made between the pharmacist and participants (in minutes).

Duration	**Phone calls**				
	First[1]	**Second**	**Third**	**Further instructions[2]**	**Total**
Mean [SD]	19 [17]	12 [10]	7 [6]	2 [1]	
Minimum	4	4	1	1	
Maximum	79	48	21	3	
Total	421	258	120	44	843

[1] The adapted DSCAQ – Greek version and employment of the MI were conducted at the 1st phone call with two participants, as they did not have enough time to conduct it at their appointment at the DC.

All participants communicated with the pharmacist via phone (which was mandatory) but were eligible to choose additional media for the intervention delivery. All additional media were used (Viber messages, text messages, and emails), and 9/22 participants chose more than one media (see Table 6.10). Only one participant (1/22) initiated a message to the participant, and it was about a query regarding foot care. Most of the messages exchanged were conducted through Viber and then through text messages (see Table 6.11).

Table 6.11

Table 6.10 Participants' choice of additional media used for pharmacist online advice to patient queries (N=22).

Media of delivery for pharmacist online advice to patient queries	Number of participants
Viber message	4/22
Text messages	3/22
Emails	2/22
Viber and text messages	3/22

Table 6.11 Number of messages/ emails exchanged throughout the intervention by medium (text messages, Viber messages, and emails) (N=22).

Number of messages/ emails exchanged	Media of delivery		
	Viber messages	Text messages	Emails
Mean [SD]	7 [8]	7 [9]	5 [1]
Minimum	2	1	4
Maximum	20	23	6
Total	50	39	10

The majority of educational leaflets (11/18) were distributed at the first appointment with the participant at the clinic (see Table 6.12**Error! Reference source not found.**). Other ways used, as preferred by the participants, were Viber message (5/16), post (4/16), email (2/16), and fax (1/16).

Table 6.12 Participants' choice regarding the media used for receiving the educational leaflets (N=16).

Media of delivery for the educational leaflets		Number of participants N (%)	Number of educational leaflets sent
At the clinic		9/16	12/36
Viber message		5/16	8/36
Post		4/16	11/36
Emails		2/16	4/36
Fax		1/16	1/36
Combination of media used	At the clinic and Viber message	2/16	N/A[1]
	At the clinic, Viber message, and fax	1/16	N/A[1]

Table 6.12 Participants' choice regarding the media used for receiving the educational leaflets (N=16).

Media of delivery for the educational leaflets		Number of participants N (%)	Number of educational leaflets sent
	At the clinic and post	1/16	N/A[1]

[1]The number of educational leaflets sent was counted per media used for more meaningful interpretation.

6.5 Participants' diabetes self – management before and after the intervention

The participants 'diabetes self - management, was evaluated individually by measuring participants' medication adherence and self-care activity before and after the intervention. This was to examine the feasibility, utility (potential value) of these measures for a larger study. To enable the comparison and draw valid conclusions the twenty-two participants who completed the intervention and attended the final appointment with the pharmacist were the sample size compared before and after the intervention (see Table 6.2 for participants' demographics and characteristics).

Whilst the study was not designed to robustly test for change nor look for statistically significant changes, participants reported improvements in self-care during the study period in three out of five domains assessed in the adapted DSCAQ – Greek version. Blood sugar testing, healthy eating, and foot care, as measured by the proportion of days covered, were increased after the intervention. In contrast, adherence to diabetes medications and physical activity remained the same. Table 6.13 displays participants' responses to the baseline adapted Diabetes Self-Care Activity Questionnaire – Greek version (DSCAQ – Greek version) before and after the intervention (N=22). At the final appointment, the adapted DSCAQ – Greek version and interview were conducted via telephone, while the arrangement for completion was conducted via the participants' preferred medium (e.g., text message, Viber, telephone).

Baseline participants' responses to the adapted Diabetes Self-Care Activity Questionnaire – Greek version

The adapted DSCAQ – Greek version results indicated that all participants reported taking their recommended diabetes medication daily. The majority of participants, 17/22 (77%), responded that they were testing their BG 7 out of 7 days in the past week and only a few proportions stated 4/22 (18%) that they did not follow their provider's instructions the past week. Although only 4 participants out of 22 (18%) reported

following a healthy eating plan over the past week, a large proportion of participants (18/22, 82%) reported eating fruit and vegetables daily for the past week. Half of the participants (11/22, 50%) reported not exercising for at least 30 minutes the past week. The highest adherence concerning foot care was marked in 2 out of 5 measurements, washing their feet and drying between their toes after washing 7 out of 7 days in the past week, with 19/22 (86%) and 17/22 (77%), respectively.

Results of the participants' medication adherence and self-care activity

At six months, the number of participants who reported taking their medication daily in the past week remained the same (22/22) before and after the intervention. In addition, 4 of the 5 measures of healthy eating and 2 out of 2 measures of self-glucose monitoring improved, as measured by the proportion of days covered, which was increased. The number of participants who reported following a healthy eating plan daily in the last seven days and the last month increased from 4/22 to 9/22 and 2/22 to 10/22, accordingly. Intake of fats was diminished after the intervention, as one-third of participants 5/22 were taking fats 7 days in the past week. In contrast, no participants responded to intaking fats the past 7 days after the intervention. The number of participants who reported spacing carbohydrates evenly through the day 7 out of 7 days almost doubled after the intervention, 5/22 and 9/22. No change in consumption of recommended servings of fruit and vegetables was observed.

Differences in adherence to both physical activity measures (exercise at least 30 minutes and exercise session) were also observed. The majority of participants were not performing any exercise in the past week before and after the intervention. The proportion of participants performing exercise sessions (e.g., swimming) 7 out of 7 days had more than doubled, from 1/22 to 3/22, while a slight increase in the proportion of participants reporting performing exercising for at least 30 minutes was observed after the intervention from 5/22 to 7/22.

Four out of five measurements of foot care were improved, as measured by the proportion of days covered. A double of participants reported examining their feet and inspecting the inside of their shoes after the intervention. No change was observed in drying between their toes after washing and soaking their feet in a solution of water and antiseptic.

Table 6.13 Participants' responses to the adapted Diabetes Self-Care Activity Questionnaire – Greek version (DSCAQ – Greek version), self-care activities, before and after the intervention (N=22).

Questions of the Diabetes Self-Care Activity Questionnaire – Greek version - How many days per week/month do participants undertake the following self-care activities?		**Days per week, participants undertake the relevant self-care activities** (All measures on a 7-day scale) (number of participants (%))															
		Pre intervention n= 22								After intervention n= 22							
		0	1	2	3	4	5	6	7	0	1	2	3	4	5	6	7
Medication adherence	Took recommended diabetes medication over the last seven days.	-	-	-	-	-	-	-	22 (100)	-	-	-	-	-	-	-	22 (100)
Blood sugar testing	Tested blood sugar over the last seven days.	-	2 (9)	-	-	-	3 (14)	-	17 (77)	-	1 (5)		1 (5)	1 (5)	1 (5)	-	18 (82)
	Tested blood sugar over the last seven days, as recommended by their provider.	4 (18)	-	-	-	-	3 (14)	-	15 (68)	-	1 (5)	1 (5)	-	-	1 (5)	2 (9)	17 (77)
Healthy eating	Followed a healthy eating plan over the last seven days.	10 (46)	1 (5)	-	-	2 (9)	4 (18)	1 (5)	4 (18)	2 (9)	-	-	-	2 (9)	5 (23)	4 (18)	9 (41)
	Followed a healthy eating plan per day in the last month.	16 (73)	-	-	1 (5)	-	2 (9)	1 (5)	2 (9)	2 (9)	-	-	1 (5)	2 (9)	2 (9)	5 (23)	10 (45)
	Ate five or more servings of fruit and vegetables over the last seven days.	1 (5)	-	2 (9)	-	-	-	1 (5)	18 (82)	-	-	1 (5)	-	1 (5)	-	2 (9)	18 (82)
	Spaced carbohydrates evenly through the day over the last seven days.	17 (77)	-	-	-	-	-	-	5 (23)	4 (18)	-	-	2 (9)	2 (9)	2 (9)	3 (17)	9 (41)

Table 6.13 Participants' responses to the adapted Diabetes Self-Care Activity Questionnaire – Greek version (DSCAQ – Greek version), self-care activities, before and after the intervention (N=22).

Questions of the Diabetes Self-Care Activity Questionnaire – Greek version - How many days per week/month do participants undertake the following self-care activities?		**Days per week, participants undertake the relevant self-care activities** (All measures on a 7-day scale) (number of participants (%))															
		Pre intervention n= 22								After intervention n= 22							
		0	1	2	3	4	5	6	7	0	1	2	3	4	5	6	7
	Ate high-fat foods such as red meat or full-fat dairy products the last seven days[2].	*3 (14)*	*3 (14)*	*5 (23)*	*5 (23)*	-	*1 (5)*	-	*5 (23)*	*6 (27)*	*5 (23)*	*5 (23)*	*4 (18)*	-	*2 (9)*	-	-
Physical activity	Participated in at least 30 minutes of physical activity[1] over the last seven days.	11 (50)	-	1 (5)	2 (9)	2 (9)	1 (5)	-	5 (23)	8 (36)	-	1 (5)	2 (9)	2 (9)	-	2 (9)	7 (32)
	Participated in a specific exercise session[3] over the last seven days.	19 (86)	1 (5)	1 (5)	-	-	-	-	1 (5)	17 (77)	-	1 (5)	1 (5)	-	-	-	3 (14)
Foot Care	Checked feet over the last seven days.	15 (68)	-	-	-	-	-	1 (5)	6 (27)	3 (14)	-	-	-	3 (14)	2 (9)	1 (5)	13 (59)
	Inspected the inside of your shoes over the last seven days.	19 (86)	-	-	-	-	-	-	3 (14)	10 (45)	2 (9)	-	-	1 (5)	2 (9)	1 (5)	6 (27)
	Washed feet over the last seven days.	3 (14)	-	-	-	-	-	-	19 (86)	-	-	-	-	-	-	-	22 (100)
	Dried between toes after washing over the last seven days.	3 (14)	-		1 (5)	1 (5)	-	-	17 (77)	4 (18)	-	2 (9)	-	-	-	-	16 (73)
	Soaked feet in the water with an antiseptic solution over the last seven days[2].	*19 (86)*	*2 (9)*	-	-	-	-	-	*1 (5)*	*20 (91)*	*1 (5)*	-	-	-	-	-	*1 (5)*

[1] Total minutes of continuous activity, including walking. [2] Reverse questions are in italics. [3]Such as swimming, walking, and biking (other than what you do around the house or as part of your work). The adapted DSCAQ – Greek version is Diabetes Self-Care Activity Questionnaire – Greek version.

6.6 Discussion

Although not all patients who visited the DC wished to participate in the study (response rate 32/62, 52%), those who agreed to participate stayed engaged to the interventions' procedures (22/32). Particularly, 6 out of 10 participants who did not complete the intervention, withdraw on or before the initial appointment, 3 were excluded from the pharmacist and only one withdraw at the 2nd appointment. Thus, this might provide a suggestion that most of the participants who experienced the intervention engaged to completion. The target sample size was achieved concerning the nature of the study (feasibility). The participants included a range of personal and diabetes characteristics, gender, age, BG, HbA1c, and medication. Consequently, this feasibility study achieved its goal of gaining information on the intervention's relevance to the intended study population and provided valuable insights for future research.

An indication of participants choices and needs were also shown through this feasibility study. Flexibility and intervention's individualization was indicated by participants choice throughout the intervention as their choices varied regarding the services, the frequency of communication and the media employed. The majority of the participants chose education from the services provided (18/22), while a small proportion chose review of patients' medications (1/22). Contrary to that, medication was the most discussed topic during the appointments between the pharmacist and the participants 20/22. After that, foot care 16/22 and then healthy eating (11/22) were the most preferred topics. Participants' choices changed throughout the intervention, with most participants choosing education at the initial appointment and then reducing the services to only receiving pharmacist online advice on patient queries, while some other participants chose education at a subsequent appointment. Educational leaflets were requested by participants throughout the intervention, with most participants requesting more than one educational leaflet and the majority of educational leaflets distributed at the DC. Similarly, the participants' choice regarding the media was different from text messages, Viber messages, phone calls, posts, fax, to emails. Their preferred media for communication were Viber and text messages, while for educational leaflets were Viber and then post.

All participants completed the two mandatory appointments, and a high proportion requested a 3rd appointment (18/22). In addition, although most of the study participants did not initiate a call to the pharmacist nor send text messages to the pharmacist, they

responded to the pharmacist's calls until the end of the study. The engagement and/or usership identified from similar studies varied as it was measured differently in each study (McLeod et al., 2020; Fortmann et al., 2017; McWhorter et al., 2015; McWhorter et al., 2014; Nundy et al., 2014b; Lau et al., 2014; Chen et al., 2013; Tang et al., 2013; Klug et al., 2011), Similarly, to that, this study evaluated the participants' engagement in different ways; usability of each service of the intervention, services which the patients chose and for how long (e.g., reminders and/or education), number of text messages sent to the pharmacist, areas where the patients' needed further support, type of questions made to the pharmacist and their frequency.

At baseline, participants reported taking their medication and monitoring their BG. However, low foot care and physical activity was stated. Low adherence rates were also reported when asked about following a healthy eating plan, but participants reported eating fruit and vegetables daily. Healthy eating and foot care were the most preferred content requested in education leaflets sent and discussed with the pharmacist (after medication). In contrary to that, despite participants reporting adherence to medication taking, medication was the most preferred topic discussed during the discussions with the pharmacist. Participants asked queries about the correct dosage scheme, medication role and why to take them and expressed worries about adverse mediation events. This might imply that the overestimated self-reported adherence to medication taking was due to social desirability bias as the pharmacist was the same person as the researcher conducting the questionnaire (Bowling, 2014; Smith, 2010). Participants at the end of the intervention reported being more adhere to blood sugar testing, healthy eating, and foot care, compared to the beginning of the intervention. This may be due to the services provided in the intervention or the participants were more aware of what to answer in the questionnaire.

A limitation of this study was that it evaluated the participants' medication adherence and self-care activity before and after the intervention and in one way (questionnaire). Also, the pharmacist delivering the intervention and the researcher were the same person. This might affect the validity of the results (Bowling, 2014; Smith, 2010). Also, another limitation was the small sample size and the lack of access to some of the participants' data (HbA1c and BG). Nevertheless, study's objectives were achieved. Results provided suggestions that the intervention was acceptable by the participants and provided reasons further to extrapolate the intervention in a more extensive examination.

It was strongly suggested that the intervention was acceptable to participants. Most of the participants, who consent to participate stayed engaged with all intervention's elements. This implies that there is a strong indication of acceptability in intervention's delivery and content. Participants choice varied in regard to their preferred services, frequency of communication and media employed to facilitated intervention's procedures. This might imply the importance of individualization when designing patient-centred interventions aimed at improving patients' self-management.

End of Chapter Six

Chapter Seven

Participants' acceptability at the end of the intervention

7.1. Introduction

This chapter reports the findings regarding the participants' acceptability of the intervention at the end of the intervention. All 22/22 participants, including the one family caregiver, who completed the intervention, were interviewed by the pharmacist when they individually finished the intervention between September 2020 and December 2020. The semi-structured interviews were conducted in the Greek language, apart from one which was conducted in the English language. Participants' characteristics are described in Table 6.2. The mean duration of the audio recordings was 20.6 (8.62 standard deviation (SD)) minutes, minimum duration 8.0 minutes, and maximum duration 46.0 minutes. This included the time for completion of the final adapted DSCAQ – Greek version and the semi-structured interview.

7.2. The final detailed coding frame

The final detailed coding frame consisting of the two main domains and corresponding codes developed for the participants' interview, is illustrated in Table 7.1 and Appendix 5.19.

Table 7.1 The final detailed coding frame consisting of the two main domains and corresponding codes developed for the participants' interview.

Domain	Code
Participants' perception regarding the utility of the intervention.	• Impact on motivation and confidence. • Role of ongoing support and communication. • Role of education and advice. • Enablement of self-management.
Participants' perception of intervention procedures.	• Burden due to participation in the study. • Proposing this intervention to a friend or relative with type 2 diabetes. • Intervention fit into the current healthcare system. • Other ways to improve self-management of diabetes. • Suggestions to improve the intervention.

7.3. Participants' perceptions regarding the utility of the intervention

The responses indicate that all 22 participants viewed the intervention positively and expressed their reasons for this. Motivational interviews (MI) aim to empower positive lasting change by empowering patients, equipping them with information, motivation, and self-confidence, and evoking them to be part of the management of their disease (Salimi et al., 2016). Most of the comments expressed by the participants reflected the perceived value of the MI approach: Impact on motivation and confidence, the role of

ongoing support and communication, recognition/value of the communication with the pharmacist, the role of education and advice, and enablement of self-management.

Impact on motivation

Participants described how this intervention increased their motivation, e.g., increasing vigilance and triggering them to seek further information to improve their self-management of diabetes.

"This [intervention][2]*, for me, is something good, very good…I benefited from the intervention because, as I told you, it motivated me to do more than I used to do before. Chatting with you, hearing what you were telling me, something I did know before… in any way, I like the intervention, and the motivation was good."*

Participant Number 20, male, 63 years old.

One participant briefly stated that after the intervention, he was better managing his diabetes.

"I can see the difference that I achieved. Because I was not measuring my blood sugar, I was mishandling my diabetes."

Participant Number 15, male, 75 years old.

Another participant stated that this intervention kept them vigilant and reminded him about areas he must focus on, for example, food care.

- *Participant: The fact that I talk to someone kept me many times on some vigilance.*
- *Pharmacist: Can you further explain it?*
- *Participant: In general, to talk to someone about anything. For example, when you asked me about my food care or any other question about diabetes, you reminded me that I must be cautious in these areas.*

Participant Number 13, male, 66 years old.

Further to that, one participant stated that it motivated him to look further and read more information about diabetes.

[2] [normal type] = words not spoken

"Now that I found these websites, now I am more careful. How can I explain it? Now I am looking for more information about diabetes. There was a time I did not pay attention to them. Then it was very useful to wait for you to call me."

Participant Number 19, male, 57 years old.

Impact on confidence

Participants were asked whether the provided intervention made a difference to their confidence in managing their diabetes. Eighteen out of twenty-two participants (18/22) said that they felt more confident in self-managing their diabetes. Three (3/22) did not respond positively or negatively; they replied that they were fine and made general comments about the intervention. Only one participant, (1/22), responded that they did not find the intervention helpful nor felt any changes due to their participation. The participant commented that he was disappointed with the diabetes management pathways, DCs and the GESY and felt nothing could help him.

"Yes, I am more confident that I will live a life without stress with my diabetes. Now, I do not have stress that I have diabetes. I will monitor my sugar at night, around 9 pm, and check whether it is 150, 170, or 130 mg/dL. Hence, I will adjust my insulin dose to one unit more."

Participant number 03, female, 72 years old.

Another participant expressed that the most critical thing is willpower. He valued the educational leaflets and the intervention provided, but he expressed that willpower is crucial to achieving improvement.

- *Participant: I felt more confident. There is no other way to improve diabetes management. When there is a will, everything can happen."*
- *Pharmacist: How about the educational leaflet distributed? Should we increase them or decrease them?*
- *Participant: The educational leaflets were good, as long as someone is responsible and deals with his problem on his own, this is what I think.*

Participant Number 09, female, 67 years old.

Only one participant (1/22), responded that they did not find the intervention helpful nor felt any changes due to their participation.

"To tell you the truth, I do not mind. I do not have any expectations. Anything I do, I do it by myself. Neither my GP, who is changing my medications, helped me. All I am looking for is a drug that does not cause any kidney problems but at the same time is strong enough not to raise my blood sugar."
Participant Number 16, male, 77 years old

Role of ongoing support and communication

Participants stated that the calls received and the discussions they had with the pharmacist were one of the reasons they found the intervention specifically helpful. Particularly, two participants valued the role of ongoing support and communication because they could confirm things about diabetes management and helped them improve their diabetes management.

"By talking to someone about a problem of yours helps you. As much as you want and as much as you know, hearing others' opinions is very helpful for you, and you have even more relief. I am very pleased with you. Some things that I had hidden in my mind were just refreshed. I am pleased with you. It was like a relaxation time for me."
Participant Number 03, female, 72 years old.

Another participant appreciated the pharmacist's support.
"We go to the GP. We speak to you too. We are ok. Our diabetologist might not give us as much attention as you. Our GP is good but might not give us as much attention."
Participant Number 12, male, 66 years old.

One participant stated that he valued the kindness and the feeling that somebody cared for him. The pharmacist explained to the below participant the procedures to refill his prescription and referred him to the diabetes nurse.
"The kindness, all the calls, good advice and taking care of me, giving me medicine, it is ok so far, so good, nothing to complain. It is helpful because of the advice you gave me. It is very good because I feel somebody is taking care of me. Very good for your mental health and the advice."
Participant Number 21, male, 45 years old.

Participants expressed that the pharmacist showed interest toward them in the improvement of their diabetes. The interest of the pharmacist toward the participants was

valued by the participants and expressed several times when asked what they found explicitly helpful in the intervention.

"Most of all, it is interesting, the interest from you to us, which we supposedly have a problem. When we are chatting, and I am describing what I am eating, and you are telling me which might be bad for me or not, I am satisfied because I can confirm what is within reason for this problem."
Participant Number 02, male, 79 years old.

In addition, a participant stated that he valued that this interest came from a stranger intending to support them in managing their diabetes.
"It is a very good service. It is very important for a stranger to be interested in you and give you advice. It is something very significant."
Participant Number 19, male, 57 years old.

The family caregiver appreciated the instructions when a problem occurred. The participant faced several health issues during the intervention, and the family caregiver contacted the pharmacist to identify possible solutions.
"Yes, this personal contact, your interest, for example. The fact that I knew that, if at any point I needed something or access to the GP or a referral, for example, the whole structure, how you handle it was perfect."
Participant Number 17, family care giver, 77 years old.

Role of education and advice

Participants reported that they valued the advice provided by the pharmacist.

"I have had diabetes for so many years, your advice (sic). For example, they never told me before, something relevant, only to take my pills, do my injections, and not worry. This is what they were telling me before. In contrast, now you are saying, for example, I have to do this, this, and this, to make a list of things. How to explain it? You told me a list of things. If I do this, then check what I am eating. For example, I will get better, and I indeed got better. Your advice, you gave me very good advice, you and the diabetes nurse gave me very good advice."
Participant Number 14, female, 66 years old.

One of the participants who expressed they valued the tailored consultation provided in the intervention, requested more educational leaflets at the end of the final interview. The pharmacist sent the requested educational leaflets. After receiving the educational leaflet, the participant called the pharmacist to thank her.

"The thing that helped me more was that intervention had some certain information which helps to tackle my problem [diabetes]."

Participant number 05, male, 68 years old.

Furthermore, one participant realized the importance of the advice and instructions provided, as it helped him improve his diabetes management.

"The instructions provided are very important. Because if I follow them, I believe I will improve".

Participant Number 01, male, 81 years old.

Two participants explained that they valued that the provision of education was delivered by a scientist.

"It is good you are informing me. First of all, you are telling me what we must do, nice things. You are telling us things that we cannot find by ourselves. A scientist is informing us."

Participant Number 11, male, 68 years old.

"I benefited from the knowledge gained. When I received information from someone else who possessed more from me. I felt more confident".

Participant Number 11, male, 68 years old

Enablement of self-management

Participants expressed that they valued that the advice provided enabled self-management of diabetes.

- *Participant: Look when I ask you, for example, does the watermelon have sugar? Much sugar or a few? And you are telling me that all fruit have natural sugar. Therefore, I know. I read it. All juices contain sugars; you can look at the box and check what it contains and their ingredients. Isn't it?*

Participant Number 02, male, 79 years old.

Another participant stated that he could not define what actually helped him, but at the end of the intervention, he improved his self-management of diabetes.

"I am careful about what I am eating, do not misjudge me. I follow your instructions many times, but sometimes I neglect and eat the ones I want. I believe my sugar is getting lower, and I started reducing the insulin. However, I do not know who helped me. Maybe because I stopped drinking might help. I believe the intervention helps, but I do not know how it helped me or did anything. But I can see the difference that I achieved."

Participant Number 15, male, 75 years old.

7.4. Participants' perception of intervention procedures.

Participants were asked to further elaborate on anything they did not like in the intervention, the required level of commitment to participate in the study, whether they would propose this intervention to a friend or relative with type 2 diabetes (T2DM), whether they would believe this intervention should be included in the healthcare system, other ways to improve self-management of diabetes and suggestions for changes to improve the intervention.

Burden due to study participation

Participants were asked about the level of commitment required to participate in the intervention. Open questions were asked about any problems caused due to their participation in general and in different aspects of the intervention. For example, the time and duration required to attend the appointments, receive/collect the educational leaflets, respond to questions and questionnaires, reply to pharmacist's messages and calls, etc. All participants stated that it was easy to participate in the study. None of the interviewed participants stated facing any problems during their participation. All participants expressed that they did not have anything they did not like.

"Why not like the intervention? If there were anything I did not like, I would have told you to drop out".

Participant Number 11, male, 68 years old.

"No, there is not something bad or something I did not like."

Participant number 05, male, 68 years old.

The level of commitment required in different aspects of the intervention

Prompted questions about specific aspects of the intervention were used to elicit more information. All participants (22), apart from one, stated that the time and duration of the intervention were satisfactory. Only one participant did not report any views and stated that he did not mind.

"Not at all. It does not bother me. It was easy to communicate, the phone calls were fine, and I had no problems with the questions."
Participant Number 14, female, 66 years old.

Proposing this intervention to a friend or relative with type 2 diabetes

Nineteen out of twenty-two (18/22) participants would recommend this intervention to a friend or relative. However, one of them (1/19) said he would recommend this service in specific circumstances. Two participants expressed that they do not have someone close to discussing diabetes (2/22). Finally, only one participant (1/22) stated that each person should do as he wishes and would not recommend it to anyone.

One participant who responded in the affirmative also expressed that this should be expanded to other diseases.
"While talking to you, my neighbour just came, asking me if you offer this service only to diabetes patients. She told me this intervention should be offered to other diseases and illnesses, and I agree."
Participant Number 12, male, 66 years old.

One stated that he would recommend this service to a friend in case they are hesitant to participate in the study. The reason for this, as described by the participant, was that he believed that this intervention would be most helpful to patients who are reluctant to seek help.
"If I understand that the other person hesitates, is restrained from expressing his fears, etc. I might tell him that there are advisors who can help him. If he replied, where do you know that? If you are not happy with the advice of your GP, now that I know that your service exists, I might tell him that this expert lady offers this service in these topics, and she might help you tackle your problem better."
Participant Number 02, male, 79 years old.

Two participants expressed that they are unwilling to share it further with other friends who do not have a close relationship. Nevertheless, one of them expressed that he already spoke about this intervention to a close friend.

"I told my best friend only. I do not want to discuss this service with people not close to me, but in general, yes, of course, I will recommend this."

Participant Number 21, male, 45 years old.

Only one participant responded negatively when asked whether he would recommend this service to a friend or relative.

"Everyone can do as he/she wishes. Look, we have a diabetes nurse at the health centre of my village who is also an expert, like you, and particularly every 5-6 months when I visit my GP, and she checks my feet and toes. These things that you are also telling me. But I do not believe that this is also necessary."

Participant Number 16, male, 77 years old.

Intervention fit into the current healthcare system

Nineteen participants out of twenty-two (19/22) responded in the affirmative when asked whether this intervention would be expected in the healthcare system. Most of the 19 responses supporting that this intervention should be included in the healthcare system were brief, stating that it would be good to have this intervention. One participant expressed that he was happily surprised that this kind of service, which is interested in patients, exists.

"I did not expect to find this kind of service which is interested in patients who have diabetes or any other disease, and which it tries to make patients better, better than they were before."

Participant Number 20, male, 63 years old.

One participant stated that this intervention should be expanded to other diseases.

"It would be good to have this intervention for other diseases and health issues".

Participant Number 17, family care giver, 77 years old.

Despite these affirmative comments, three participants had different views. One participant specifically stated that he is too old and does not care. The other one replied that he does not have a problem receiving this information, whether from the pharmacist

or the GP, or the diabetes nurse, and the third one stated that this intervention might not be suitable for a particular population.

"To people who are shy or are afraid to discuss that they have diabetes, this [intervention][3] *will not help them. Alternatively, people who do not want to hear about themselves from others or who are afraid to express that they have diabetes. I am saying this because I have diabetes which is not bad. I am neither the first to have it nor the last one. I am not going to die due to diabetes. I will die from diabetes if I am not doing things properly."*

Participant Number 08, male, 67 years old.

Suggestions to improve the intervention

Participants, when explicitly asked if there were any ways to improve the intervention or other ways to improve diabetes management, did not express any suggestions. However, as part of the other questions, a few suggestions were provided (see Table 7.2). Most of their comments regarding the intervention procedure were about the time of the phone calls. Mixed responses were received about which media they preferred most to facilitate the intervention, by phone, in person, or through texts. Mixed responses were also expressed regarding the frequency of the follow-up appointments. Two participants expressed their opinions regarding the educational leaflets.

[3] [normal type] = words not spoken

Table 7.2 The suggestions regarding changes in the intervention procedure and technology use.

Category of suggestions	Participants' suggestion	Quotes	Participants
Scheduling - Timing of the phone appointments	• To schedule follow-up appointments more systematically to enable participation and avoid rescheduling.	*"Look, it was not difficult, but it just happened that the times you called me, I had work to do. After that, I forgot that you called me. Do you understand what I mean? It is not that I did not want to call you back. I just forgot about it. I did not do it on purpose."*	Number 20, male, 63 years old.
		- *Participant: If you remember, I told you to call me later one day because I was at work. I could not talk to you and told you to call me another time.* - *Pharmacist: Apart from that. What are your views about phone calls and appointments?* - *Participant: It was fine, it was fine.*	Number 22, male, 63 years old.
		"Look, the difficulty was because of this period, I had much work to do, and for that, you caught me many times, and I could not reply. I had my phone on silent."	Number 13, male, 66 years old.
		"The only problem for me was the time, but usually the time that you were calling me is generally the time that I am sleeping, but ok, the times that you called me later on, I was awake."	Number 04, female, 65 years old.
Media of delivering the intervention	Mixed responses were received between face-to-face appointments, the use of phone calls, text messages and emails.	*"I prefer the telephone, not texts."*	Number 13, male, 66 years old.
		- *Pharmacist: Could you tell me about the emails we exchanged?* - *Participant: Emails and phone communication are very important.* - *Pharmacist: Do you believe it was something helpful?* - *Participant: Yes, it was very helpful.*	Number 01, male, 81 years old.
		"I believe it would not make any change whether the appointment was in person or not. In contrast, I believe it would be more difficult. To be honest, a person feels more comfortable calling you or replying to a text, for example."	Number 17, family care giver, 77 years old.
		- *Pharmacist: Would you prefer face-to-face appointments or phone calls?* - *Participant: Ok, every once and a while and sometimes in person, I believe it would be helpful.*	Number 09, female, 67 years old.

		- *Pharmacist: So how frequent do you believe?* - *Participant: Every once and a while.*	
Frequency of the follow-up appointments	Mixed responses were received; some participants stated that the follow-up appointments were enough, and some requested more frequent follow-up appointments.	- *Participant: There is no need for more phone appointments.* - *Pharmacist: Do you believe once a month is ideal?* - *Participant: As you wish, and you think is the best.*	Number 16, male, 77 years old.
		- *Participant: Ok, you can add one more follow-up phone call.*	Number 13, male, 66 years old.
Educational leaflets	• Be more personalized. • Already aware of them.	*"Look, the educational leaflets are good, but the leaflets are general and not personalized to each patient."*	Number 01, male, 81 years old.
		"OK, everything was useful, in my opinion. OK, most of the things I already knew, but OK, I read the educational leaflets, the things that I did not know, I learned them, it was good."	Number 04, female, 65 years old.
Valued general physicians (GPs) versus pharmacist	• Pharmacists as part of the healthcare professional team	*"Look, basically, it helped me, but I also had my GP, so I listened to him more."*	Number 04, female, 65 years old.
Lack of participants' motivation	Participants understand/ want to improve, but do not always do as they should regarding managing diabetes.	*"I understand what I have to do, but I do not do everything as I should."*	Number 06, female, 75 years old.
		"You saw that when we were talking, I was careful. I might do something I should not do. I do not do it on purpose."	Number 10, female, 75 years old.
Other suggestions of the procedure for the intervention	• Might be more helpful for younger diabetes patients.	*"The best is the communication (sic) at a younger age. I am old, and to tell you the truth, the telephone calls for me are boring because I am negligent, one a month, I do not care, only to be a time that I am available."*	Number 08, male, 67 years old.
	• Focus group.	- *Participant: It would be good if this service would create a focus group of people who will cooperate and discuss their personal concerns.* - *Pharmacist: Do you mean the patients or the healthcare professionals?* - *Participant: I mean you with the patients, to have more face-to-face follow-ups.*	Number 01, male, 81 years old.

Other ways to improve self-management of diabetes

Participants stated that the intervention was good, and no further changes were needed. No other ways were suggested that can improve the self-management of diabetes. Some of the participants were satisfied, while others did not have anything to add.

One participant expressed that the intervention covers a wide range of things about diabetes management.

"I believe that you holistically cover it. How can I say it? The requirements, I believe you cover them".

Participant Number 17, family care giver, 77 years old.

Two participants expressed appreciation towards the pharmacist and stated that the intervention was more than enough and exceeded their expectations.

"No, I hope God will give you strength to be by our side, to every patient. Nothing else. I cannot say anything else because the things you provided me are beyond my expectation. I am very pleased that you got into my life, and you enlightened me and everything."

Participant number 03, female, 72 years old.

7.5. Discussion

The interviews highlighted participants' perspectives regarding their experience in participating in a novel digital health intervention (DHI) delivered by a pharmacist. The results illustrate that participants received the intervention positively. They particularly valued the elements of the MI principles which shaped the intervention. Those were to increase motivation and confidence, create informed participants, and enable self-management. In addition, participants' responses indicated that they recognized the relationship developed with the pharmacist and valued the communication and information provided by the pharmacist. Affirmative responses were received when asked whether they would propose this intervention to a friend and whether they would like this intervention to be included in the healthcare system. None of the participants complained about the intervention or faced any major barriers to participation. Their comments regarding the level of commitment due to their participation were minimum. Participants expressed that all instruments and appointments were easy and satisfactory. Mixed responses were expressed, and some suggestions were made. Those were regarding the intervention procedure concerning the media of delivery and the frequency of the follow-up appointments. Moreover, participants raised the importance of scheduling follow-up

appointments to enable participation and avoid rescheduling. This again strengthens the value of the tailored intervention, appreciating participants' needs and lifestyles and evoking them to be part of managing their disease. All these elements fall under the umbrella of the principles of MI.

A similar pattern of participants' responses was observed in previous studies identified through the literature evaluating behaviour change. In Nundy et al., 2014a study, participants reported feeling more motivated, optimistic, confident, and accountable for managing diabetes (Nundy et al., 2014a). Corresponding results were identified in another previous study, with most of the participants (79%) expressing that the intervention was beneficial for their disease state, and a substantial number of participants believed that the use of the intervention increased the amount they exercised (McWhorter et al., 2014). Similarly, participants expressed that the intervention helped them with self-care in another two studies identified in the scoping review (Sun et al., 2019; Fortmann et al., 2017). Increased knowledge was one of the most common findings of our study and the international literature. Specifically, in two studies identified in the scoping review, participants expressed that they felt that the intervention helped them recall information and/or provided them with new information (e.g., the importance of foot care) (Nundy et al., 2014a; Nundy et al., 2014b). Participants in this study valued communication with the pharmacist, which was also identified in two other studies in the scoping review (Ladner et al., 2022; Nundy et al., 2014b). Klug et al., 2011 study participants reported they were satisfied with the education provided, which was also expressed by this study participants (Klug et al., 2011).

Another finding in our study was that participants valued the pharmacist's contribution. Participants also expressed their appreciation of other HCPs (diabetes nurse and GP), they valued the access to an HCP and recognised the pharmacist's expertise. They particularly mentioned that they valued the pharmacist's approach and interest towards them as participants. Another study identified similar responses, participants reported that knowing a health professional reviewed their messages was important for their engagement (88%) (Nundy et al., 2014b).

The sample of patients in this study reported that they were satisfied with the intervention procedure (questionnaires, communication, interviews). Furthermore, mixed responses were obtained when asked about the intervention's delivery media and follow-up

frequency. Participants' preferences varied between the media of delivery employed in the intervention. The problem reported regarding the phone appointments in our study was scheduling the appointments more conveniently. Similar studies identified through the scoping review have not evaluated the participants' perception regarding the media of delivery (comparing text, email, phone call, and post) and frequency of the follow-up. However, previous literature assessed the level of commitment to participate in their study and the difficulty with using the technology to facilitate the service provided. Participants reported "very easy" or "quite easy" regarding the use of a mobile telephone application aimed at patients with diabetes (Orsama et al., 2013).

A limitation of this study included the fact that interviews were conducted through phone calls which has drawbacks to a face-to-face interview (Bowling, 2014; Smith, 2010). Also, the interview was conducted by the pharmacist offering the intervention, which increased bias compared to conducting the interviews by an independent person. (Bowling, 2014; Smith, 2010). Often, participants' expectations are low in new services and have minimum criticism, thus, more favourable responses might be obtained (Smith, 2010). Additionally, this is a self-selecting sample that may be more motivated to be included in the research and potentially more willing to improve their diabetes and thus provide more positive outcomes. However, due to the small number of participants in our study, a more extensive study focusing on the uptake of Cypriote patients with diabetes regarding DHIs delivered by pharmacists aiming at improving self-management of diabetes would be of benefit.

The findings of a feasibility study are limited and should be approached with caution due to the small sample size. However, the findings have shed light on the factors that participants valued in a DHI delivered by a pharmacist aiming to improve self-management of diabetes. This study showed that a small group of patients in Cyprus well received a new DHI delivered by a pharmacist. This finding can be correlated with other studies in the international literature evaluating DHIs aiming to improve self-management of diabetes (Ladner et al., 2022; Sun et al., 2019; Fortmann et al., 2017; Nundy et al., 2014a; Nundy et al., 2014b; McWhorter et al., 2014; Orsama et al., 2013; Tang et al., 2013; Klug et al., 2011; Funnell and Anderson, 2004). The study raises awareness that larger studies could be beneficial in understanding diabetes patients' behaviour around effective DHIs delivered by a pharmacist aiming to improve diabetes self-management.

End of Chapter Seven

Chapter Eight

Feasibility of the intervention from the healthcare professional's perspective

8.1 Introduction

This chapter presents the results of the intervention's feasibility from the perspective of the healthcare professionals (HCPs). This chapter is divided into the HCPs' actions on recruitment and the pharmacist's recommendations, and HCPs' perception of the intervention. Chapter 5 described the methodology of evaluating the HCPs' acceptability in detail. During recruitment all communications with the HCPs were conducted face-to-face, while during the intervention delivery, the pharmacist visited the DC to obtain participants' data and contacted the general physicians (GPs) via different media based on their preferred medium. Emails were chosen by two GPs, and messages and phone calls, chosen by the other GP. The diabetes nurse was contacted several times by the pharmacist through Viber messages, text messages, and phone calls. The pharmacist interviewed all HCPs at the end of the intervention in February 2021. Final interviews were audio-recorded with the consent of all HCPs. The mean duration of the interviews was 5.3 (0.6 standard deviation (SD)) minutes, minimum duration 4.5 minutes, and maximum duration 6.0 minutes.

8.2 Healthcare professionals' views on the recruitment

The number of recruited patients and healthcare professionals' assistance varied based on the operation of the DC, as presented in Table 8.1. The total number of working days of the DC was 44 (21 part-time days and 23 full-time days). The pharmacist was present at the DC on 23 of the 44 working days. The days when the DC was partially operated led to fewer opportunities to identify patients for recruitment since fewer patients attended the clinic, and the DC only operated three days a week. Contrary to that, on days of full operation, the pharmacist did not have enough time to approach all patients, and the diabetes nurse was busier and did not have time to assist with the recruitment. Particularly, on the days when the DC was working with one GP, the diabetes nurse had the time to discuss with the pharmacist early in the morning which patients were eligible, and which were not. On days when the DC was in full operation, she pointed out eligible patients in between patients' appointments, where possible. The diabetes nurse identified eligible patients and referred 25 patients (out of 62) to the pharmacist. Consequently, on days of full operation, the pharmacist aimed to speak with all patients attending the clinic (to identify eligible patients), which was time-consuming and, on some days, not feasible. This increased the time the pharmacist needed for recruitment and led to missing some potentially eligible patients.

Although GPs did not refer patients, they supported the pharmacist in displaying the leaflets and welcoming the pharmacist as part of the DC. The pharmacist, at each visit, checked how many information leaflets were left and refilled them. Each day around 1-2 information leaflets were used at each office and 3-4 from the stand outside the diabetes nurse's office. However, it was not possible to identify who took the information leaflet, whether the patient or the GP. From the 200 information leaflets printed, only 30 information leaflets remained. No patients' expressions of interest reply slips were returned to the HCPs involved.

Table 8.1 Number of patients who attended the diabetes clinic, referred by the healthcare professionals at the diabetes clinic, were eligible, approached by the pharmacist, and recruited based on the operation of the diabetes clinic.

Number of patients		Days with covid restriction (per day)	Days of full operation (per day)	Total of days of the recruitment period
Number of patients booked an appointment		≤10	≤30	201
Number of patients attended the diabetes clinic		4 - 9	12 - 17	165
Number of eligible patients		3 - 8	7 - 12	107
Number of patients referred by the diabetes nurse		3 - 5	0 - 2	25
Number of patients referred by the general physicians (GPs)		0	0	0
Number of patients approached by the pharmacist	Before patients' appointment with the diabetes nurse	3 - 7	6 - 7	49
	Before patients' appointment with the general physicians (GPs)	0	1 - 3	13
	Total	3 - 7	7 - 9	62
Number of patients recruited		0 - 2	1 - 3	32

Moreover, it was agreed between the pharmacist and the HCP staff not to interfere with their work and thus the pharmacist needed to identify the gaps between patients' appointments and not cause any appointment delays (patients' pathway at the DC is presented in Figure 8.1). In some cases, HCPs waited for the patient to complete the initial appointment with the pharmacist before attending their appointment. However, three times there was not enough time between patients' appointments with the diabetes nurse and GP, and the patient left the appointment without finishing it. Also, the pharmacist

was in the DC recruiting patients, using patients' medical files, and asking HCPs questions about the patients.

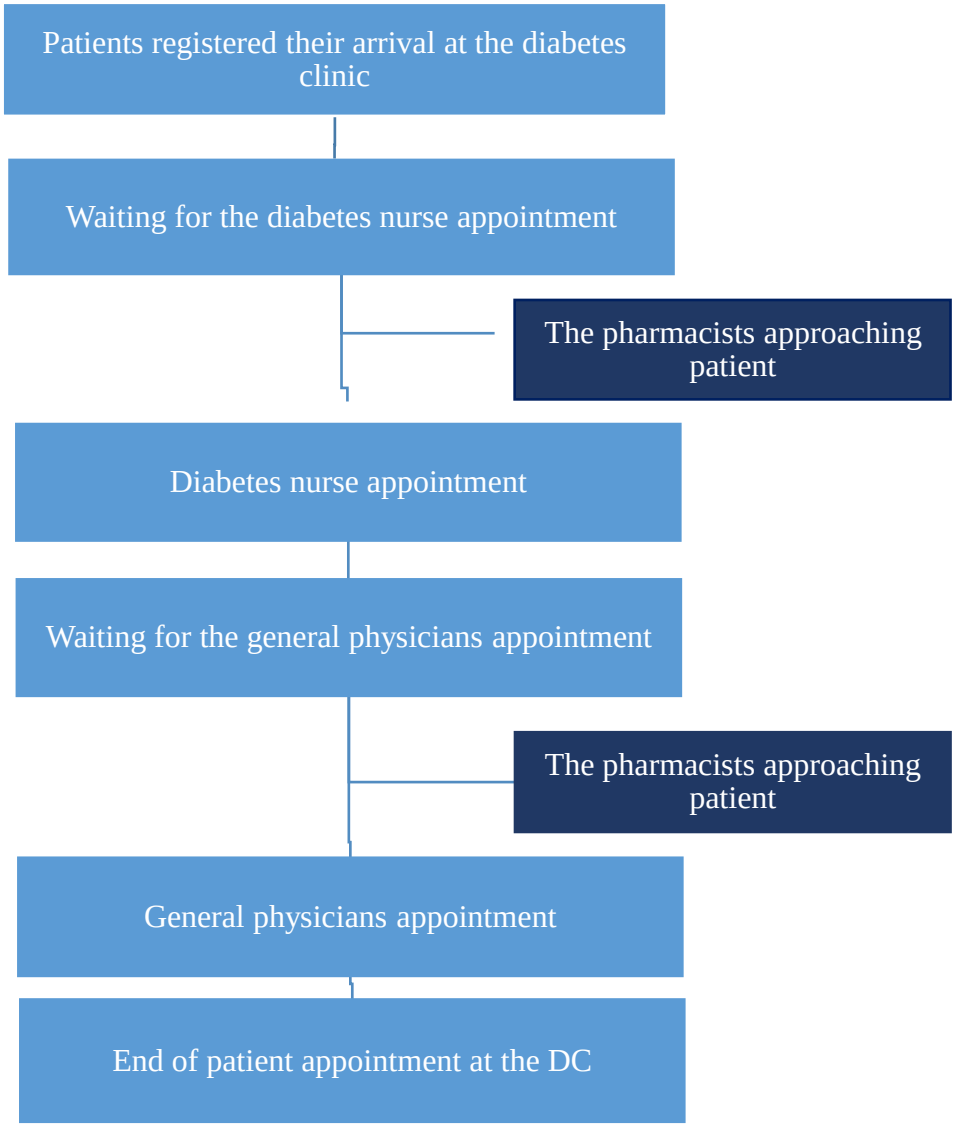


Figure 8.1 Patients' pathway at the diabetes clinic and time available for the pharmacist to approach patients.

Difficulties regarding the eligibility criteria were expressed at the end of the intervention, by the HCP through the interviews. One HCP stated that the eligibility criteria of the patients made the recruitment of participants more difficult.

"Not all patients of the DC could participate made recruitment more difficult. For example, patients had to fulfil specific criteria and screening procedures were needed to check their eligibility. It would be better if all patients of the DC would participate".

Healthcare professional 3.

8.3 Healthcare professionals' actions on the pharmacist's recommendations on pharmacotherapy

Before implementing the intervention, the pharmacist agreed with the HCPs working at the DC to discuss participants' diabetes management and make recommendations for participants' pharmacotherapy. Throughout the intervention, 25 issues concerning 19 participants (19/22) were identified by the pharmacist and discussed with the HCPs at the DC. Of those 25 issues, 5 (5/25) concerned participants' pharmacotherapy, 6 issues (6/25) were triggered due to participants' symptoms (hypoglycaemia or diarrhoea), and 14 (14/25) were due to foot care participants' queries. Of the 25 issues, 8 needed further actions and discussions with the GPs and the remaining 17 concerns were resolved by the pharmacist providing instructions to the participant (see Figure 8.2). The pharmacist contacted the HCPs through emails in 4 cases (4/25) and through text messages, 1 (1/25) and 14 (14/25) through Viber messages, and 4 (4/25) were resolved face to face. In addition, the participants were advised by the pharmacist to contact their HCPs in two cases (2/25). Table 8.2 illustrates how each issue emerged, the nature of the issue, details of the problem, contacts made, and the outcome.

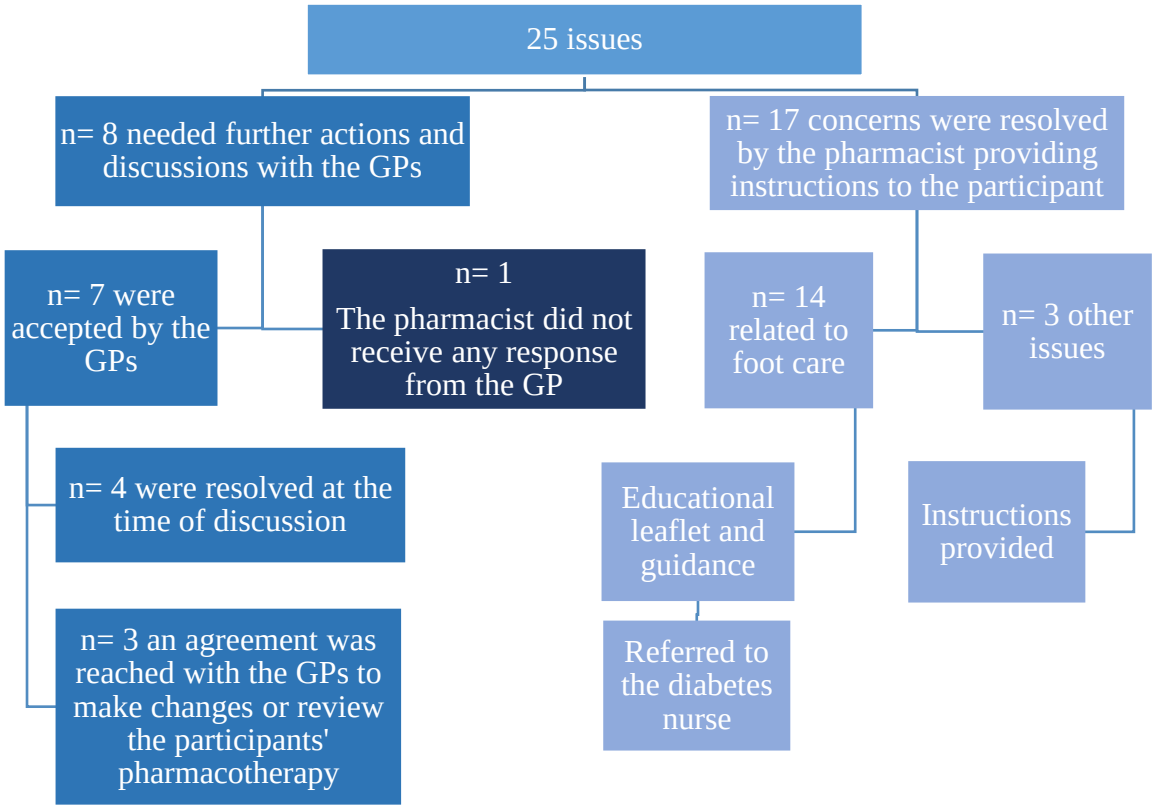


Figure 8.2 Flowchart of the pharmacist's actions to resolve the 25 issues identified.

Table 8.2 Description of the issues identified by the pharmacist regarding participants' diabetes pharmacotherapy through the intervention.

	Number of issue	How issue emerged	Nature of issue	Details of problem	Contacts made	Outcome
Pharmacotherapy	By pharmacist					
	1. (Patient number 1)	Review of patients' medications	Current therapy - Contraindication	Prescription of sulfonylureas and kidney disease.	Email to the GP.	• GP agreed to change the participant's regimen, after contacting the participant's nephrologist.
	2. (Patient number 2)	Reviewing blood test results	Current therapy - Laboratory results	Elevated potassium.	Discussion with GP.	• The GP agreed that the potassium was slightly elevated. • No other indication was presented. • It was decided that the participant's blood test results would be reviewed in the future.
	By participant					
	3. (Patient number 3)	The family caregiver requested a review of patients' medications	Current therapy -Optimisation of therapy	Suggestion to replace medication regimen for cardiovascular disease with the first-line treatment.	Email to the GP.	• GP agreed to review the participant's pharmacotherapy. • GP contacted the participant's cardiologist for medication changes.
	4. (Patient number 17)	By participant	Current therapy - Duplication of therapy	Taking two different brands of metformin.	Discussion with GP.	• Instructions were provided to the participant by the GP and pharmacist. • The GP removed one of the duplicate medications.
	Discussions with the pharmacist					

Table 8.2 Description of the issues identified by the pharmacist regarding participants' diabetes pharmacotherapy through the intervention.

	Number of issue	How issue emerged	Nature of issue	Details of problem	Contacts made	Outcome
	5. (Patient number 11)	Pharmacist online advice to patient queries	Current therapy - Contraindication	Using a corticosteroid cream for her wound.	Discussion with GP.	• Instructions were provided to the participant by the pharmacist. • The patient stopped using the corticosteroid cream.
Participants' symptoms	Hypoglycaemia – Discussions with the pharmacist					
	6. (Patient number 2)	Pharmacist online advice to patient queries	Current therapy - Resulting in hypoglycaemia	He stopped his/her fast-acting regimen due to hypoglycaemia.	Oral instructions through the phone. *There were no further actions as he had an appointment the next day at the diabetes clinic.*	• Participant attending the diabetes clinic. • The GP decreased the insulin dose.
	7. (Patient number 5)	Pharmacist online advice to patient queries	Resulting in hypoglycaemia – past incidents	Had a few incidents of hypoglycaemia before starting the intervention.	Oral instructions through phone about hypoglycaemia; symptoms and treatment.	• Participant did not express having hypoglycaemia again. • Did not request further instructions.
	Queries hypoglycaemia and self-monitoring of blood glucose interpretation- Discussions with the pharmacist					
	8. (Patient number 6)	Pharmacist online advice to patient queries	Current therapy – Interpretation of hypoglycaemia	Queries about interpreting blood glucose results and adjusting his/her insulin regimen.	Educational leaflet and referred to diabetes nurse. The diabetes nurse was informed by phone.	• In the next appointment, the participant's blood glucose was within normal ranges. • Participant did not request further instructions.
	Diarrhoea - Discussions with the pharmacist					
	9. (Patient number 3)	Pharmacist online advice to	Diarrhea	Participant expressed having symptoms of	Pharmacist texted the GP.	• Diarrhoea stopped without any changes to pharmacotherapy.

Table 8.2 Description of the issues identified by the pharmacist regarding participants' diabetes pharmacotherapy through the intervention.

	Number of issue	How issue emerged	Nature of issue	Details of problem	Contacts made	Outcome
		patient queries		diarrhoea the past few days.	Instructions were provided to the participant by the pharmacist by phone.	
	10. (Patient number 4)	Pharmacist online advice to patient queries	Diarrhea	The family caregiver expressed that the participant has had symptoms of diarrhoea the past few days.	Email to the GP.	• The GP replied to the email. • Agreed that the participant needed to book an appointment as soon as possible for review.
	By participant					
	11. (Patient number 7)	Pharmacist online advice to patient queries	Current therapy - Resulting in hypoglycaemia	Had a few incidents of hypoglycaemia.	Email to the GP.	• No reply from the GP.
Foot care[1]	Discussions with the pharmacist					
	12-25. (Patients number 1,4,8-19)	Pharmacist online advice to patient queries	Foot problems	Expressed foot aches.	Referred to the diabetes nurse working at the diabetes clinic. The diabetes nurse was informed through Viber text.	• Educational leaflets about diabetes foot care. • Send a list of all participants having foot ache to the nurse and Informing participants to book an appointment with the diabetes nurse for a foot check.

[1]Due to the high demand of those participants for foot examination, by the end of the intervention the diabetes nurse asked the pharmacist to send a list of all participants who expressed foot aches throughout the intervention. GP is general physician.

8.4 Results of healthcare professionals' perception regarding the intervention

During the interviews at the end of the intervention, when asked if there was anything, in particular, they liked/ did not like about the intervention, all four HCPs stated that they liked the intervention. None of the interviewed HCPs declared any dislikes about the intervention.

Healthcare professionals' perception regarding the pharmacists' role

After implementing the intervention, all four health professionals believed this intervention contributed positively to managing T2DM, and the pharmacist's contribution was reported as very important. HCPs described their thoughts about the advantages of the pharmacist's contribution to the benefit of the diabetes patient in clinical aspects and specifically medication adherence, stating that pharmacists could serve as diabetes educators, and follow-up patients (see Table 8.3). One HCP highlighted the rapport relationship patients usually develop with their pharmacists.

Table 8.3 Healthcare professionals' perception regarding the pharmacists' role.

Perception	Quotes	Healthcare professional
Benefit of the diabetes patient in clinical aspects	*"Yes, it would be very helpful for everyone in all areas of diabetes management."*	Number 1
	"Again, this intervention contributes to better-managing diabetes, weight management, medication, and preventing short-term and long-term complications. I think this intervention can contribute positively."	Number 3
Improving medication adherence	*"It was good that there was this follow-up with the patients, which was performed from the perspective of a pharmacist, and this helped in the matter of possible adherence to medication, better medication adherence."*	Number 1
	"It was good that there was this follow-up with the patients from the perspective of a pharmacist. This might help in increase of compliance."	Number 4
Pharmacists serve as diabetes educators	*"I think pharmacist has an important role, community pharmacist as diabetes education."*	Number 4
	"Good to have this intervention and someone to educate and review patients."	Number 3
	"I believe community pharmacists have an important role in educating diabetes patients and improving adherence."	Number 4
Follow-up by the pharmacist	*"It was good because of the follow-up by the pharmacist because you could check some things in depth and you contributed positively to the better assessment of the patient."*	Number 4

Table 8.3 Healthcare professionals' perception regarding the pharmacists' role.

Perception	Quotes	Healthcare professional
	"Good to have this intervention - medication should also be reviewed by a pharmacist and discussed with the doctor. To confirm some things [about the patients][4] it was helpful."	Number 2
Rapport relationship between patients and their pharmacists	*"I think pharmacists play a significant role because, for better or worse, generally, patients have/want to build a very good relationship with their pharmacist. The pharmacist will ask first if they do not understand what we told them - the doctor told them, the person with whom will have closer contact, the next person there will get the instructions more clearly."*	Number 1

Healthcare professionals' acceptability regarding digital health interventions (DHIs)

All four HCPs responded that technology/applications are helpful and could make significant changes in healthcare, but also stated the same concerns as before the intervention.

"Useful, but our society is not very familiar with technology, and we will find it difficult to adopt it."

Healthcare professional 4.

"They are very useful, in my opinion, they will make their lives easier, and they can communicate with health professionals - more directly and quickly. However, this is quite difficult for people not related to technology, either due to financial difficulties or age. They do not have a good relationship (with technology). However, on the other hand, all can be established as long as patients are trained."

Healthcare professional 3.

Participation and burden of the intervention of health professionals

The burden of the intervention was identified as minimal. All four HCPs stated they did not face any problems or interference with their work.

"I think it was ok. I did not understand that it was something time-consuming or lasted for a long time - I think it [the duration of the intervention] was adequate".

Healthcare professional 1.

[4] words not spoken

HCPs' responses differed regarding the length of the intervention duration in respect of the management of diabetes. Two of them stated that the intervention should be long-term.

"enough time - but because diabetes is also a life-threatening disease and people need to manage their condition forever and this intervention positively helped them to self-care should be offered in the long term."

Healthcare professional 3

"It [the intervention][5] should exist in the long run."

Healthcare professional 4

Appropriateness of the intervention in the diabetes clinic services and healthcare services

HCPs expressed positive thoughts about how this intervention fits in with what they expect in healthcare services for patients with T2DM (see Table 8.4). One HCP pointed out that this intervention could assist patients with T2DM in different areas, and the other two highlighted again how this intervention could increase medication adherence and follow-up. Only one of the interviewed HCPs suggested alternative solutions that could provide the same/better results than the intervention for patients with T2DM. He expressed his views about the hospital pharmacist's importance in all healthcare areas.

Table 8.4 Healthcare professionals' perception of the appropriateness of the intervention in the diabetes clinic services and healthcare services.

Perception	Quotes	Healthcare professional
Assist patients with T2DM in different areas	*"Yes, I think that this service covers a wide range of diabetes management aspects, including education, weight management, adherence to medication, and prevention of short-term and long-term complications."*	Number 1
Increase medication adherence and follow-up	*"An intervention that has to offer in medication adherence and follow-up."*	Number 4
	"It was an auxiliary tool which enabled me to evaluate patients better and not leave anything behind due to my lack of time or haste because of the increased number of patients. I felt more confident - it was an additional tool to evaluate patients better."	Number 3

[5] words not spoken

Table 8.4 Healthcare professionals' perception of the appropriateness of the intervention in the diabetes clinic services and healthcare services.

Perception	Quotes	Healthcare professional
Alternative solutions that could provide the same/better results than the intervention for patients with T2DM	*"very important for outpatients as well, but more important to me for inpatients - generally talking about having a clinical pharmacist and attending patient visits and talking to doctors."*	Number 2

Perception on collaboration between the pharmacists and other healthcare professionals

All four HCPs agreed that patients' data must be shared (laboratory examination, GP notes, etc.) with the pharmacist (see Table 8.5). They also highlighted the importance of good collaboration between HCPs.

Table 8.5 Healthcare professionals' perception on collaboration between the pharmacists and other healthcare professionals

Perception	Quotes	Healthcare professional
Patients' data must be shared with the pharmacist	*"Yes, I consider this very important."*	Number 1
	"Definitely pharmacist should have access."	Number 2
	"Yes, of course.	Number 3
	"Yes, I consider this very important."	Number 4
The importance of good collaboration between healthcare professionals	*"It is very important to have a good collaboration between the doctor and the pharmacist because they can help each other."*	Number 1
	I believe it is better to have two-way communication better for the patient – counselling (between the pharmacists and other HCPs)."	Number 4
Value of the pharmacist's recommendations	*"Yes, it was helpful to double check patients' pharmacotherapy and have this conversation [between the pharmacist and patients' physician][6]."*	Number 2
	"Yes, it helped to thoroughly evaluate patients."	Number 3

8.5 Perceptions of the value of research and views of participation in the study

Two of them expressed that this intervention could lead to valuable data that can provoke future improvements.

"It was very good for research purposes; it is something good that I believe helps the clinic. We can review your results, and I think it is very good to have these views from patients and young scientists."

[6] words not spoken

Healthcare professional 1.

"Yes, of course, it is important because this service will give us some results which will inform us about possible improvements of the participants' status and also some negative results concerning the service provided at the DC, which we can improve in the future." Healthcare professional 3.

8.6 Results on the pharmacist's experience with delivering the intervention

This section provides the pharmacist's experience in delivering the intervention. The methods employed were described in chapter 5.

Challenges during intervention delivery

The pharmacist faced some challenges when trying to identify participants' data and access patient records for pharmacotherapy as not all information was reported in patients' hardcopy file and assistance was needed from GPs to access patients records.

Facilitators during the intervention delivery

The pharmacist felt that when she correctly followed the MI principles, the participants were willing to hear her advice and open to discussing possible solutions. Particularly, through the audio recordings of the appointments, the pharmacist realized how important was the use of the MI techniques in eliciting participants' barriers and concerns, allowing space for each participant to express their views about their diabetes self-management, and understand that each participant needed different time to reach for help and feel ready to make lifestyle changes. When the pharmacist followed the MI principles, she noted that patients were reflective and forthcoming. She felt that the participants needed support from the pharmacist to recognize their effort and applaud them for even small changes achieved. To a higher degree, the pharmacist felt that MI assisted her work with more resistant participants. Although, at the beginning of the intervention, those participants resisted providing information or setting goals, they appeared to be more willing to contact the pharmacist as the intervention proceeded. Three participants who initially did not respond to the pharmacist's phone call meetings were among those who initiated the phone calls to the pharmacist explaining how they wanted to improve their management of diabetes.

An example of how the pharmacist employed principles of MI and how a participant changed her behaviour during this intervention is described below. The participant did not feel it was necessary to add a second type of insulin to her pharmacotherapy. She told the pharmacist, "I am thinking of throwing them out of the window. The only thing stopping me is that they are expensive". The pharmacist kept the conversation based on the MI principles. The pharmacist did not lecture the participant on why she must take insulin and left enough space for the participant to think and reflect on her statements. At the end of that initial appointment, the participant agreed to receive educational leaflets about healthy eating (as she chooses healthy eating as her goal). She said she would think about what she will do with the injections. The pharmacist called her at the following phone appointment to check her progress. The participant said she could not complete the phone appointment and was not home. This was repeated two times. During those short phone calls, the pharmacist kept the conversation based on the MI principles and accepted the participant's preference to reschedule the phone appointment for later. Before the next phone call appointment, the participant called the pharmacist for support and stated that she was taking all her injections, started a diet, and booked another appointment at the DC. After this point, the phone calls and appointments continued as scheduled, and the participant attended all phone appointments with the pharmacist.

Although the pharmacist felt that MI played a significant role in assisting her job, it required dedicated time for preparation before each appointment. The pharmacist needed time to prepare to approach the participants and remember to use MI principles throughout intervention delivery. For this reason, the pharmacist made notes of the type of questions and examples of MI techniques, which she kept in front of her at each appointment. In addition, the intervention was personalized to the participant's needs and preferences. Hence, organization and structured and clear data collection were needed to assist the pharmacist. This increased the burden of the pharmacist but concurrently assisted her in remembering each participant's needs and avoiding repetition. The pharmacist faced minimal difficulties in contacting participants based on their preferred medium. The only service which increased the pharmacist's commitment and money was sending the educational leaflets through the post, as she was responsible for identifying the educational leaflets, preparing them, writing the correct address to the correct participant, visiting the post office, and paying the relevant fees. Nonetheless, the pharmacist felt that the principles of MI assisted her in identifying participants' needs and

providing valuable and meaningful solutions for each participant. Essential factors which, without the principles of MI, might be more time-consuming to identify.

8.7 Discussion

The data collected showed the perspectives of HCPs regarding a novel intervention delivered by a pharmacist. To our knowledge, this is the first study to assess the view of HCPs in Cyprus regarding interventions provided by pharmacists and employed technology. In general, HCPs supported the provision of the intervention and expressed positive thoughts about the pharmacist's involvement. However, recruitment procedures could not be completed by the HCPs. One HCP expressed that the eligibility criteria made the recruitment procedure more difficult. Only the diabetes nurse referred patients to the pharmacists. GPs did not refer patients to the pharmacist but supported the pharmacist in displaying information leaflets and recruiting patients between their appointments. Moreover, HCPs' statements indicated that they valued the pharmacists' intervention due to the benefit of the diabetes patient in clinical aspects by improving medication adherence and enabling follow-up of the patients were the most comments described. Also, HCPs did not express any problems caused by the intervention and stated that this intervention did not interfere with their work.

Another point assessed was HCPs' views regarding their collaboration with the pharmacist. All four health professionals highlighted the importance of good collaboration between HCPs and expressed that this intervention fits in with what they expect in healthcare services for patients with T2DM. This was also shown by the diabetes nurse requesting the pharmacist's list of participants with foot problems. This might indicate that the diabetes nurse was willing to collaborate with the pharmacist to benefit their patients and them. Also, most of the pharmacist's recommendations were accepted and GPs were willing to discuss the issues triggered by the pharmacist. However, one GP did not reply to the pharmacist.

HCPs argued that technologies are helpful in healthcare, but some participants might not be familiar with technology, find it difficult to adapt and training might be needed. Despite these controversial responses, HCPs used different media to communicate with the pharmacist (emails, text messages, Viber messages, phone calls, and face-to-face discussions) and technology might augment the communication between the HCPs at the DC and the pharmacist.

Although dedicated time and training were required (before the intervention delivery) for the pharmacist to learn MI techniques, from the pharmacist's perspective, the pharmacist felt that MI techniques were crucial in achieving the intervention's aims. From the scoping review, only Klug et al., 2011 study, evaluated HCPs' satisfaction and revealed that CP found the device easy to use, and some efficiency was gained.

The findings in this study are preliminary and should be approached with caution due to the small sample size and the short length of the interviews. Due to the increased workload pressures, mainly caused by the Covid-19 pandemic, HCPs had minimal time to be interviewed about the intervention. Questions regarding the pharmacist's recommendations were not thoroughly explored at the final interviews. Also, another study limitation was the fact that the pharmacist delivering the intervention was the same as the researcher. HCPs interviewed worked in the same DC in Cyprus and were not diverse in age and gender. Only one diabetes nurse and one pharmacist (the same as the researcher) participated in the study. Thus, the findings could not be generalized nor reflect all HCPs in Cyprus and a larger study evaluating the feasibility of the intervention from the healthcare professional's perspective would be beneficial.

To conclude, this study showed that HCPs welcomed a new intervention delivered by a pharmacist. Despite the small sample, the short length of the interviews and study's limitations, data set triangulation showed that HCPs were willing to collaborate with the pharmacist and integrate this intervention into existing healthcare pathways. However, of the HCPs working at the DC, only the diabetes nurse referred patients to the pharmacists. Thus, the recruitment procedure was not offered by the other HCPs involved, and in case of further extrapolation of the study, this should be considered. Regarding the pharmacist's perspective, she reported that she was satisfied with the MI techniques, and the only obstacle encountered was the training and preparation time required to implement MI techniques. The study showed that HCPs were willing to assist, support and collaborate with the pharmacist in implementing a DHI delivered by a pharmacist.

End of Chapter Eight

Chapter Nine

Workability of the intervention

9.1 Introduction

This chapter presents the workability of the intervention. It is divided into the following subcategories; pharmacist's workload, the delivery time of the intervention, workability of the intervention (barriers and facilitators) and cost estimation for the delivery of the intervention.

9.2 Pharmacist's workload and delivery time of the intervention

The method to measure the pharmacist's workload and delivery time of the intervention is described in chapter 5. The pharmacist's workload and time spent per task for delivering the intervention are illustrated in Table 9.1 (see Appendix 9.1 for a graphical representation of the time range per task). The tasks that required the most prolonged time were the preparation before the 1st and 2nd phone call (27 and 9 hours), the phone call appointments in total (14 hours), the motivational interview discussion at the initial appointment (11 hours), the review of participants' pharmacotherapy (10 hours), the recruitment (9 hours), identification of participants' information (9 hours) and conducting the adapted DSCAQ – Greek version questionnaire (8 hours). However, the time required to accomplish each task diminished as the pharmacist gained more experience.

Based on the time required for the pharmacist to familiarize herself with the intervention's procedures (4 hours) (it was the same person as the researcher who developed the intervention), it is assumed that a substantial time for training other pharmacists will be required in case of future extrapolation of the intervention. Based on the pharmacist's workload and time spent on each task and the fact that the pharmacist delivering the intervention was working part-time, it is assumed that one pharmacist can provide this intervention concurrently to up to 22 participants if this intervention is accommodated into a community/hospital pharmacist's daily schedule in the future. On an average day (and after the pharmacist is trained), it was estimated based on the pharmacist's workload, that 2 hours would be required for the provision of this intervention.

Table 9.1 Pharmacist's workload for the intervention delivery (in minutes).

Pharmacist's tasks			Min–max (mean) [SD]	Total	Comments
The preparation for the delivery of the intervention	Training for Motivational interview techniques		N/A[1]	240 (4 hours)	• Online training.
	Familiarized with the intervention's flowcharts and procedures		N/A[1]	240 (4 hours)	• The pharmacist read all intervention procedures and notes before commencing the intervention.
	Prepare notes based on principles of motivational interview		N/A[1]	240 (4 hours)	
Recruitment and consent	Recruitment procedure (talking to patients, providing information, and signing the consent form)		10 – 30 (18) [7], N=31	567 (9 hours)	• Pharmacist present at diabetes clinic for the whole day (7:30-15:30). • Approaching potential eligible patients.
Delivered of the initial appointment	Demonstrating the Viber application to participants.		3 and 5, N=2 (Requested by two participants)	8	• Most participants who chose the Viber application were aware of its uses.
	The adapted DSCAQ – Greek version[2] (mean) [SD]		5 – 56 (16) [11], N=31	496 (8 hours)	• The adapted DSCAQ – Greek version[2]: as recorded by Qualtrics XM®.
	Motivational interview[3] (mean) [SD]		7 – 18 (11) [3], N= 22	239 (11 hours)	• MI2: as recorded by the pharmacist.
Delivery of the subsequent appointments	Identify participants' information - Collect and analyse baseline data (HbA1c, blood glucose, etc.)		3 – 60 (25) [24], N= 22	560 (9 hours)	• Varied based on the information available for the pharmacist to review or the need to seek other sources. • Required to attend to the diabetes clinic to request information or contact the healthcare professionals' staff.
	Preparation before contacting the	First call	30 – 180 (74) [41], N=22	1620 (27 hours)	• Varied based on each participant case and took longer at the beginning of

Table 9.1 Pharmacist's workload for the intervention delivery (in minutes).

Pharmacist's tasks			Min–max (mean) [SD]	Total	Comments
	participants per each phone call (reviewing earlier recorded messages, motivational interview principles and notes)	Second call	12 - 33 (24) [5], N=22	520 (9 hours)	the intervention (e.g., needs to review and identify information).
		Third call	2-19 (7) [4], N=18	122 (2 hours)	
	Organization of the appointments (Scheduling and rescheduling calls, maintaining records)		2 per patient after each appointment	124 (2 hours)	• Whom to call and when; the appointments between the pharmacist and participant were scheduled based on each participant's preference.
	Review participants' pharmacotherapy (Drugs guidelines and protocols, identify SPC)	Diabetes	5 – 60, N=6	601 (10 hours)	• E.g., identify drug interaction, drug side effects, reasons for adding or removing drugs, etc. • Participants' pharmacotherapy was identified to 17 out of 22 participants.
		Diabetes and other conditions (such as kidney disease)	20-180, N=5		
		Medication and laboratory results	5-10, N=3		
	Review participants' diabetes management (e.g., foot care, healthy eating, exercise, etc.) (Diabetes management guidelines and protocols)		60 minutes at the beginning of the intervention per issue 5 minutes after the information were organized and ready to be used	360 (6 hours)	For example: • Identify information about healthy eating, foot care, and/or exercise, • Record participants' symptoms. • Refer to the relevant healthcare professionals (a list of participants having foot aches was sent to the diabetes nurse).

Table 9.1 Pharmacist's workload for the intervention delivery (in minutes).

Pharmacist's tasks			Min–max (mean) [SD]	Total	Comments
Contact the participants	Respond to participants' queries, prepare messages, and identify and send educational leaflets (per participant)	Medication	2 – 6 (4) [1], N= 20	72	• Identifying information to respond to the queries. • Prepared the information to be sent to the participant. For example, write the text message along with the educational leaflet sent.
		Foot care	2 – 20 (5) [5], N= 16	77	
		Blood glucose	2 – 15 (5) [4], N= 11	57	
		Healthy eating	3 – 25 (8) [8], N= 8	72	
		Exercise	3 – 20 (7) [7], N= 7	47	
		Vaccination	3 – 10 (6) [4], N= 3	18	
		Alcohol	3 – 30 (17), [19], N= 2	33	
	Sending educational leaflets through fax, post, Viber, or face to face (per participant)	Face to face	2 – 11 (5) [3], N= 12	47	• The pharmacist organized all the educational leaflets to be sent at the end of each day and posted them all together.
		Viber	2 – 8 (5) [2], N= 8	37	
		Post	15 – 30 (21) [7], N= 5	105	
		Email	8 – 14 (11) [4], N= 2	22	
		Fax	20, N= 1	20	
	Phone call appointments in total (including the time participants were unavailable)		7 – 286 (114) [122], N= 22	843 (14 hours)	• The pharmacist's mobile phone device tracked the duration of all phone calls.
	Final call		8- 46 (21) [9], N= 22	85	• The adapted DSCAQ – Greek version and a semi-structured interview.
Contact other HCPs	Sending emails/text messages/ or, contacting them face to face		5 – 30, N= 2	140 (2 hours)	• Only includes the time needed to write and send information.
Total time spent delivering the intervention.				7612	127 hours (64 days with 2 working hours per day)

[1]Preparation for intervention delivery was one time task completed before intervention delivery. [2]The adapted DSCAQ – Greek is Diabetes Self-Care Activity Questionnaire – Greek version. Number of the adapted DSCAQ – Greek version responses: 31. [3]Number of MI of which their length of time was measured: 11 (the duration of the MI was not able to be measured to all interviews, as they were sometimes interrupted and not all were audio-recorded). ADA/AADE is the American Diabetes Association/American Association of Diabetes Educators. The adapted DSCAQ – Greek version is the Diabetes Self-Care Activity Questionnaire – Greek version. HbA1c is glycated haemoglobin. MI is motivational interview. SPC is summary of product characteristics. HCPs is healthcare professionals. SD is standard deviation.

9.3 The workability of the intervention (barriers and facilitators)

Workability of the questionnaire employed to deliver the intervention

It was shown that most of the participants responded to the questionnaire, they did not face any difficulties, and the time was similar to the average time required for completion of the baseline questionnaire. From the 62 patients approached, 31 responded to the adapted DSCAQ – Greek version, and only one study participant withdrew without responding to the questionnaire. The time required were; a minimum of 5 minutes, a maximum of 56 minutes, a mean of 16 (11 SD) minutes, and a total of 8 hours (496 minutes). Whereas the total time required to conduct the adapted DSCAQ – Greek version after the intervention was 8 hours (452 minutes), the mean was 21 (9 SD), the minimum was 8, and the maximum was 46 minutes.

Barriers to accessing participants' information

Different sources were sought to identify participants' information (see Figure 9.1). Because the HIO did not approve direct access to the researcher to the participants' electronic files, other sources of information were sought. The main source of information consisted of the diabetes nurse's notes, participants' hardcopy files and asking the GPs and participants. Each source recorded different information and had limitations, as described in Figure 9.1. For example, the diabetes nurse did not record all participants' information, hardcopy files were declining, and each HCP had access to specific patients' information for a certain period (e.g., GPs had access to patients' files if they were still visiting the DC). Thus, the researcher tried to retrieve participants' information through different sources to increase their validity. Table 9.2 shows the types of sources sought to identify participants' information, by number of patients. Not all information was retrieved, and 3 out of 4 HCPs responded and assisted the researcher in identifying participants' information.

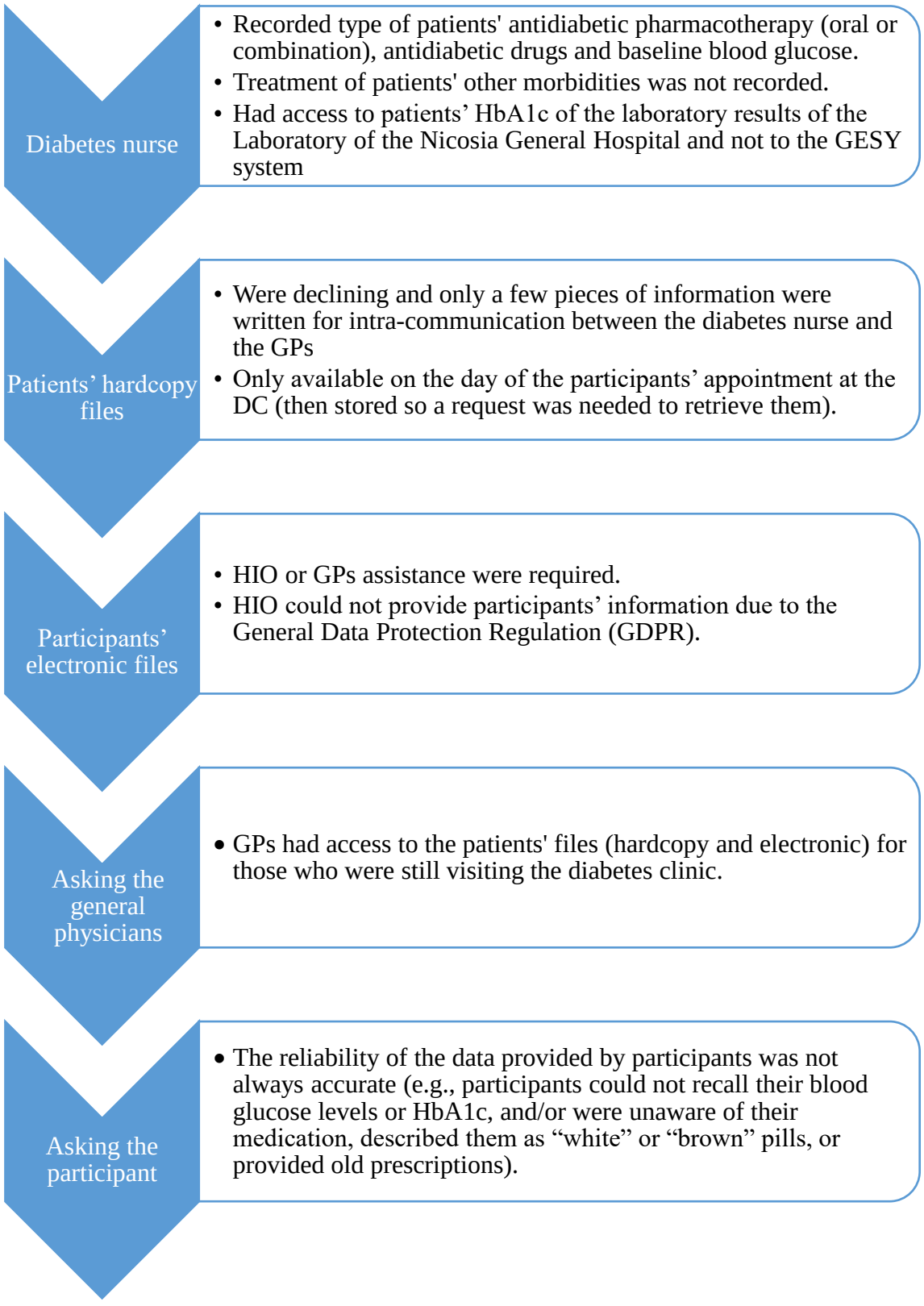


Figure 9.1 The information sources searched and the information identified per information source.

Table 9.2 The different sources used to identify participant information by number of patients.

Source of information		Participants' information identified by number of patients				
		Baseline blood glucose levels	Glycated haemoglobin (HbA1c)		Baseline pharmacotherapy	
			Baseline	After the intervention	Diabetes	Other comorbidities
The diabetes nurse' notes		20/22[1]	11/22	13/22	11/22	11/22
Participants' file – hardcopy	Available at the diabetes clinic	N/A[2]	11/22	13/22	7/22	2/22
	Requested/ (Identified)	N/A[2]	20/22 (6/20)	9/22 (0/9)	2/22	2/22
Laboratory of the Nicosia General Hospital		0/2	8/22	13/22	N/A[2]	N/A[2]
Older version of participants' prescription book.		N/A[2]	N/A[2]	N/A[2]	5/22	2/22
The latest version of participants' prescription[3]		N/A[2]	N/A[2]	N/A[2]	2/22	2/22
Asking GPs[4]	Requested	2/2	20/22	9/22	4/22	4/22
	Identified	0/2	8/20	4/9	2/4	0/4
Asking the participant	Requested	2/2	10/22	4/22	6/22	6/22
	Responded/ (Identified)	2/2 (0/2)	10/10 (1/10)	4/4 (1/4)	6/6 (2/6)	6/6 (0/6)
Total		20 (20/22)	21[5] (21/22)	18[5] (18/22)	19[5] (19/22)	17[5] (17/22)

[1]The diabetes nurse did not record blood glucose measurements for two participants because they visited the clinic for a prescription refill. [2]Those data were not recorded in those types of sources. [3]Printed version of prescription from the centralized information system of GESY. [4]One GP did not respond to the pharmacist. [4]More than one source was used each time to identify all participants information and double check the information identified**.** GESY is general healthcare system. GP(s) is general physician(s).

9.4 Cost for pharmacist's training to deliver the intervention

Set up costs

The set-up costs for the intervention delivery are presented in Table 9.3. Pharmacist training, particularly in motivational interviewing, was a prerequisite for delivering the proposed intervention (see presented in Appendix 4.13).

Table 9.3 Set up costs for the provision of the intervention based on the 22 patients, in Cyprus, in Euro (all costs are based on costs in Cyprus).

Item	Description of cost	Quantity of the item	Cost (Euro)
Phone contract for the pharmacist	Initial phone contract A dedicated professional line was required for the delivery of the intervention. The phone contract was required for 7 months. *(28 euros per month was based on the cheapest contract identified with unlimited calls and short message service).*	7 months	196 (28/month)
Cost of technology used to deliver the intervention	Viber application/ Email The Viber application and emails are free. Viber is a commonly used application in Cyprus and is available in Greek.	1 application/ email	0
	Fax machine	1 unit	N/A[2]
Mobile phone device	Mobile phone is essential equipment for the delivery of the intervention.	1 unit	100
Office	Office with chair, desk, etc Already exists; there is an office for use by all healthcare professionals - No additional cost.	1 office	N/A[1]
Heating and lighting	Already exists; the government already provides heating and lighting for the whole hospital - No additional cost.	1 service	N/A[1]
Cleaning service, electricity/water bill/ Internet bill	Already provided by the government for the whole hospital. No additional cost.	1 service	N/A[1]
Stationery	Notepad Already exists; the government provides all the stationery for the whole hospital. No additional cost.	1 unit	N/A[1]
	Computer	1 unit	N/A[1]
	Fax machine per intervention	1 unit	N/A[1]
	Printers per intervention	1 unit	N/A[1]
	Pens per intervention	3 units	N/A[1]
Training costs for the pharmacist(s)	Motivational interview training	1 course	200

Table 9.3 Set up costs for the provision of the intervention based on the 22 patients, in Cyprus, in Euro (all costs are based on costs in Cyprus).

Item	Description of cost	Quantity of the item	Cost (Euro)
Costs related to promotion	Cost for production of: • Information leaflets for patients. • Promotional and recruitment materials. • All documentation required for the delivery of the intervention. *(The "Graphiteque" agreed to design all relevant documents and have them printed and prepared for use. The agreement for all documents was 200 euros.)*	200 information leaflets	200
Books and resources	Educational leaflets Already provided by the government for the diabetes clinic. Copies were available and a printer machine to reproduce them. No additional cost.	1 copy per educational leaflet	N/A[2]
Total set-up costs			696

[1] The diabetes clinic offered for free these products to the pharmacist. [2] Educational leaflets already provided at the DC were used for providing educational leaflets.

9.5 Costs to deliver the intervention

The cost estimation for the delivery of the intervention is illustrated in Table 9.4. The main item in the delivery costs was the pharmacist's hours spent to deliver the intervention. The pharmacist's salary cost was calculated based on the pharmacist's hours invested in the intervention's provision. Table 9.1 shows that a substantial amount of time is required for the intervention's delivery, particularly at the beginning of the intervention. Thus, it was reasonable to base the pharmacist's salary cost on the hours spent on the intervention's delivery, which were estimated to be 127 working hours. In case of integration of the proposed intervention at the DC, the pharmacist's hours must be calculated to estimate the pharmacist's salary. Contrary to that, the resources provided by the DC will continue to be available free of charge. Most of the stationery expenses are provided by the clinic (such as fax machines, photocopying).

Table 9.4 Costs for the provision of the intervention based on the 22 patients, in Cyprus, in Euro (all costs are based on costs in Cyprus).

Item	Description of cost	Quantity of the item	Cost (Euro)
Pharmacist's salary cost	The gross monthly salary of a pharmacist working at the hospital pharmacy at the Nicosia General Hospital (where the	22 patients	1905[1]

Table 9.4 Costs for the provision of the intervention based on the 22 patients, in Cyprus, in Euro (all costs are based on costs in Cyprus).

Item	Description of cost	Quantity of the item	Cost (Euro)
	diabetes clinic is located) is 2475 (equivalent to 15 euros per hour, based on the working hours per month). Thus, assuming that the intervention's delivery requires 127 working hours for 22 patients (15*127 =1905)[1]		
Books and resources	Photocopying educational leaflets charges Photocopier provided by the government for the diabetes clinic[3]. No additional cost.	1 photocopy machine	N/A[2]
Post services	Eleven educational leaflets were dispatched via post[4].	11 educational leaflets dispatched	44
Total delivery costs			1949

[1]The pharmacist was not paid for the provision of the intervention. If the proposed intervention is incorporated into the DC, the pharmacist's salary cost will be based on the hours spent for the intervention's provision. [2]Already provided by the diabetes clinic. Thus, no additional cost was estimated. [3] From the 15 educational leaflets identified, 7 (7/15) were provided by the CDA, and 8 (7/15) by the diabetes nurse. [4]From the 36 educational leaflets sent, 11 (11/36) were dispatched via post. Each post costs 4 euros. All estimates are in Euro, based on the exchange rate of 1 EURO = 0.88 pounds (exchange rates from 29/03/2023 to 29/03/2023).

9.6 Discussion

The data collected evaluating the workability of the intervention suggested that the intervention could be workable and feasible to be integrated into current practices at the diabetes clinic. If the intervention is extended further, pharmacists' training will be required. Specifically, the pharmacist providing the intervention should be trained in basic MI techniques, diabetes management, optimizing diabetes pharmacotherapy, and operational aspects to ensure the intervention's reliability. Based on the results obtained regarding the pharmacist's workload and HCPs' actions, it could be said that the recruitment depended on the pharmacist. Thus, the pharmacists involved in the intervention should be willing to recruit patients. It was generally suggested that it was feasible for a pharmacist to provide this intervention to a maximum of 22 participants, based on the fact that 22 patients participated and completed the intervention.

To our knowledge, the adapted DSCAQ – Greek version was implemented in a Cypriot population for the first time in the proposed intervention. It was shown that the participants completed the questionnaire and did not encounter any difficulties.

According to Intas et al., 2012 study, the average time required for completion is 8 minutes (standard deviation ±4.2 minutes) (Intas et al., 2012). Thus, the time required to complete the questionnaire in the proposed intervention was slightly longer but relevant to the time stated in the Intas study. It could be suggested that the instrument employed for the intervention delivery could be used in case of further extrapolation of the intervention.

The main barrier identified was the pharmacist accessing participants' information (baseline BG, HbA1c, pharmacotherapy). Missing data were not due to participants' burden but due to lack of access to resources. Specific access to the central information system of the GESY was required, which was not possible to achieve for the proposed study. However, this could be resolved in future studies.

The set-up cost and delivery cost of the proposed intervention were estimated at 696 and 1949 euros accordingly. The main cost for delivering the intervention was the pharmacist's salary cost. Although the pharmacist delivering the intervention was not paid (as was the researcher), it was a significant cost for the intervention and thus was estimated on the hours spent for the intervention's provision. In addition, building services and stationery were provided by the DC and will be free of charge in case of future integration of the intervention into the DC. In case this intervention is implemented in other settings, these costs should be added. This study included only information on cost estimation for the delivery of the intervention. Further research is required to provide sound conclusions whether this intervention could potentially succeed in both cost-saving and cost avoidance. Only two studies were identified through the scoping review that evaluated the costs of a digital health intervention (DHI) (Hawes et al., 2018; Nundy et al., 2014b). However, they evaluated costs differently and concluded that they were cost savings or avoidance (Hawes et al., 2018; Nundy et al., 2014b).

The limitation of the provision of the intervention was mainly the access to the participants' information, which affected the pharmacist reviewing of participants' medications and the reliability of the collected data regarding participants' HbA1c, BG, and pharmacotherapy. Nonetheless, for this intervention to be an established pharmacy service would require approval from the HIO to the pharmacist involved to access the centralized information system of the GESY. This would increase the reliability of the data collected and support pharmacists' efforts in making recommendations to the GPs

about participants' pharmacotherapy. Moreover, the data were collected and analyzed by only one person. However, the aim was to estimate the pharmacist's workload, time, and costs to enable assumptions for future intervention implementation.

The findings indicated that the intervention could be workable and feasible. A setup period for additional pharmacist training and skills will be required. The main barrier to the intervention was access to participants' data. However, this could be overcome in future studies. Limited studies focus on the workability of DHIs delivered by a pharmacist in Cyprus and this study shed light on how this type of intervention could be implemented to current practices.

End of Chapter Nine

Chapter Ten

Key findings, health policy implications, and recommendations

10.1 Introduction

This chapter is divided into the key findings, health policy implications, study limitations, and recommendations.

10.2 Key findings from the combined datasets

What is already known

The lack of patient adherence to diabetes management is the main contributory factor to poor diabetes management and further diabetes complications (Mogre et al., 2019; WHO, 2003; Vermeire et al., 2001). Various diabetes interventions offered by different HCPs have been developed and shown to have some benefits in improving diabetes self-management and have been employed in international healthcare systems (Cross et al., 2020; Nieuwlaat et al., 2014). However, which intervention is more beneficial and global strategies successfully and holistically supporting diabetes patients have not been implemented in all countries (O'Connell et al., 2018; Vermeire et al., 2005; Renders et al., 2000; Bajis and Khadir, 2022; Lauren and Ekpenyong, 2021; FIP, 2019a).

What this research adds

This work has resulted in developing a robust intervention based on evidence and theoretical frameworks, which is individually driven, covers a range of services, and involves and enhances the collaboration between HCPs. It has identified essential barriers to the successful implementation of pharmacy-led intervention employing technology within the GESY framework in Cyprus. This research provided insights into participants' and HCPs' views regarding interventions led by a pharmacist in Cyprus employing technology. Although the results were not statistically powered, as this was a feasibility study, there was an indication that this intervention could holistically support diabetes patients. Comparing the findings indicated the potential value of the intervention to patients and healthcare professionals. It also provided the following steps to support the intervention's implementation and integration in Cyprus, which could be further scaled up nationally and in other settings with similar healthcare systems.

<u>The feasibility of the intervention from the perspective of participants</u>

Despite the preliminary findings and the fact that this feasibility study provided an indication of the extent to which clinical results were likely to be achieved. All data sets and analyses confirm that the participants received the intervention well and expressed that it kept them motivated and increased their confidence in managing diabetes. The

results concluded from the participants' interviews highlighted that they valued the intervention as it enabled self-management and participants' ownership of diabetes control. They also reported improvements in the questionnaire in three out of five domains (blood sugar testing, healthy eating, and foot care).

Their positive expressions at the final interview confirmed the participants' low attrition and engagement throughout the intervention. Participants stated they did not encounter any problems during their participation. Each participant followed their path throughout the intervention. They chose different services, discussed different media, and scheduled appointments with the pharmacist based on their lifestyle. A trend regarding the media used could not be concluded. Different media were requested for communication and different for receiving educational leaflets. Similarly, the number and duration of the phone calls between participants and the pharmacist also varied based on each participant. Correspondingly, participants expressed contrasting views on the media employed, the frequency of follow-up appointments, and the way the appointments should be delivered (focus group, face-to-face, phone call). Moreover, participants raised the importance of scheduling follow-up meetings to enable participation and avoid rescheduling. Although only three participants requested rescheduling the appointments, this was a common problem expressed by the participants at the final interviews. Thus, this will need to be addressed in future recommendations.

The feasibility of the intervention from the perspective of healthcare professionals

The analysis of the data sets regarding other HCPs' assistance during recruitment and in delivering the intervention corresponded to the data sets obtained through the final interviews indicating an overall positive reception. HCPs supported the intervention but there was not enough time to recruit patients. Consequently, in case of further extrapolation of the study, recruitment procedures should be carried out mainly by the pharmacists involved in the intervention and not by the GPs or the diabetes nurse.

Even though currently there is no standard procedure for collaboration and communication between other HCPs and pharmacists, HCPs supported that this should be established. From the final interviews, it could be drawn that HCPs were aware of and valued the clinical pharmacy profession. Also, HCPs accepted most of the pharmacist's recommendations.

Workability of the intervention

It could be suggested that the intervention was workable and feasible to integrate into Cypriote diabetes pathways, based on the pharmacist's workload, the time required to deliver the intervention and the cost estimate for the intervention's delivery. Although employing MI techniques required a dedicated time for preparation and training, it could be concluded that it played a significant role in achieving study objectives as supported by participants' statements at the final interviews and the pharmacist delivering the intervention.

The adapted DSCAQ – Greek version was first implemented in a Cypriot population in the proposed intervention (Intas et al., 2012). It was shown that the participants completed the questionnaire and did not find it difficult, as described in their interviews.

The main barrier faced during the intervention was accessing participants' information. Accessing participants' data required additional tasks which depended on other people's assistance. Participants and other HCPs were needed to identify essential information from the recruitment until the end of the intervention. If the pharmacist knew patients' basic information (blood glucose levels, glycated haemoglobin (HbA1c), pharmacotherapy), it would increase the information's validity. Also, another problem faced was the scheduling of participants' appointments, as described in the final interview of a small proportion of participants. As suggested by participants, scheduling the appointment should include a precise date and time to avoid rescheduling. This should take into consideration in case of future extrapolation of the intervention.

Possible integration of the intervention into the current pathways and recommendations for modifications to the intervention and/or future service provision

The results illustrated that participants and HCPs received the intervention positively. Affirmative responses were received when they were asked whether this intervention was something they would expect in the current healthcare system. Similarly, most study participants would propose this intervention to a friend. None of the interviewed HCPs and participants stated alternative solutions that could provide the same/better results than the proposed intervention for patients with T2DM. Although the pharmacist delivering the intervention was the same as the researcher and conclusive results could not be concluded, based on the intervention workload, the intervention could be integrated into current practices at the DC and MI assisted in achieving the intervention's aims.

The proposed intervention received positive statements during the final interviews with participants and HCPs. Despite the initial concerns of the HCPs about the media, it emerged that the HCPs and participants used all media provided in the intervention. Preference to one of the media employed did not result.

In case of future extrapolation of the proposed intervention, the training needed for the intervention's delivery was stated. Specifically, the pharmacist providing the intervention should be trained in basic MI techniques, diabetes management, and operational aspects to ensure the reliability of the intervention. It was suggested that one pharmacist could simultaneously provide the intervention to a maximum of 22 participants. Also, an initial setup period will be required for training the pharmacists delivering the intervention to offer the intervention.

10.3 The wider development of community pharmacy services and digital health interventions in primary care

Globally, and in Cyprus, there is a need for interventions supporting diabetes patients, and this intervention was developed based on evidence and evaluated through different perspectives with positive results (IDF, 2021; Cross et al., 2020; Nieuwlaat et al., 2014). Community pharmacists worldwide offer various services to support patients with chronic diseases, including diabetes (Viegas et al., 2021; Okoro and Nduaguba, 2021). The services offered differ widely worldwide, depending on the country's regulations and healthcare system (FIP, 2021a; Viegas et al., 2021; Okoro and Nduaguba, 2021). As technology continues to evolve, the abundance of literature is enriched with even more community pharmacists' services employing telemedicine to enable the provision of additional services or enhance the already available services (Söderlund and Griffin, 2021; FIP, 2019c). Notably, in Australia, changes were made to program rules allowing pharmacists to undertake medication reviews via videoconference or teleconference (Viegas et al., 2022, Australian Pharmacist, 2020). In addition, changes in regulations have allowed pharmacies to utilize teleconferencing platforms in the United States, which would have otherwise been non-compliant with privacy standards (Viegas et al., 2022, United States Congress, 2020). Another example is the remote pharmacy service "Cloud Pharmacy Care," a medication consultation service system and Telepharmacy service model based on the social software WeChat application (app) developed in China (Viegas et al., 2022; Li et al., 2021). Similarly, in Denmark, a national online Telepharmacy chat service was developed for all individuals to receive counselling, irrespective of where

medicines were purchased, as part of the strategy for Danish pharmacies (Viegas et al., 2022; Ho et al., 2015).

Based on the scoping review described in chapter 2, some of the previously mentioned services can be offered by diabetes educators and nurses (McLeod et al., 2020; de Vasconcelos et al., 2018; Baron et al., 2017; Threatt and Ward, 2017; McWhorter et al., 2015; McWhorter et al., 2014; Nundy et al., 2014a; Nundy et al., 2014b; Orsama et al., 2013; Bond et al., 2007; Bond et al., 2006). For instance, provision of education, adjustment of diabetes medications, blood glucose (BG) monitoring, etc. Notwithstanding, community pharmacists are the HCPs patients see regularly and have the expertise to provide information and educate diabetes patients (RPS, 2016; Hepler, 2004). Moreover, diabetes patients are usually on different medications besides those prescribed for diabetes management (IDF, 2021; IDF, 2017b; WHO, 2016a; NICE, 2015b; NICE, 2008). Pharmacists' expertise covers a holistic review of patients' medications for different diseases that cannot and are not usually reviewed by other HCPs (Lauren and Ekpenyong, 2021; RPS, 2016).

The developed intervention aimed to offer individually driven and patient-centred education and identified media which could be employed to send the educational leaflets. A similar example of an education program identified in the literature (offered by a diabetes educator) is Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (DESMOND) (Skinner et al., 2006). DESMOND program is available in the United Kingdom (UK) and Australia and covers education on healthy food choices, physical activity, BG monitoring, medication management, and personal goal setting (DESMOND Australia, 2023; DESMOND UK, 2020).

In the UK and Portugal, community pharmacists provide diabetes screening services to patients, including point-of-care measurements such as weight, BP, BG, total cholesterol, triglycerides, and patient counselling (NHS, 2022; Diabetes UK, 2018; Costa et al., 2006). The BG monitoring services might include teaching patients how to use BG meters, interpreting BG results, and providing advice on adjusting medication doses based on BG levels (NHS, 2022; Diabetes UK, 2018; Costa et al., 2006). These services were similar to the ones provided in the developed intervention, although the participants did not choose them. Similar interventions were identified in the scoping review in chapter 2. These services are mainly focused on one aspect of diabetes self-management, compared

to the developed intervention, which included other services (NHS, 2022; Diabetes UK, 2018; Costa et al., 2006).

Further to that, an extensive literature can be found for mobile applications (apps) assisting patients with diabetes in tracking their BG levels, monitoring their medication use, and tracking their food intake and physical activity (FIP, 2019; FIP, 2021b; Donevant et al., 2018). Moreover, in the same logic, wearable technology is also evolving. Wearable technologies are mainly employed for continuous glucose monitoring devices and insulin pumps and can provide real-time data on BG levels and insulin use (FIP, 2019; FIP, 2021b; Donevant et al., 2018). From the FIPs survey (published in 2019) it was resulted that apps are available to allow pharmacists to set medication reminders to improve patient medication adherence, collect information on blood sugar levels, and make medication recommendations to patients with chronic diseases, including diabetes (FIP, 2019c). Examples of those were found in Croatia: eTerapija, Unigluko, Lung Manager, Lexicomp, Bellabeat, Little Dot, Alergo, and Diavitas (FIP, 2019c). Another example was found in New Zealand. Pharmacists employ an app called Zoom to improve medication adherence by setting reminders, medication doses, videos educating patients on how to use their medication (including asthma, insulins, etc.), and reminders for medication refills (FIP, 2019c).

Several services providing medication management were identified. One similar example of the developed intervention is the "New Medicine Service" program offered in the UK (NHS, 2023; PSNC, 2023). It provides support to people with long-term conditions, including diabetes. The service includes a medication review and counselling session with a community pharmacist to help ensure that patients are taking their medications correctly (NHS, 2023; PSNC, 2023). This service included the community pharmacists' advice on how patients must take their medication correctly, assisting them in monitoring for potential side effects or drug interactions, and counselling patients on medication adherence.

Although a variety of generic services could be identified, none offered all aspects and components available in the developed intervention. Available interventions integrated into the healthcare system around the world provide different services in a variety of modes. Most of them provide parts of the services offered in the developed intervention. The proposed intervention aimed to include different services and media to holistically

support diabetes patients. Focusing on being patient-centred and individualized at each step of participants' lifestyle, employing MI techniques, and aiming to enhance the communication between HCPs. Moreover, contrary to the non-interactive apps and wearable technologies available, the developed intervention aimed to enhance communication with patients and empower and motivate them to be part of their disease management.

As stated by World Health Organization (WHO), most of the studies identified in the literature inadequately describe the intervention' procedure, structure, and communication between the HCPs (Agarwal et al., 2016). Another strength of the study was the holistic way of evaluating the intervention's feasibility and the triangulation method employed, which was based on the Medical Research Council (MRC) framework (Skivington et al., 2021; Bleijenberg et al., 2018; Craig et al., 2008a; Craig et al., 2008b). Moreover, compared with the developed intervention, some of the identified studies/interventions do not describe the theoretical framework underpinning their intervention (Ladner et al., 2022; Clark et al., 2020; Lee et al., 2020; Majithia et al., 2020; Dixon et al., 2019; Sun et al., 2019; Hawes et al., 2018; Jeong et al., 2018; Baron et al., 2017; Fortmann et al., 2017; Threatt and Ward, 2017; McWhorter et al., 2015; Lau et al., 2014; McWhorter et al., 2014; Chen et al., 2013; Klug et al., 2011). Whereas results suggested that individualization and employing MI techniques were the elements which played a valuable role in participants' engagement with the intervention. To our knowledge, this is the first intervention, aiming to improve T2DM, individualizing each step based on participants' lifestyle, from the services provided to the media employed and the frequency of the follow-up.

Although similar interventions were identified through scanning the literature on HCPs services and DHIs supporting diabetes self-management, identical interventions were not identified. Despite this the study was not designed to statistically evaluate the intervention's effectiveness, the study suggested that this intervention could potentially be integrated into current practice and was well received by HCPs and patients.

10.4 Health policy implications

The results obtained in this research have implications for stakeholders at the micro and macro levels in the systems and processes of healthcare delivery. The stakeholders at the micro level include the community/hospital pharmacists, the diabetes nurses, the GP

interested in diabetes, and specialist physicians relevant to diabetes (such as endocrinologists, ophthalmologists, etc.). At the same time, the macro level involves other higher stakeholders (such as MOHR and HIO), which affect policy and practices. Correspondingly, this study's findings also impact policies at national levels.

The stakeholders at the micro level, and notably, pharmacists should be a part of the multidisciplinary team and provide services aiming to support diabetes patients as stated by the HCPs in the study and participants. Also, HCPs in the study expressed the need to enhance collaboration between HCPs. Thus, pharmacists' skills and knowledge should be employed while supporting interventions like the proposed one.

Regarding stakeholders at the macro level, they should work together in developing and implementing interventions supporting and optimizing diabetes management. The results obtained through the participants' interviews reported in this study show a need for comprehensive interventions supporting T2DM management. Governments and policymakers should promote and support the deployment of robustly designed interventions with a clear development plan and specific structure, which will be audited for further modifications and recommendations. The current research focused on developing an intervention into current practices in a diabetes clinic in Cyprus and was based on robust evidence, and its feasibility was evaluated.

Policies at international levels are constantly changing, aiming to support diabetes management. Global efforts of essential policymakers such as FIP and WHO suggest plans to create more opportunities for the delivery via community pharmacies of interventions and employing digital health, as the one utilised in this research (FIP, 2019b; FIP, 2021a). As WHO identified, similar interventions should be comprehensibly explained and evaluated to allow reproduction (Agarwal et al., 2016). This intervention presented each step to allow for reproductivity and also provided information to support the intervention's integration into the Cyprus healthcare system and other similar settings.

10.5 Study limitations

- The same person developed, delivered, and evaluated the intervention. More positive results might be obtained as the pharmacist delivering the intervention also collected the data collection, analysed them, and made interpretation of the data. Particularly, more favourable responses might be obtained from participants

and HCPs because the intervention and final interview were conducted by the pharmacist offering the intervention.

- Some form of bias might be that this is a new service, and it is common to collect favourable responses (Smith, 2010).
- This is a self-selecting sample of patients, who might be more motivated to be included in the research. In particular, the sample recruited were patients visiting a DC in addition to their appointment with their GP. Hence, this might indicate that they are more motivated to improve their management of diabetes.
- Some form of bias is also expected as participants may not have been entirely honest when asked to give an account of their self-management of diabetes.
- The fact that the recruitment process took place at a single DC may limit the generalisability of the study results to broader populations.
- The interviews targeted specific stakeholders within the DC only. Only one community pharmacist was involved in the intervention. Other healthcare providers working on other DCs/pharmacies or collaborating with the DC, such as endocrinologists, and cardiologists were not interviewed.
- The participants' and HCPs' sample size was relatively small and may not represent the perception of the Cypriote population and HCPs in Cyprus.

Notwithstanding, data obtained in different ways were compared to reduce bias in interpreting study findings. Different data sets were analysed, and the findings were triangulated to increase the study's validity and provide solid recommendations.

10.6 Recommendations

The results obtained through the evaluation of the intervention concluded recommendations for further research and future recommendations for modifications to the intervention.

Recommendations for further research

Based on the MRC framework, the next step after feasibility evaluation is an evaluation that goes beyond asking whether the intervention was workable and identifying a broader range of questions, such as the intervention's impact (Skivington et al., 2021). While this study has identified a feasible and potentially beneficial intervention to improve diabetes self-management, more work is needed for the intervention integration into current

practises and future intervention evaluation. Future research will also require addressing the clinical outcome of the developed intervention, as this study evaluated an indication of the extent to which clinical outcomes were likely to be achieved. Priorities for research will include the effectiveness of the intervention, measured in changes to critical parameters such as HbA1c, knowledge, empowerment, adherence to diabetes management, etc. The proposed intervention was developed by a researcher who was also the pharmacist developing, delivering, and evaluating the intervention. This should be considered when further expanding the intervention to a wider setting. The evaluation should be conducted by a researcher (or research team) independent of the intervention's delivery to minimise subjectivity and potential bias and in the case of a full evaluation, researchers should be blind to intervention/ control groups. In this way, reflexivity bias will be limited as the pharmacist's influence on the intervention's evaluation will be minimized.

More research is needed to explore the views of other stakeholders in implementing this intervention. These include community/hospital pharmacists, patients, extended healthcare providers, and others outside the primary care setting involved in the practice and policy changes such as MOHRC, HIO, PSMH, and CDA to generate more robust data with more substantial relevance for internal and external policies. Pharmacists' competency to deliver such interventions, aiming to improve diabetes management, evaluate patients' pharmacotherapy, and employ telemedicine is another objective that should be assessed in the future. Furthermore, cost evaluation is also essential to address the intervention's feasibility and potential cost avoidance and saving. This could be evaluated by calculating the cost for the delivery of the intervention and the cost that could be avoided/saved due to the intervention implementation, such as costs for changes to patients' medication, outpatient, inpatient and emergency department visits etc.

Recommendations for changes to the intervention for piloting the intervention into community/hospital pharmacy within the GESY framework

The modified intervention for piloting within the GESY framework is described below and summarized in Table 10.1. Community/hospital pharmacists will deliver the intervention based on their working hours. However, recruitment and initial appointments will be held in the involved DCs. The standard operating procedures, pharmacists' training, intervention services and media will remain the same.

Table 10.1 Summary of the modified intervention for pilot introduction into community/hospital pharmacies within the GESY framework.

Modified intervention integrated into community/hospital pharmacy within the GESY framework	
Location	Recruitment and initial appointment: Diabetes clinics involved. Rest appointments: phone calls
Pharmacist	Community/hospital pharmacists will deliver the intervention. Each community/hospital pharmacist can offer the intervention to approximately 20 participants.
Working Hours	Usual working hours of hospital or community pharmacies. *Nevertheless, each pharmacist could choose the days on which the appointments will be scheduled.*
Standard operating procedures	The procedures followed for delivering the intervention were developed through this thesis and described in appendices: Appendix 4.1, Appendix 4.4, Appendix 4.5, Appendix 4.6, Appendix 4.7, Appendix 4.8, Appendix 4.9, Appendix 4.10, Appendix 4.12 Appendix 4.13, and Appendix 4.16.
Education /Training	Pharmacists delivering the intervention will need to be trained in basic MI techniques, diabetes management, optimizing diabetes pharmacotherapy, and operational aspects to ensure the intervention's reliability.
Services	• Pharmacist online advice to patient queries. • Tracking and uploading blood glucose readings. • Graphical reports of blood glucose readings. • Reminders for self-monitoring blood glucose, medication taking, medication refill, and appointment. • Education (healthy lifestyle and diabetes). • Review of patients' medications.
Media	Viber application, phone calls, text messages, emails, fax, and posts.

Recruitment process

Figure 10.1 illustrates the recruitment procedure, and Figure 10.2 the steps patients willing to participate will need to follow to start the intervention.

- Integrating recruitment procedure into the community/hospital pharmacy workload. Eligible patients would be those visiting the DCs involved. The rest of the eligibility criteria will remain the same.
- Separating recruitment and initial appointment. In this way, the pharmacist will not interrupt the GPs' appointments at the DC and will have more time to recruit patients, the diabetes nurse and GPs will have more time to refer patients, and patients will have more flexibility in when they will begin their initial appointment.
- The aim will be the referral of patients being conducted through the GESY information system.

Initial and subsequent appointment

- The appointment should be scheduled accurately with date and time (to avoid rescheduling).

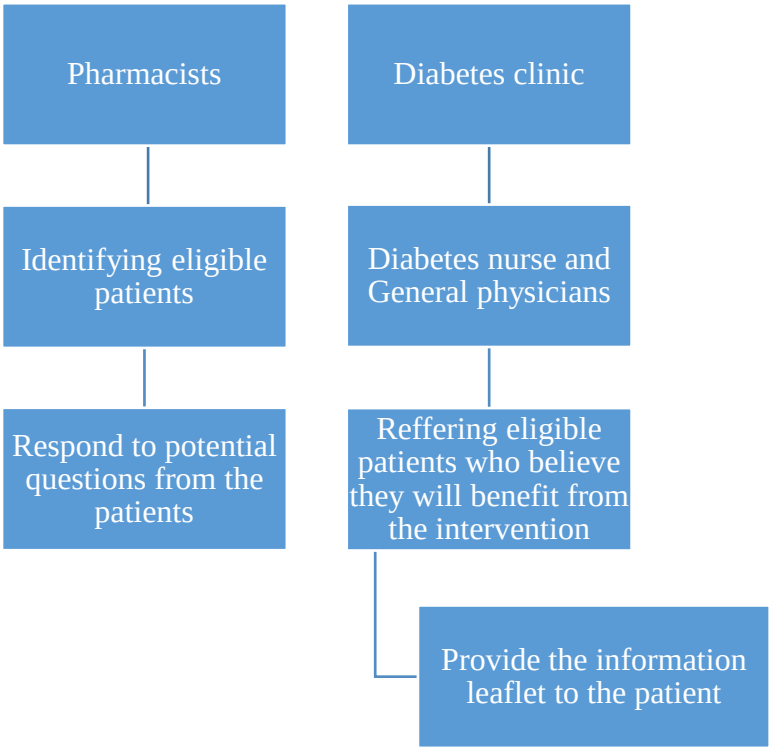


Figure 10.1 The recruitment procedure of the modified intervention.

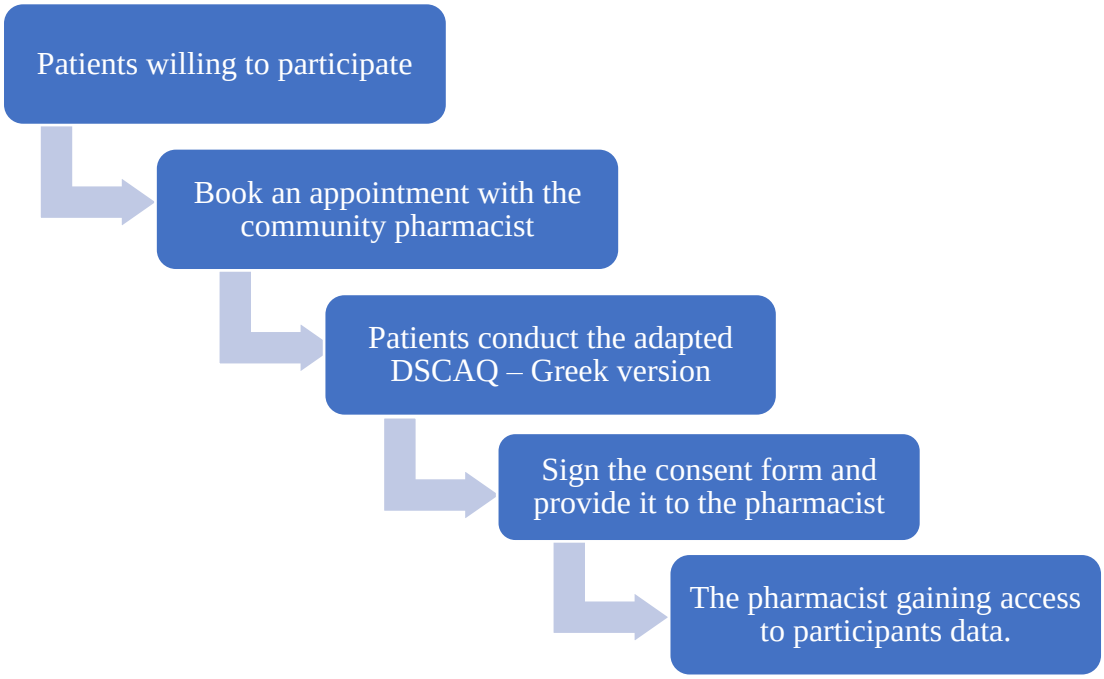


Figure 10.2 The pathway of the patients willing to participate in the intervention.

Appointment scheduling procedure

The pharmacists delivering the intervention should be precise when scheduling the next phone appointment. A specific date and time should be set. The pharmacist should

provide clear instructions to the participants that it is essential to set a time when they will be available, have a private room to talk, and be prepared for the meeting to ask any queries of the pharmacists. The reason is to solve the problem that arose with the rescheduling of appointments between the pharmacist and the participants.

Accessing participants' information

Access to participant information will be resolved if this intervention is integrated into the GESY. The pharmacist will gain access to the GESY information system and, therein, to the entire medical history of the participants who signed the consent form. This will probably require time to implement and further discussions with the Health Insurance Organization (HIO), the Ministry of Health of The Republic of Cyprus (MOHR), and the Commissioner for Personal Data Protection before the service establishment. Nevertheless, the recent implementation of the GESY provides an enormous opportunity to resolve this issue.

Communication between healthcare professionals

The pharmacists delivering the intervention should communicate with the HCPs at the DC. The services and media employed will not be altered.

Policymakers to support the intervention becoming a service in Cyprus

It is recommended to the national policymakers (MOHRC) in Cyprus to pilot the proposed intervention involving more DCs and pharmacists. More community/hospital pharmacists should be encouraged to participate and deliver this intervention who will not also participate in the intervention as a researcher. Support by other relevant HCPs will be essential. This will include referring diabetes patients and supporting pharmacists' recommendations for medication modifications. Also, more patients should be recruited, and the sample size of the pilot intervention should be calculated based on the anticipated change in specific outcome measures.

HIO should ensure a proper remuneration for pharmacists will be in place. MOHRC and HIO should support this pilot intervention by providing access to those community/hospital pharmacists involved. An audit of the pilot intervention will be presented to the policymakers to indicate reasons for the intervention's existence in the GESY pathways. Thereafter, if the results obtained prove reasons for further

extrapolation of the intervention more community/hospital pharmacists should be involved.

10.7 Conclusion

To conclude, T2DM management requires constant self-care and support from various HCPs. An extensive list of services and interventions was identified in the literature and implemented in several countries and territories worldwide. However, the incidence of T2DM is increasing rapidly, and there is still a lack of adherence to self-care among patients with T2DM. The intervention developed aimed to support T2DM patients holistically and was developed on robust evidence and adjusted to standard practices in Cyprus. The procedure, structure, and feasibility evaluation of the intervention are clearly explained.

This intervention received positive results from participants and HCPs. Participants valued the MI techniques and achieved high response and engagement rates. Also, participants reported improved self-care in three domains (blood sugar testing, healthy eating, and foot care) assessed in the adapted DSCAQ – Greek version. HCPs also expressed positive responses and provided essential information for the interventions' development and delivery. Participants' and HCPs' behaviours and actions showed that pharmacists must be part of a multidisciplinary team. However, HCPs faced some challenges in assisting the pharmacist, which need further evaluation to draw robust conclusions on the successful collaboration among HCPs involved in the study. Even though MI techniques required pharmacist's preparation and training, the feasibility study proved that it played a valuable role in achieving the research aim. Technology assisted in the individualization of the intervention and enhanced communication among the pharmacist, participants, and HCPs. Refinements during the recruitment period and accessing participants' data could resolve the main problems encountered during the provision of the intervention. The cost for the intervention's delivery was estimated, and the intervention's workability and feasibility were shown, which could eventually prove reasons for integration into current practices in Cyprus.

The results showed that the intervention currently possible in the existing setting and used by the patients could be determined as telemedicine instead of digital health intervention. Initially, based on the current practices, the intervention employed technology to facilitate the delivery of the intervention services. At this point, reasons for developing an app

and/or automation of the services were not concluded. This was mainly based on the participants' engagement and usage of the services provided. Although the intervention involved several services, participants primarily valued communication with the pharmacist and used media to enable their communication. They mostly used face-to-face, phone calls, messages, and posts (for education provision), and only a few chose the Viber app. None of the participants used the Viper app to transfer their BG or used the reminder services. The results showed that participants valued the individualization of the intervention and the interaction with a healthcare professional. This also emerged from the participants' final interviews. They valued the approach of the pharmacist and the support, motivation, and education provided.

Consequently, even though the researcher's ambition was to initially design a digital health intervention, the result showed that the definition of telemedicine is a more appropriate term to describe the intervention's components. Requiring patients to use all the intervention's services could potentially lead to a completely different intervention, study, and outcome. Also, developing an app before assessing participant perspectives and the current situation in the existing setting would potentially lead to another app with low participant engagement. The researcher's primary goal was to understand the needs of the current setting, what can be conducted and implemented, and what different patient groups need. In this manner, and by triangulating the results, the researcher aimed to truly understand which intervention's components might be most beneficial for each diabetes patient. For these purposes, feasibility studies are an essential step, before fully evaluation the study and proceeding with a defined intervention. Despite the limitations of feasibility studies, the proposed study demonstrated the possible intervention in the existing setting and participants' preference for the proposed intervention. Nevertheless, future steps may result in the automation of the intervention services valued by the Cypriot population with the possibility of transforming into a DHI in the future. Moreover, it could be said that the success of this intervention was based on its individualization. Thus, providing different services and patients' freedom of choice may be the optimal way to further define the intervention.

End of Chapter Ten

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Appendices

Appendix 1.1 Digital health categories, descriptions/definitions, and functions.

Term	Description/Definition
Digital health	*"The field of knowledge and practice associated with the development and use of digital technologies to improve health. Digital health expands the concept of eHealth to include digital consumers, with a wider range of smart-devices and connected equipment. It also encompasses other uses of digital technologies for health such as the Internet of things, artificial intelligence, big data, and robotics."* (WHO, 2021, page 40)
Health telematics	*"Health telematics is a composite term for health-related activities, services and systems, carried out over a distance by means of information and communications technologies, for the purposes of global health promotion, disease control and health care as well as education, management and research for health"* (WHO, 1998, page 10).
Telemedicine	*"The delivery of health care services, where distance is a critical factor, by all healthcare professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities"* (WHO, 2021, page 40; WHO, 1998, page 10).
Telehealth	Telehealth has a variety of synonyms and is usually another term used instead of telemedicine. (WHO, 2016b). It was found that telemedicine was strictly defined as services delivered solely by physicians, and telehealth signified services provided by health professionals in general, including nurses, pharmacists, and others (WHO, 2010).
e-Health	*"The cost-effective and secure use of information and communications technologies in support of health and health-related fields, including health care services, health surveillance, health literature, and health education, knowledge and research."* (WHO, 2021, page 40)
Mobile health or m-Health	The use of mobile and wireless devices with remote to support the achievement of health objectives. M-Health is a component of eHealth (FIP, 2019c; Partnership for Maternal, Newborn, and Child Health, 2017; WHO, 2011).
Digital hospital	*"The digital hospital provides services within and outside the hospital walls shifting away from the facility-based delivery of care to a smart virtual network of care centred on the patient, embedded in the health continuum."* (WHO, 2021, page 40).
Health data	*"The systematic application of information and communications technologies, computer science, and data to support informed decisionmaking by individuals, the health workforce, and health systems, to strengthen resilience to disease and improve health and wellness. It includes all data pertaining to the health status of a data subject which reveal information relating to the past, current or*

Appendix 1.1 Digital health categories, descriptions/definitions, and functions.

Term	Description/Definition
	future physical or mental health status of the data subject. This includes information about the natural person collected in the course of the registration for, or the provision of, health care services to that natural person; a number, symbol or particular assigned to a natural person to uniquely identify the natural person for health purposes" (WHO, 2021, page 41).
Health information system	*"A system that integrates data collection, processing, reporting, and use of the information necessary for improving health service effectiveness and efficiency through better management at all levels of health services."* (WHO, 2021, page 41).
Telepharmacy	The remote provision of pharmaceutical care through technologies. (Viegas et al., 2022)

Appendix 3.1 The self-care diabetes education checklist, followed by diabetes nurse in EUBIROD system.

	Date	Written instructions	Notes
Insulin: Preparation, Administration, Points of injections, Storage			
Syringes, Pen, needles: Use, material removal			
Tablets: when to take, actions, adverse effects			
Hypoglycaemia: cause, symptoms, tackle			
Hyperglycaemia: cause, symptoms, tackle			
Disease: action, medication, fluids			
Self-check: how, when, evaluation of results			
Foot: daily care, nails, calves, shoes			
Eyes: annual check			
Teeth: check every 6 months			
Driving: hypoglycaemia			
Safety: Life, Driving			
Healthy eating: appointment with dietitian			
Alcohol			
Smoking			
Exercise			
Trips			
General health issues: Menstruation, Contraception, Preparation for pregnancy, Pregnancy, Sexual inability			

Appendix 3.2 Educational leaflets identified in Cyprus provided by the CDA and the diabetes nurse at the DC.

Educational leaflets	
Identified by the CDA	**Identified by the diabetes nurse**
• Life and diabetes (look ahead and take control, live the life). • Diabetes and information (Pancyprian diabetes association, Ministry of Health). • Diabetes (Pancyprian diabetes association, Ministry of Health). • What I should know about diabetes mellitus (Ministry of health - nursing services).	• General nutrition instructions for diabetes mellitus and weight body balance (Polli Michaelidou Clinical Dietician). • Diabetes, Nutrition and Exercise (Acon). • Food Exchange Lists (Ministry of Health).
• What I should know about diabetes mellitus (Ministry of health - nursing services).	• Diabetes, Nutrition and Exercise (Acon).
• Diabetes, Heart Disease and Stroke (Pancyprian diabetes association, Ministry of Health and Cyprus Diabetes Company). • What I should know about diabetes mellitus (Ministry of health - Nursing Services).	• Hypoglycaemia (Pancyprian diabetes association, Ministry of Health). • Hypoglycaemia – Everything you need to know (MSD).
	• Foot care (Greek Diabetes Association). • Prevention of foot ulcers and amputations in diabetics (Pancyprian diabetes association, Ministry of Health and Cyprus Diabetes Company).

Appendix 4.1 Motivational Interviewing techniques - Open questioning, Affirming, Reflecting, and Summarizing (OARS): Key Techniques Sheet.

(Adopted by Sabeeh, 2015, Steinberg and Miller, 2015 and Ogedegbe et al., 2007)

Open questioning, Affirming, Reflecting and Summarizing (OARS)	
Open Questions	• For example: Tell me about; What do you think about, etc.
	• Avoid closed questions.
	• Take care, not to 'stack' questions or continue questions – allow space for an answer.
Affirmations	• Mention their successes, appreciate progress and comment positively on attributes (e.g., patient values, desires, behaviours)
	• Express hope, caring, and support
Reflections	• Simple reflections: Repeat or rephrase using comparable words
	• Complex reflections: Paraphrase what you heard, reflect back on the feeling, continue the paragraph
	• Amplified Reflections: Take what you hear, lift it, increasing intensity
	• Keep voice neutral, do not turn into a question by lifting voice
	• Avoid pre-statements (padding!), e.g., so, it seems like, etc.
Summaries	• Reflect on the content of the discussion over the past few minutes, joining it together
	• Enable deeper thinking by joining together the content of the discussion
Recognise ambivalence:	• Patients' conflicting positive and negative thoughts on a topic
	• Reflect these back
	• Reflect on their negative thoughts FIRST, then their positive thoughts
Spot Change Talk	• Reflect this back
	• Elicit more through open questions
	• Affirm

Informing: ELICIT – PROVIDE - ELICIT	
ELICIT (1):	• Ask what the patient already knows
	• Ask what the patient thinks they should do to proceed
PROVIDE:	• Ask for permission to inform
	• E.g., "would you like to know about some other approaches that some people have found useful?" "Would it be ok if I told you some concerns, I have about your plan?"
Resistant patients:	• Ask if they would like to hear your information now or later
	• Prefacing: "There's something I have to tell you, but I'd really like to know what you think about it." "This may or may not concern you, but…"
ELICIT (2):	• Ask open questions: "What do you make of that?" "What does this mean for you?"

Appendix 4.2 Permission to use the Diabetes Self-Care Activity Questionnaire – Greek version.

Pavlidou, Antria <antria.pavlidou.15@ucl.ac.uk>
Thu 29/08/2019 08:45

Αξιότιμοι κύριε Ίντα και κυρία Καλογιάννη,

Σας αποστέλνω αυτό το email, καθώς θα ήθελα να χρησιμοποιήσω το **"Diabetes Self-Care Activity Questionnaire – Greek version"** στη διδακτορική μου έρευνα. Έχω διαβάσει το άρθρο σας για τη δημιουργία και επικύρωση του ερωτηματολογίου και ενδιαφέρομαι πολύ στη χρήση του στην έρευνα μου. Παρακαλώ ενημερώστε με για τις διαδικασίες που θα πρέπει να ακολουθήσω για να αποκτήσω πρόσβαση και χρήση του ερωτηματολογίου σας.

Ονομάζομαι Άντρια Παυλίδου και είμαι υποψήφια διδάκτωρ του Πανεπιστήμιο University College London (UCL) της Αγγλίας, με βάση μου (και της έρευνας μου) τη γενέτειρα μου, Κύπρο.
***Θέμα διατριβής:** Αντίκτυπος της χρήσης εφαρμογών στο κινητό, με την στήριξη του κοινοτικού φαρμακοποιού, για εξωτερικούς ασθενείς στην αυτό-διαχείριση του διαβήτη, σε συνεργασία με άλλους επαγγελματίες του τομέα της υγείας, στην Κύπρο.*

Σας ευχαριστώ εκ των προτέρων

Με εκτίμηση

Άντρια Παυλίδου
Υποψήφια Διδάκτωρ, UCL
MSc Κλινικός Φαρμακοποιός, UCL
antria.pavlidou.15@ucl.ac.uk

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Room: 339, 29-39 Brunswick
Square
London WC1N 1AX

Re: Πρόσβαση και χρήση ερωτηματολογίου "Diabetes Self-Care Activity Questionnaire – Greek version"

Γεώργιος Ίντας
Wed 04/09/2019 23:35
To: Pavlidou, Antria <antria.pavlidou.15@ucl.ac.uk>

2 attachments (357 KB)
Development and validation of a Diabetes Self-Care Activities Questionnaire.pdf; Ερωτηματολόγιο.doc;

Αγαπητή κα Παυλίδου,

αρχικά θα ήθελα να σας συγχαρώ για την επιλογή σας που επιλέξατε να ακολουθήσετε ένα τόσο απαιτητικό μονοπάτι.

Σας επισυνάπτω το ερωτηματολόγιο και είμαι στη διάθεσή σας για κάθε περαιτέρω διευκρίνηση.

Καλή επιτυχία και καλή δύναμη για την ολοκλήρωση της προσπάθειάς σας.

Δρ. Ίντας Γεώργιος
Προϊστάμενος Β Παθολογικής Γ.Ν.Ν.Άγιος Παντελεήμων
Καθηγητής μέλος ΣΕΠ, ΔΜΥ 50, Ελληνικό Ανοικτό Πανεπιστήμιο
Καθηγητής Νοσηλευτικής, Μητροπολιτικό κολλέγιο

Appendix 4.3 The Diabetes Self-Care Activity Questionnaire – Greek version (without any adjustments for the proposed study).

Ερωτηματολόγιο εκτίμησης της συμμόρφωσης των ασθενών με σακχαρώδη διαβήτη τύπου ΙΙ στη θεραπεία τους

Παρακαλώ απαντήστε στις ακόλουθες ερωτήσεις, εάν έχετε διαγνωσθεί με σακχαρώδη διαβήτη τύπου ΙΙ.

Ηλικία:

Φύλο: Άνδρας □ Γυναίκα □

Οικογενειακή κατάσταση: Με σύζυγο □ Χωρίς σύζυγο □

Ζείτε: Μόνη/ος □ Όχι μόνη/ος □

Επίπεδο εκπαίδευσης: Απόφοιτος λυκείου □ Ανώτερη/ανώτατη εκπαίδευση □ Μεταπτυχιακό □

Βάρος: Ύψος:

Δείκτης μάζας σώματος (βάρος σε κιλά διά το ύψος στο τετράγωνο σε μέτρα):

Μηνιαίο εισόδημα σε ευρώ: <600 □ 601- 1000 □ 1001-1500 □ >1501 □

Ασφάλεια: Ναι □ Όχι □

Έτη που έχετε διαγνωσθεί με διαβήτη: ☐

Έχετε τον ίδιο ιατρό; Ναι □ Όχι □

Αν ναι, πόσα έτη έχετε τον ίδιο ιατρό; ☐

Πόσες φορές το χρόνο επισκεφθήκατε τον ιατρό σας;

ΦΥΣΙΚΗ-ΨΥΧΙΚΗ ΥΓΕΙΑ

Έχετε κάποια από τις ακόλουθες ασθένειες;

Ασθένεια	**Ναι**	**Όχι**
Καρδιακή Ανεπάρκεια		
Στεφανιαία νόσος		
Υπέρταση		
Αγγειακό εγκεφαλικό επεισόδιο		
Ακράτεια ούρων		
Σοβαρή νεφρική νόσος		
Απώλεια νεφρού		

Χρόνια λοίμωξη του ουροποιητικού συστήματος		
Τύφλωση		
Διαταραχές στην όραση		
Νευροπάθεια		
Προβλήματα με τις κατώτερες πλευρές (αγγειονεύρωση)		
Κατάθλιψη		

Δίαιτα

Πόσες φορές τις τελευταίες 7 ημέρες (τελευταία εβδομάδα) ακολουθήσατε υγιεινή διατροφή;

0	1	2	3	4	5	6	7

Πόσες ημέρες την εβδομάδα, από τον τελευταίο μήνα, ακολουθήσατε το πλάνο διατροφής σας;

0	1	2	3	4	5	6	7

Πόσες φορές τις τελευταίες 7 ημέρες (τελευταία εβδομάδα) καταναλώσατε πέντε ή περισσότερες μερίδες φρούτων και λαχανικών;

0	1	2	3	4	5	6	7

Πόσες φορές τις τελευταίες 7 ημέρες (τελευταία εβδομάδα) καταναλώσατε φαγητά με υψηλά λιπαρά (κόκκινο κρέας, γαλακτοκομικά κτλ);

0	1	2	3	4	5	6	7

Άσκηση

Πόσες φορές τις τελευταίες 7 ημέρες (τελευταία εβδομάδα) ξοδέψατε 30 συνεχή λεπτά για φυσική άσκηση (πχ, περπάτημα);

0	1	2	3	4	5	6	7

Πόσες φορές τις τελευταίες 7 ημέρες (τελευταία εβδομάδα) κάνατε έντονη άσηση (πχ, κολύμβηση, ποδηλασία, χορός κτλ);

0	1	2	3	4	5	6	7

Εξετάσεις αίματος – έλεγχος σακχάρου αίματος

Πόσες φορές τις τελευταίες 7 ημέρες (τελευταία εβδομάδα) ελέγξατε το σάκχαρό σας;

0	1	2	3	4	5	6	7

Πόσες φορές τις τελευταίες 7 ημέρες (τελευταία εβδομάδα) ελέγξατε το σάκχαρό σας σύμφωνα με τις οδηγίες του ιατρού σας;

0	1	2	3	4	5	6	7

Φροντίδα ποδιών

Πόσες φορές τις τελευταίες 7 ημέρες (τελευταία εβδομάδα) ελέγξατε τα πόδια σας;

0	1	2	3	4	5	6	7

Πόσες φορές τις τελευταίες 7 ημέρες (τελευταία εβδομάδα) ελέγξατε το εσωτερικό των παπουτσιών σας;

0	1	2	3	4	5	6	7

Κάπνισμα

Καπνίσατε τις τελευταίες 7 ημέρες; Όχι □ Ναι □

Εάν ναι, πόσα τσιγάρα καπνίσατε την ημέρα;

Συστάσεις-Συμβουλές για αυτοφροντίδα

1) Ποιο από τα ακόλουθα συμβουλευτήκατε (ιατρός ή νοσηλευτής) να κάνετε;

A. Δίαιτα χαμηλή σε λιπαρά

B. Δίαιτα σε συνδυασμό με υδρογονάθρακες

C. Μείωση των καθημερινών θερμίδων για απώλεια βάρους

D. Κατανάλωση φαγητών πλούσιων σε φυτικές ίνες

E. Κατανάλωση φρούτων και λαχανικών (5 μερίδες την ημέρα)

F. Μείωση στην κατανάλωση νερού στο ελάχιστο

G. Άλλο (παρακαλώ διευκρινίστε)

H. Δεν πήρα οδηγίες από κανέναν

2) Ποιο από τα ακόλουθα συμβουλευτήκατε (ιατρός ή νοσηλευτής) να κάνετε;

A. Κάντε ήπια καθημερινή άσκηση (περπάτημα)

B. Κάντε συνεχή άσκηση για 20 λεπτά τουλάχιστον 3 φορές την ημέρα

C. Υιοθετήστε μερικές ασκήσεις σε καθημερινή βάση (πχ, χρησιμοποιείστε τις σκάλες αντί του ανελκυστήρα, χρησιμοποιείστε το λεωφορείο αντί του αυτοκινήτου, κατεβείτε μία στάση νωρίτερα από αυτή που επιθυμείτε κτλ).

D. Υιοθετείστε ένα συγκεκριμένο είδος, διάρκεια και βαθμό άσκησης

E. Άλλο (παρακαλώ διευκρινίστε)

F. Δεν πήρα οδηγίες από κανέναν

3) Ποιο από τα ακόλουθα συμβουλευτήκατε (ιατρός ή νοσηλευτής) να κάνετε;

A. Ελέγξτε το σάκχαρο του αίματός σας χρησιμοποιώντας μία σταγόνα αίματος από το δάχτυλο σε μία ειδική ταινία που αλλάζει χρώμα ανάλογα με τα επίπεδα του σακχάρου

B. Ελέγξτε το σάκχαρο του αίματός σας χρησιμοποιώντας ένα μηχάνημα

C. Ελέγξτε το σάκχαρο στα ούρα

D. Άλλο (παρακαλώ διευκρινίστε)

E. Δεν πήρα οδηγίες από κανέναν

4) Ποιο από τα ακόλουθα συμβουλευτήκατε (ιατρός ή νοσηλευτής) να κάνετε;

A. Έγχυση ινσουλίνης 1 ή 2 φορές την ημέρα

B. Έγχυση ινσουλίνης 3 ή περισσότερες φορές την ημέρα

C. Αντι-διαβητικά χάπια - ταμπλέτες

D. Άλλο (παρακαλώ διευκρινίστε)

E. Δεν πήρα οδηγίες από κανέναν

Δίαιτα

Πόσες φορές τις τελευταίες 7 ημέρες (τελευταία εβδομάδα) μοιράσατε τα γεύματά σας σε ίσες ποσότητες υδρογοναθράκων;

0	1	2	3	4	5	6	7

Φάρμακα

Πόσες φορές τις τελευταίες 7 ημέρες (τελευταία εβδομάδα) πήρατε τα φάρμακά σας;

0	1	2	3	4	5	6	7

Πόσες φορές τις τελευταίες 7 ημέρες (τελευταία εβδομάδα) πήρατε ινσουλίνη;

0	1	2	3	4	5	6	7

Φροντίδα ποδιών

Πόσες φορές τις τελευταίες εβδομάδες πλύνατε τα πόδια σας;

0	1	2	3	4	5	6	7

Πόσες φορές τις τελευταίες εβδομάδες μουλιάσατε σε διάλυμα νερού και αντισηπτικού τα πόδια σας;

0	1	2	3	4	5	6	7

Πόσες φορές τις τελευταίες εβδομάδες στεγνώσατε προσεκτικά τα κενά μεταξύ των δακτύλων των ποδιών σας;

0	1	2	3	4	5	6	7

Κάπνισμα

Στην τελευταία επίσκεψη στον ιατρό σας, σας ρώτησε εάν καπνίζετε και πόσο;

Όχι □ Ναι □

Εάν καπνίζετε, στην τελευταία επίσκεψη στον ιατρό σας, σας συνέστησε να σταματήσετε το κάπνισμα ή σας ανέφερε κάποιο πρόγραμμα διακοπής του καπνίσματος;

Όχι □ Ναι □

Πότε καπνίσατε για τελευταία φορά;

A. Περισσότερο από δύο χρόνια ή δεν κάπνισα ποτέ

B. Πριν 1-2 χρόνια

C. Πριν 4 – 12 μήνες

D. Πριν 1-3 μήνες

E. Λιγότερο από 1 μήνα

F. Σήμερα

Appendix 4.4 The adapted Diabetes Self-Care Activities Questionnaire (adjusted for the proposed intervention) (English and Greek versions).

Patients' answers to the questionnaire will immediately interpret using online Qualtrics XM®.

English Version (Adopted by Toobert et al., 2000)

1. Participation Identification Number:

Medications:

2. On how many of the last SEVEN DAYS, did you take your recommended diabetes medication?

0	1	2	3	4	5	6	7

Blood Sugar Testing:

3. On how many of the last SEVEN DAYS did you test your blood sugar?

0	1	2	3	4	5	6	7

4. On how many of the last SEVEN DAYS did you test your blood sugar the number of times recommended by your health care provider?

0	1	2	3	4	5	6	7

Healthy eating:

5. How many of the last SEVEN DAYS have you followed a healthy eating plan?

0	1	2	3	4	5	6	7

6. On average, over the past month, how many DAYS PER WEEK have you followed your eating plan?

0	1	2	3	4	5	6	7

7. On how many of the last SEVEN DAYS did you eat five or more servings of fruit and vegetables?

0	1	2	3	4	5	6	7

8. On how many of the last SEVEN DAYS did you eat high-fat foods such as red meat or full-fat dairy products?

0	1	2	3	4	5	6	7

Exercise:

9. On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking).

0	1	2	3	4	5	6	7

10. On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work?

0	1	2	3	4	5	6	7

Foot Care:

11. On how many of the last SEVEN DAYS did you check your feet?

0	1	2	3	4	5	6	7

12. On how many of the last SEVEN DAYS did you inspect the inside of your shoes?

0	1	2	3	4	5	6	7

Self-Care Recommendations:

13. Which of the following has your health care team (doctor, nurse, dietitian, or diabetes educator) advised you to do?
    - ☐ Test your blood sugar using a drop of blood from your finger and a colour chart.
    - ☐ Test your blood sugar using a machine to read the results.
    - ☐ Test your urine for sugar.
    - ☐ Other (specify):
    - ☐ I have not been given any advice either about testing my blood or urine sugar level by my health care team.
14. Which of the following has your health care team (doctor, nurse, dietitian, or diabetes educator) advised you to do?
    - ☐ Follow a low-fat eating plan
    - ☐ Follow a complex carbohydrate diet
    - ☐ Reduce the number of calories you eat to lose weight
    - ☐ Eat lots of food high in dietary fibre
    - ☐ Eat lots (at least 5 servings per day) of fruit and vegetables
    - ☐ Eat very few sweets (for example: desserts, non-diet sodas, and candy bars)
    - ☐ Other (specify):
    - ☐ I have not been given any advice about my diet by my health care team.
15. Which of the following has your healthcare team (doctor, nurse, dietitian, or diabetes educator) advised you to do?
    - ☐ Get-low level exercise (such as walking) on a daily basis.
    - ☐ Exercise continuously for a least 20 minutes at least 3 times a week.
    - ☐ Fit exercise into your daily routine (for example, take stairs instead of elevators, park a block away and walk, etc.)
    - ☐ Engage in a specific amount, type, duration, and level of exercise.
    - ☐ Other (specify):
    - ☐ I have not been given any advice about exercise by my health care team.

Healthy eating:

16. On how many of the last SEVEN DAYS did you space carbohydrates evenly through the day?

0	1	2	3	4	5	6	7

Foot Care:

17. On how many of the last SEVEN DAYS did you wash your feet?

0	1	2	3	4	5	6	7

18. On how many of the last SEVEN DAYS did you soak your feet?

0	1	2	3	4	5	6	7

19. On how many of the last SEVEN DAYS did you dry between your toes after washing?

0	1	2	3	4	5	6	7

Smoking:

20. At your last doctor's visit, did anyone ask about your smoking status?
    - ☐ No
    - ☐ Yes
21. Are you a smoker?
    - ☐ No
    - ☐ Yes

If smoker:

22. Have you smoked a cigarette—even one puff—during the past SEVEN DAYS?
    - ☐ No
    - ☐ Yes
23. Number of cigarettes per day:
24. When did you last smoke a cigarette?
    - ☐ More than two years ago, or never smoked
    - ☐ One to two years ago
    - ☐ Four to twelve months ago
    - ☐ One to three months ago
    - ☐ Within the last month
    - ☐ Today
25. At your last doctor's visit, did anyone counsel you about stopping smoking or offer to refer you to a stop-smoking program?
    - ☐ No
    - ☐ Yes

Greek Version (Adopted by Intas et al., 2012)

Ερωτηματολόγιο εκτίμησης της συμμόρφωσης των ασθενών με σακχαρώδη διαβήτη τύπου ΙΙ στη θεραπεία τους

1. Αριθμός αναγνώρισης συμμετοχής:

Φάρμακα

2. Πόσες φορές τις τελευταίες 7 ημέρες (τελευταία εβδομάδα) πήρατε τα φάρμακά σας;

0	1	2	3	4	5	6	7

Εξετάσεις αίματος – έλεγχος σακχάρου αίματος

3. Πόσες φορές τις τελευταίες 7 ημέρες (τελευταία εβδομάδα) ελέγξατε το σάκχαρό σας;

0	1	2	3	4	5	6	7

4. Πόσες φορές τις τελευταίες 7 ημέρες (τελευταία εβδομάδα) ελέγξατε το σάκχαρό σας σύμφωνα με τις οδηγίες του ιατρού σας;

0	1	2	3	4	5	6	7

Δίαιτα

5. Πόσες φορές τις τελευταίες 7 ημέρες (τελευταία εβδομάδα) ακολουθήσατε υγιεινή διατροφή;

0	1	2	3	4	5	6	7

6. Πόσες ημέρες την εβδομάδα, από τον τελευταίο μήνα, ακολουθήσατε το πλάνο διατροφής σας;

0	1	2	3	4	5	6	7

7. Πόσες φορές τις τελευταίες 7 ημέρες (τελευταία εβδομάδα) καταναλώσατε πέντε ή περισσότερες μερίδες φρούτων και λαχανικών;

0	1	2	3	4	5	6	7

8. Πόσες φορές τις τελευταίες 7 ημέρες (τελευταία εβδομάδα) καταναλώσατε φαγητά με υψηλά λιπαρά (κόκκινο κρέας, γαλακτοκομικά κτλ);

0	1	2	3	4	5	6	7

Άσκηση

9. Πόσες φορές τις τελευταίες 7 ημέρες (τελευταία εβδομάδα) ξοδέψατε 30 συνεχή λεπτά για φυσική άσκηση (πχ, περπάτημα);

0	1	2	3	4	5	6	7

10. Πόσες φορές τις τελευταίες 7 ημέρες (τελευταία εβδομάδα) κάνατε έντονη άσηση (πχ, κολύμβηση, ποδηλασία, χορός κτλ);

0	1	2	3	4	5	6	7

Φροντίδα ποδιών

11. Πόσες φορές τις τελευταίες 7 ημέρες (τελευταία εβδομάδα) ελέγξατε τα πόδια σας;

0	1	2	3	4	5	6	7

12. Πόσες φορές τις τελευταίες 7 ημέρες (τελευταία εβδομάδα) ελέγξατε το εσωτερικό των παπουτσιών σας;

0	1	2	3	4	5	6	7

Συστάσεις-Συμβουλές για αυτοφροντίδα

13. Ποιο από τα ακόλουθα συμβουλευτήκατε (ιατρός ή νοσηλευτής) να κάνετε;
    - ☐ Ελέγξτε το σάκχαρο του αίματός σας χρησιμοποιώντας μία σταγόνα αίματος από το δάχτυλο σε μία ειδική ταινία που αλλάζει χρώμα ανάλογα με τα επίπεδα του σακχάρου
    - ☐ Ελέγξτε το σάκχαρο του αίματός σας χρησιμοποιώντας ένα μηχάνημα
    - ☐ Ελέγξτε το σάκχαρο στα ούρα
    - ☐ Άλλο (παρακαλώ διευκρινίστε)
    - ☐ Δεν πήρα οδηγίες από κανέναν
14. Ποιο από τα ακόλουθα συμβουλευτήκατε (ιατρός ή νοσηλευτής) να κάνετε;
    - ☐ Δίαιτα χαμηλή σε λιπαρά
    - ☐ Δίαιτα σε συνδυασμό με υδρογονάθρακες
    - ☐ Μείωση των καθημερινών θερμίδων για απώλεια βάρους
    - ☐ Κατανάλωση φαγητών πλούσιων σε φυτικές ίνες
    - ☐ Κατανάλωση φρούτων και λαχανικών (5 μερίδες την ημέρα)
    - ☐ Μείωση στην κατανάλωση νερού στο ελάχιστο
    - ☐ Άλλο (παρακαλώ διευκρινίστε)

Δεν πήρα οδηγίες από κανέναν

15. Ποιο από τα ακόλουθα συμβουλευτήκατε (ιατρός ή νοσηλευτής) να κάνετε;
    - ☐ Κάντε ήπια καθημερινή άσκηση (περπάτημα)
    - ☐ Κάντε συνεχή άσκηση για 20 λεπτά τουλάχιστον 3 φορές την ημέρα

- ☐ Υιοθετήστε μερικές ασκήσεις σε καθημερινή βάση (πχ, χρησιμοποιείστε τις σκάλες αντί του ανελκυστήρα, χρησιμοποιείστε το λεωφορείο αντί του αυτοκινήτου, κατεβείτε μία στάση νωρίτερα από αυτή που επιθυμείτε κτλ).
- ☐ Υιοθετείστε ένα συγκεκριμένο είδος, διάρκεια και βαθμό άσκησης
- ☐ Άλλο (παρακαλώ διευκρινίστε)
- ☐ Δεν πήρα οδηγίες από κανέναν

Δίαιτα

16. Πόσες φορές τις τελευταίες 7 ημέρες (τελευταία εβδομάδα) μοιράσατε τα γεύματά σας σε ίσες ποσότητες υδρογοναθράκων;

0	1	2	3	4	5	6	7

Φροντίδα ποδιών

17. Πόσες φορές τις τελευταίες εβδομάδες πλύνατε τα πόδια σας;

0	1	2	3	4	5	6	7

18. Πόσες φορές τις τελευταίες εβδομάδες μουλιάσατε σε διάλυμα νερού και αντισηπτικού τα πόδια σας;

0	1	2	3	4	5	6	7

19. Πόσες φορές τις τελευταίες εβδομάδες στεγνώσατε προσεκτικά τα κενά μεταξύ των δακτύλων των ποδιών σας;

0	1	2	3	4	5	6	7

Κάπνισμα

20. Στην τελευταία επίσκεψη στον ιατρό σας, σας ρώτησε εάν καπνίζετε και πόσο;
    - ☐ Όχι
    - ☐ Ναι
21. Είστε καπνιστής;
    - ☐ Όχι
    - ☐ Ναι

Εαν ναι:
Κάπνισμα

22. Καπνίσατε τις τελευταίες 7 ημέρες;
    - ☐ Όχι
    - ☐ Ναι
23. Πόσα τσιγάρα καπνίσατε την ημέρα;
24. Πότε καπνίσατε για τελευταία φορά;
    - ☐ Περισσότερο από δύο χρόνια ή δεν κάπνισα ποτέ
    - ☐ Πριν 1-2 χρόνια
    - ☐ Πριν 4 – 12 μήνες
    - ☐ Πριν 1-3 μήνες
    - ☐ Λιγότερο από 1 μήνα

Σήμερα

25. Στην τελευταία επίσκεψη στον ιατρό σας, σας συνέστησε να σταματήσετε το κάπνισμα ή σας ανέφερε κάποιο πρόγραμμα διακοπής του καπνίσματος;
    - ☐ Όχι
    - ☐ Ναι

Appendix 4.5 Instructions on scoring scales and adherence cut-off points for estimating patients' adherence levels based on their responses to the Diabetes Self-Care Activities Questionnaire.

Instructions on scoring scales (Adopted by Toobert et al., 2000)	
Diabetes activity	**Instructions**
General Diet	The mean number of days for items 5 and 6.
Specific Diet	The mean number of days for items 7, and 8, reversing item 8 (0=7, 1=6, 2=5, 3=4, 4=3, 5=2, 6=1,7=0). Given the low inter-item correlations for this scale, using the individual items is recommended.
Exercise	The mean number of days for items 9 and 10.
Blood-Glucose Testing	The mean number of days for items 3 and 4.
Foot-Care	The mean number of days for items 11 and 12.
Smoking Status	Item 21 (0 = nonsmoker,1 = smoker), and number of cigarettes smoked per day.
Scoring for Additional Items	
Recommended regimen	No scoring is required for items 13-15 and 20 and 24 - 25.
Diet	Use total number of days for item 16.
Medications	Use item 2; use total number of days for item 2.
Foot-Care	The mean number of days for items 17 - 19, after reversing 18 and including items 11 and 12 from the brief version.

Instructions on cut-off points of adherence level	
Adherence level	**Percentage**
Low Adherence	(< 60%)
Medium Adherence	(60% to <80%)
High Adherence	(≥ 80%)

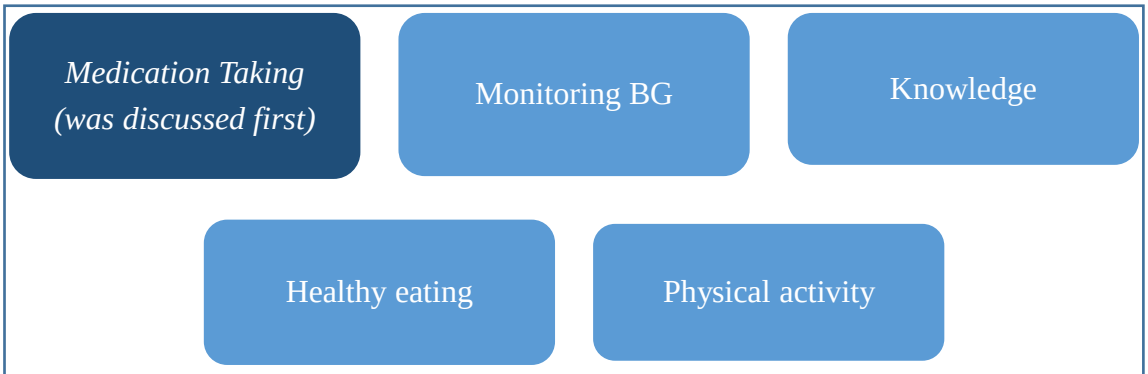
Appendix 4.6 The content and procedure for the initial appointment.

Adapted from: Ogedegbe et al., 2007 and Sabeeh, 2015

Consultation appointment 1: Initial appointment (face-to-face)

1. Introductions: The pharmacist should introduce him/herself to the patient and Discuss confidentiality to assure participants.
2. Review consent: "I would like to remind you that confidentiality and anonymity will be maintained, and it will not be possible to be identified in any publications."
3. The pharmacist should briefly outline to the patient the purpose of the intervention and the nature of the consultation. "The purpose of this consultation is to learn about you and your diabetes to tailor the intervention as much as possible according to your needs and lifestyle and develop a personalized plan just for you. The services of the intervention and how to use it will also be explained in this consultation."
4. Give a brief description of the questionnaire and its aim. This is a questionnaire about understanding how you manage your diabetes, and I will use it to develop a personal plan for you) Diabetes Self-Care Activities Questionnaire (presented separately below).
   With the assistance of Qualtrics XM®, the results from the questionnaire will be immediately ready for interpretation.

   The patient will be asked to choose from the agenda 1-2 topic(s) most important to them. Not all the topics on the agenda will be discussed.
5. Agenda setting: ask an open question to find out which topic is more important for the patient (From the agenda-setting topics, which is the most important to you?)



(Adopted by Welch et al., 2006 and Powell et al., 2014 studies)

6. Respond to this using the core MI Skills: OARS (see techniques sheet). The pharmacist should use these consistently during the remainder of the consultation.
   a. Open Questions
   b. Affirmations
   c. Reflections
   d. Summaries

Focus on medication *(In case the patient chose medication as a topic from the agenda setting, this was discussed first, and then other patient-preferred topics)*

7. Information Gathering: Elicit: What do you know about the medication you are taking and how you should take it?

   a. The pharmacist should respond to this using MI techniques and allow the patient to direct discussion regarding their medication, emotions, behaviours, etc.

8. Assess the patient's motivation and confidence:
   a. When appropriate, ask: On a scale from 1 to 10 (with 10 being the highest), how motivated/interested are you in taking your medication as prescribed?
   b. On a scale from 1 to 10 (with 10 being the highest), how confident are you that you can take your diabetes medication as prescribed?
9. Elicit barriers, concerns, and positive self-motivational statements: depending on the patient's responses to the above questions, the pharmacist can follow-up with additional questions or OARS techniques:
   a. For high numbers: Can you tell me why you chose X (number) rather than a lower number, like a 1 or a 2? (Eliciting positive motivational statements)
   b. For low numbers (ask as appropriate): Can you tell me why you chose X (number) rather than a higher number like a 9 or 10? What would it take to get you to a 9 or 10?

Reminder: Always allow space for the patient to express their views and respond with OARS.

Move to the rest topics of the questionnaire

10. Information Gathering: Elicit: What do you know about monitoring your BG/learning more about diabetes disease/ follow a healthy diet/ be active/screen your foot (replace with the relevant topic) and how you should monitor your BG/ eat healthy/ exercise/screen your foot?

    a. The pharmacist should respond to this using MI techniques and allow the patient to direct discussion regarding their medication, emotions, behaviours, etc.

11. Assess the patient's motivation and confidence:
    a. When appropriate, ask: On a scale from 1 to 10 (with 10 being the highest), how motivated/interested are you in monitoring your BG/learning more about diabetes disease following a healthy diet/ physical activity/screening your foot as instructed (replace with the relevant topic)?
    b. On a scale from 1 to 10 (with 10 being the highest, how confident are you that you can monitor your BG/learn more about diabetes disease/ follow a healthy diet/ be active/screen your foot as instructed (replace with the relevant topic)?
12. Elicit barriers, concerns, and positive self-motivational statements: depending on the patient's responses to the above questions, the pharmacist can follow-up with additional questions or OARS techniques:
    a. **For high numbers:** Can you tell me why you chose X (number) rather than a lower number, like a 1 or a 2? (Eliciting positive motivational statements)
    b. **For low numbers** (ask as appropriate): Can you tell me why you chose X (number) rather than a higher number like a 9 or 10? What would it take to get you to a 9 or 10?

Reminder: Always allow space for the patient to express their views and respond with OARS.

13. Summaries: The pharmacist should draw together the discussions thus far, summarising the major content for the patient.
14. Elicit: What do you think about all this? Is there something else you want to add?

Follow the intervention's flowchart to provide possible solutions - Demonstrate the app/digital health intervention

- If necessary, provide information:
  15. Ask permission: "Would it be ok if I shared with you some information regarding…" (e.g., educational material)
  16. Would it be a good idea to send you… (e.g., reminders)
  17. Provide information: Take care to do this in short bursts and to maintain the balance in the consultation so that the patient talks more than the pharmacist.
  18. Elicit: "What do you make of that information?" or similar.

If you need to provide additional information, continue to use the ELICIT-PROVIDE-ELICIT approach (see techniques sheet)

- Assess the patient's values and goals:
  19. Elicit: Can you tell me about your life goals and how your health relates to these?
  20. Spot ambivalence: Reflect on this
  21. Pharmacist should listen carefully for CHANGE TALK and respond appropriately using EARS:
      a. Evoking (open questions)
      b. Affirmations
      c. Reflections
  22. Summary: The pharmacist summarises the discussion about goals and values
  23. Elicit: "So what do you think you will do…?"
  24. Thanks: Pharmacist to thank the patient for their participation and engagement in their consultation
  25. Follow-up: Pharmacist to arrange or discuss the 6-8 weeks follow-up appointment. Provide the patient with Pharmacy/Pharmacist contact details where appropriate.

Appendix 4.7 The subsequence appointment content and procedure (appointments 2 and 3).

Up to 6-8 weeks follow-up:

In case the topic "medication" was agreed to be included in the patient's personal plan, this was discussed first, and then other patient-preferred topics.

1. Review: In our last appointment, we spoke about a few issues regarding medication taking and diabetes management (replace with the relevant topic), and we highlighted some key points. Can you tell me how are you doing?
2. Worries: Can you tell me about any concerns you have had with your medication since we last met? Then discuss other topics about diabetes management and the use of the application.

a. Allow the patient to outline concerns and reflect upon them.

b. If necessary, provide advice using ELICIT (permission) – INFORM – ELICIT formula (see Action-mapping Sheet).

3. Solution-focused: Some patients have found it helpful to review what approaches/solutions/techniques did or did not work for them. What would you think about doing this?
    a. Tell me what approaches/solutions/techniques you have tried/worked for you since last time.
    b. Use OARS to respond and elicit more information regarding these.
4. Future-oriented: Having considered how you are doing great with the application in the past few weeks, tell me about your plans for your medication and health in the next few months.
5. If appropriately set new goals, allowing them to be patient-driven.

(Monitoring your BG/learning more about diabetes disease following a healthy diet/ physical activity/screening your foot)

Appendix 4.8 The American Diabetes Association/American Association of Diabetes Educators (ADA/ AADE) curriculum and available leaflets at DC.

(Adapted by Mensing et al., 2000).

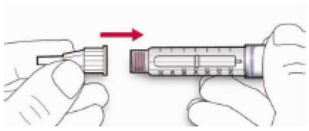
American Diabetes Association/American Association of Diabetes Educators	Leaflets available
Describing the diabetes disease process and treatment options	• Life and diabetes (look ahead and take control, live the life). • Diabetes and information (Pancyprian diabetes association, Ministry of Health). • Diabetes (Pancyprian diabetes association, Ministry of Health). • What I should know about diabetes mellitus (Ministry of health - nursing services).
Incorporating appropriate nutritional management	• General nutrition instructions for diabetes mellitus and weight body balance (Polli Michaelidou Clinical Dietician). • Diabetes, Nutrition, and Exercise (Acon). • Food Exchange Lists (Ministry of Health).
Incorporating physical activity into the lifestyle	• Diabetes, Nutrition, and Exercise (Acon).
Utilizing medications (if applicable) for therapeutic effectiveness	• Pharmaceutical Services Database (SPC and PIL).
Monitoring blood glucose and urine ketones (when appropriate) and using the results to improve control	• 1. Life and diabetes (look ahead and take control, live the life).
Preventing, detecting, and treating acute complications	• Hypoglycaemia (Pancyprian diabetes association, Ministry of Health). • Hypoglycaemia – Everything you need to know (MSD). • What I should know about diabetes mellitus (Ministry of health - nursing services).
Preventing (through risk reduction behavior), detecting, and treating chronic complications	• Foot care (Greek Diabetes Association). • Prevention of foot ulcers and amputations in diabetes (Pancyprian diabetes association, Ministry of Health, and Cyprus Diabetes Company). • Diabetes, Heart Disease, and Stroke (Pancyprian diabetes association, Ministry of Health, and Cyprus Diabetes Company). • What I should know about diabetes mellitus (Ministry of Health - Nursing Services).
Goal setting to promote health, and problem-solving for daily living	• Initial appointment and continuously adjusted throughout the intervention. • Covered through the above available leaflets.

American Diabetes Association/American Association of Diabetes Educators	Leaflets available
Integrating psychosocial adjustment into daily life	• Not applicable to the proposed intervention.
Promoting preconception care, management during pregnancy, and gestational diabetes management (if applicable)	• Not applicable to the proposed intervention.

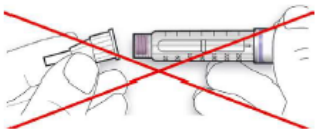
Appendix 4.9 Example educational leaflets employed.

(Adapted by the Pharmaceutical Services of Ministry of Health (PSMH)'s drug database).

B. Line up the needle with the pen, and keep it straight as you attach it (screw or push on, depending on the needle type).



- If the needle is not kept straight while you attach it, it can damage the rubber seal and cause leakage, or break the needle.

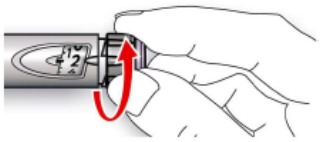


Step 3. Perform a Safety test

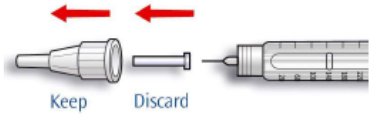
Always perform the safety test before each injection. This ensures that you get an accurate dose by:

- ensuring that pen and needle work properly
- removing air bubbles

A. Select a dose of 2 units by turning the dosage selector.



B. Take off the outer needle cap and keep it to remove the used needle after injection. Take off the inner needle cap and discard it.



C. Hold the pen with the needle pointing upwards.

D. Tap the insulin reservoir so that any air bubbles rise up towards the needle.

Examples of educational leaflets for healthy eating – diet and

Πόλλυ Μιχαηλίδου
Κλινική Διαιτολόγος

Γενικό Νοσοκομείο Λευκωσίας

ΓΕΝΙΚΕΣ ΔΙΑΤΡΟΦΙΚΕΣ ΟΔΗΓΙΕΣ ΓΙΑ ΣΑΚΧΑΡΩΔΗ ΔΙΑΒΗΤΗ ΚΑΙ ΕΛΕΓΧΟ ΤΟΥ ΣΩΜΑΤΙΚΟΥ ΒΑΡΟΥΣ

ΑΠΟΦΥΓΕΤΕ ΤΡΟΦΕΣ ΠΛΟΥΣΙΕΣ ΣΕ ΖΑΧΑΡΗ, ΚΟΡΕΣΜΕΝΟ ΛΙΠΟΣ ΚΑΙ ΧΟΛΗΣΤΕΡΟΛΗ:

- Κόκκινο κρέας και αλλαντικά όπως αρνί, βοδινό, πολυπίφ, σαλάμι, λουκάνικα,
- Ολόπαχα τυριά όπως κεφαλοτύρι (κασκαβάλι), χαλούμι κ.ά.
- Κρέμα γάλακτος, βούτυρο
- Τηγανητά φαγητά όπως τηγανιτές πατάτες, τηγανητό κρέας, τηγανητό ψάρι, τηγανητό αυγό, κεφτέδες, λουκουμάδες, πουρέκια.
- Τυρόπιτα, λουκανικόπιτα, πίτσα, κρουασάν, οτιδήποτε περιέχει σφολιάτα
- Γλυκίσματα: τάρτες, μπισκότα, σοκολάτες, ταχινόπιττα, μαρμελάδα, μέλι
- Ζαχαρούχα αναψυκτικά, φρουτοποτά, φρουτοχυμοί
- Παπαδάκια, τσιπς, μαγιονέζα, αλατισμένοι ξηροί καρποί, αλμυρά φαγητά.
- Αλκοολούχα ποτά όπως μπύρα, ουίσκι, βότκα, κρασί σε μεγάλες ποσότητες (να καταναλώνετε με μέτρο)
- Αποφύγετε να παραλείπετε γεύματα.
- Αποφύγετε να τρώτε λαίμαργα μεγάλες ποσότητες φαγητού στα γεύματα.
- Αποφύγετε να τσιμπολογάτε ανεξέλεγκτα ενδιάμεσα στα γεύματα ή τα βράδυ.

ΤΡΩΤΕ ΜΕ ΜΕΤΡΟ ΤΡΟΦΕΣ ΠΟΥ ΒΟΗΘΟΥΝ ΣΤΗΝ ΡΥΘΜΙΣΗ ΤΟΥ Σ. ΔΙΑΒΗΤΗ:

- Τρώτε μικρά, τακτικά γεύματα και ιδιαίτερα ένα υγιεινό πρόγευμα όπως 1-2 μικρές φέτες ψωμί ολικής αλέσεως με τυρί διαίτης ή αναρή ανάλατη ή γαλοπούλα, ντομάτα αγγούρι ή 1 μικρό φλιτζάνι δημητριακά ολικής αλέσεως χωρίς ζάχαρη ή 3-4 κουταλιές βρώμη (π.χ. κουάκερ) και γάλα με μειωμένα λιπαρά.
- Τρώτε σαλατικά και λαχανικά της αρεσκείας σας καθημερινά π.χ. μαρούλι, αγγούρι, ντομάτα, κολοκούδι, φασολάκι, καρότο, σπανάκι, μπρόκολο κτλ.
- Τρώτε φαγητά μαγειρεμένα στη σχάρα στο φούρνο ή βραστά. Όχι τηγανητά.
- Περιορίστε το κρέας και προτιμήστε όσπρια, ψάρι, κοτόπουλο ή κουνέλι.
- Τρώτε 1 μικρό φλιτζάνι μαγειρεμένα όσπρια της αρεσκείας 2 φορές την εβδομάδα π.χ. λουβί, φασόλια, φακές, κουκιά, ρεβίθια, λουβάνα και άλλα.
- Ψάρι στη σχάρα, στο φούρνο ή βραστό 1 με 2 φορές την εβδομάδα. Δοκιμάστε τσιπούρα, σαλομό, λαυράκι, φαγκρί, και άλλα.
- Μικρή μερίδα κοτόπουλο χωρίς την πέτσα, γαλοπούλα, χαμηλά σε λιπαρά, κιμάς χαμηλός σε λιπαρά 2 με 3 φορές την εβδομάδα.
- Αλλαντικά χαμηλά σε λιπαρά όπως είναι το χαμ γαλοπούλα
- Τυρί με μειωμένα λιπαρά (6-12% λίπος) ή αναρή ανάλατη.
- Γάλα ημι-άπαχο ή άπαχο ή ντε λαχτ ή γάλα σόγιας. Γιαούρτι με μειωμένα λιπαρά (0-2% λίπος).
- Προσθέστε γεύση στα φαγητά χρησιμοποιώντας πιπέρι, κρεμμυδι, σκόρδο, τζίντζερ, δυόσμο, βασιλικό, κανέλα, λεμόνι, χυμό ντομάτας κ.ά.
- Ένα κουταλι ελαιόλαδο ανά γεύμα. Λίγη μαργαρίνη χαμηλή σε λιπαρά
- **ΤΡΩΤΕ ΜΕ ΜΕΤΡΟ:** ψωμί ολικής αλέσεως ή βραστά μακαρόνια ή ρύζι ή πουργούρι ή 1 μικρή βραστή ή ψητή πατάτα
- 2-3 μερίδες φρούτο την ημέρα, ενδιάμεσα στα γεύματα
- Λίγοι ανάλατοι ξηροί καρποί όπως 5-10 αμύγδαλα ή 4-5 καρύδια ημερησίως
- Μέχρι 1-2 βραστά αυγά την εβδομάδα
- Τακτική σωματική άσκηση ανάλογα με την κατάσταση της υγείας του ατόμου

Τι είναι οι Διαβητικές Ανταλλαγές;

Οι διαβητικές ανταλλαγές είναι οι ομάδες τροφών που κατατάσσονται μαζί σε καταλόγους ή κατηγορίες γιατί είναι όμοιες σε ποσότητα θερμίδων και θρεπτικές ουσίες.

Κάθε μερίδα στην αντίστοιχη ομάδα είναι ισοδύναμη σε θερμίδες, υδατάνθρακες, πρωτεΐνες και λίπος. Γι' αυτό το λόγο κάθε τροφή από την ίδια κατηγορία τροφών μπορεί να «αντικατασταθεί» ή είναι ισοδύναμη με οποιαδήποτε άλλη της ίδιας κατηγορίας (ή του ίδιου καταλόγου).

Τα φαγητά σε κάθε κατηγορία/κατάλογο εμφανίζονται με τη μονάδα μέτρησης των μερίδων τους και είναι μετρημένα αφού μαγειρευτούν.

Διαβητικές Ανταλλαγές				
Ομάδα	Cho (gr)	Prot. (gr)	Fat. (gr)	Kcal
Ομάδα Υδατανθράκων				
Ψωμί/Δημητριακά/Ισοδύναμα	15	3	1ή<	80
Φρούτα	15	-	-	60
Γάλα				
Άπαχο	12	8	0-3	90
Ημι-	12	8	5	120
Ολόπαχο	12	8	8	150
Λαχανικά	5	2	-	25
Κρέας/Ισοδύναμα				
Πολύ-άπαχο	-	7	0-1	35
Άπαχο	-	7	3	55
Μέτριο Λίπος	-	7	5	75
Ψηλό Λίπος	-	7	8	100
Λίπος	-	-	5	45

CHO - υδατάνθρακες, Prot - πρωτεΐνες, Fat - λίπος

Οι διαβητικές ανταλλαγές προσφέρουν πολλές επιλογές από τρόφιμα.

Αυτό επιτρέπει την ποικιλία στα γεύματα του διαβητικού. Μερικά τρόφιμα, όπως τα όσπρια, τα μπιζέλια, το μπέικον, το φυστικοβούτυρο, μπορούν να ανήκουν σε δύο κατηγορίες/ καταλόγους.

Όποτε διαλέγετε καινούργια φαγητά, ελέγξετε της ποσότητα σακχάρου στο αίμα για να δείτε πως τα διαφορετικά φαγητά επηρεάζουν το επίπεδο της γλυκόζης του αίματος.

Οι περισσότερες τροφές από την ομάδα υδατανθράκων παρέχουν περίπου την ίδια ποσότητα υδατανθράκων ανά μερίδα. Έτσι, λοιπόν, μπορείτε να ανταλλάξετε τις επιλογές του ψωμιού/ισοδύναμων, των φρούτων, του γάλακτος στο πρόγευμα της διατροφής σας. Τα λαχανικά ανήκουν στην ομάδα των υδατανθράκων αλλά περιέχουν μόνο 5γρ. υδατανθράκων.

Οι ημερήσιες διαβητικές ανταλλαγές μπορούν να υπολογιστούν για τον διαβητικό από εγγεγραμμένο διαιτολόγο/κλινικό διαιτολόγο σύμφωνα με τις θερμιδικές ανάγκες του ατόμου, τα επίπεδα της γλυκόζης του αίματος, και τη φαρμακευτική αγωγή του ατόμου σε συνεννόηση με τον θεράποντα ιατρό.

Κατάλογος αμύλου (Ψωμί/Δημητριακά/Ισοδύναμα)

Αμυλούχες τροφές θεωρούνται τα δημητριακά, τα μακαρόνια, το ψωμί, τα αμυλούχα λαχανικά όπως μπιζέλια, τα όσπρια.

Κάθε ΜΙΑ ΜΕΡΙΔΑ ψωμίου ανταλλάσσεται με ΕΝΑ απο τα ακολουθα:

1 φέτα ψωμί (25-30γρ) – ολικής αλέσεως ή άσπρο
1/3 φ όσπρια
1/3 φ ρύζι
1/2 φ πουργούρι/κριθαράκι
1/3 φ κουσκούς
1/2 φ μπιζέλι ή καλαμπόκι
1/2 φ μακαρόνια
90 ρ. πατάτα (βραστή ή οφτή – μικρή πατάτα)
1/2 φ πατάτες πουρέ
1 digestive
2-3 φρυγανιές (ολικής αλέσεως)
2 παξιμάδια (μικρά 4 ίντσες Χ ½ ίντσα)
2-3 κράκερ
3/4 φ έτοιμα δημητριακά προγεύματος καλαμποκιού
1/2 φ έτοιμα δημητριακά προγεύματος πίτουρου
1/3 φ μαγειρευτά δημητριακά προγεύματος βρώμης
25-30 γρ. (1/4) πίττα (μεγάλη)
1/2 φραντζολάκι μικρό (25-30γρ)
1φ γλυκοκόλοκο (με κίτρινη ψίχα)
1/2 φ κολοκάσι
1/2 φ γλυκοπατάτα
3 φ ποπ-κορν
3 Κ αλεύρι καλαμποκιού (κορνφλάουερ)
1/2 φ φρέσκα κουκιά
3 Κ αλεύρι
5-6 κάστανα
30 γρ φύλλο (1)

Σημείωση: *οι πιο πανω ποσότητες είναι για μαγειρεμένα, εκτός και αν διευκρινιστεί διαφορετικά)*

Κατάλογος φρούτων και τα ισοδύναμα τους

Κάθε ΜΙΑ ΜΕΡΙΔΑ των ακόλουθων φρούτων ανταλλάσσεται με ΕΝΑ απο τα ακολουθα:

1/2 φ χυμό πορτοκαλιού
1/2 φ χυμό κύτρου (grapefruit)
1/2 φ χυμό ανανά
1/3 φ χυμό σταφυλιού
*1/3 χυμό δαμάσκηνου
2 σύκα, μικρά
1/2 κίτρο (grapefruit)
1 πορτοκαλι, μικρό
2 μανταρίνια, μικρά
*1 μήλο, μικρό
1 μπανάνα, μικρή
15 ρόγες σταφυλιού, μικρές
1 ροδάκινο μέτριο
1 αχλάδι, μικρό
12 κεράσια, μικρά
1 ακτινίδιο
4 βερίκοκα (χρυσόμηλα)
4 μούσμουλα (μέσπιλα)
120 γρ. φραγκόσυκα (παπουτσόσυκα)
170 γρ ρόδι (3/5)
2 φορμόζες μικρές
1 νεκταρίνι μικρό
1 φ πεπόνι (κύβοι)
1 & 1/4 φ καρπούζι (κύβοι) (229 γρ)
*1 & 1/4 φ φράουλες (σωστές)
*3 ποστά δαμάσκηνα (μέτρια)
2 Κ σταφίδες
*1 & 1/2 ποστόσυκο
*4 ποστά βερίκοκα (χρυσόμηλα)
3 φοινίκια
1+ 1/3 φ (220 γρ) πεπόνιου
1/2 φ φρουτοσαλάτα
1/2 μάγκο, μικρό
1 λοτό, μικρό

(*) Υψηλή ποσότητα φυτικών ινών/ κυτταρίνη

Κατάλογος γάλακτος

Άπαχο Γάλα

Άπαχο γάλα	1 φλ.
1/2 % γάλα	1 φλ.
1% γάλα	1 φλ
Γάλα, σκόνη άπαχο	1/3 φλ
Αγνό, άπαχο γιαούρτι	1 φλ.

Ημιαποβουτυρωμένο γάλα (χαμηλό σε λιπαρά)

Εβαπορέ άπαχο γάλα	1/2 φλ
2% γάλα	1 φλ.
Ημιαποβουτυρωμένο γιαούρτι	1 φλ.

Πλήρες γάλα

Ολόπαχο γάλα	1 φλ.
Εβαπορέ πλήρες γάλα	1/2 φλ.
Γιαούρτι πλήρες	1 φλ.

$$ΔΜΣ = \frac{Βάρος}{(ύψος)^2}$$

Το βάρος σε κιλά και το ύψος σε μέτρα (m)

Για ένα άτομο βάρους 50kg και ύψους 1.57m είναι ΔΜΣ είναι = $\frac{50}{(1.57)^2}$ = 20.3 που βρίσκεται μέσα στα επιθυμητά όρια.

ΔΜΣ	Βαθμός κινδύνου για προβλήματα υγείας
20-25	Πολύ χαμηλός κίνδυνος
26-30	Χαμηλός κίνδυνος
31-35	Μέτριος κίνδυνος
36-40	Υψηλός κίνδυνος
40+	Πολύ υψηλός κίνδυνος

Αν πίνετε αλκοόλ: Ελέγξτε αν το αλκοόλ επηρεάζει τις πιθανές παθήσεις ή επιπλοκές που παρουσιάζονται (π.χ. καρδιοπάθειες) ή τα φάρμακα που παίρνετε. Ακόμα όμως και αν σας επιτρέπεται να πίνετε [illegible] διαβητικές ανταλλαγές [illegible] με τα ισοδύναμά τους π.χ. ½ φλ. ξηρό κρασί ισοδυναμεί με 2 κουταλάκια λάδι που πρέπει να αφαιρεθούν από τις ημερήσιες σας ανταλλαγές.

Επίσης θα πρέπει να ξέρετε ότι το αλκοόλ σε άδειο στομάχι μπορεί να προκαλέσει υπογλυκαιμία.

Διαβητικές Ανταλλαγές Αλκοόλ		
1 ¼ φλ. Μπίρα	=	1 μερίδα ψωμιού + 2 κουταλάκια του γλυκού λάδι
45ml (3 κουταλιές της σούπας) ουίσκι	=	2 κουταλάκια του γλυκού λάδι
90ml (6 κουταλιές της σούπας) κρασί ξηρό	=	2 κουταλάκια του γλυκού λάδι

Για την αντιμετώπιση της υπογλυκαιμίας (10γρ. γρήγορη ενέργεια υδατάνθρακα)
120ml (½ φλ.) χυμό πορτοκαλιού ή μήλου
60ml (4 κουταλιές της σούπας) χυμό σταφυλιού
90ml (6 κουταλιές της σούπας) αναψυκτικό όχι διαίτης
2 κουταλάκια του γλυκού σιρόπι καλαμποκιού / [illegible]
2 ½ κουταλάκια του γλυκού ζάχαρη
5-6 Lifesavers [illegible]
2 κουταλάκια του γλυκού μαρμελάδα
¼ - ½ φλ. Lucozade (ποτό ενέργειας)
2-3 κουταλιές της σούπας Λεμονάδα Squash

Ποιές είναι οι Θρεπτικές Ουσίες:

Υδατάνθρακες:	- Πηγή ενέργειας του εγκεφάλου και μυών. - Άμυλο (ψωμί, μακαρόνια, δημητριακά, πατάτα, όσπρια, ρύζι). - Ζάχαρη (φυσική – φρούτα, γάλα, λαχανικά αλλά και επιπρόσθετη – γλυκά, μαρμελάδα). - 1γρ υδατάνθρακα (CHO) παρέχει 4 θερμίδες - Ο οργανισμός χρειάζεται ινσουλίνη για την χρησιμοποίηση CHO
Πρωτεΐνη:	- Οικοδομεί το σώμα – παραγωγή/ανανέωση κυττάρων – ενέργεια - Κρέας, ψάρι, γάλα, αυγά, όσπρια - 1γρ πρωτεΐνης (Pro) παρέχει 4 θερμίδες - Ο οργανισμός χρειάζεται ινσουλίνη για την χρησιμοποίηση της πρωτεΐνης.
Λίπος:	- Μεταφορέας λιποδιαλυτών βιταμινών, θερμοστάτης οργανισμού, ενέργεια. - Κορεσμένο (ζωικό + φοινικέλαιο, ινδοκάρυδο), μονοακόρεστο (ελαιόλαδο), πολυακόρεστο (καλαμποκέλαιο, ψάρι). - Λάδια, βούτυρο, μαργαρίνη, λίπος κρέατος και κοτόπουλου, ολόπαχα γαλακτοκομικά - 1γρ λίπους (Fat) παρέχει 9 θερμίδες - Ο οργανισμός χρειάζεται ινσουλίνη για την αποθήκευση του λίπους στον οργανισμό.
Βιταμίνες και Ιχνοστοιχεία:	- Διαδραματίζουν λειτουργικό και ρυθμιστικό ρόλο στον οργανισμό - Κάθε βιταμίνη ή ιχνοστοιχείο παρέχουν τη δική τους λειτουργία - Ικανοποιητικές ποσότητες CHO-Pro-Fat παρέχουν επαρκείς ποσότητες αυτών των ουσιών.
Νερό:	- Μεταφορέας θρεπτικών ουσιών, θερμοκρασία του σώματος, Μεταβολισμός - 6-8 φλ/Μέρα - Πόσιμο νερό τρόφιμο.

Μετρήσεις:
1 φλ. = 250ml — φ = φλυτζάνι
1 κουταλιά σούπας (Κ) = 15ml — Κ = κουτάλι σούπας
1 κουταλάκι γλυκού (κ/γ) = 5ml — κ/γ = κουταλάκι γλυκού

Κατάλογος λαχανικών

Κάθε ΜΙΑ ΜΕΡΙΔΑ λαχανικών ανταλλάσσεται με ΕΝΑ απο τα ακόλουθα:

1 φ λαχανικά φρέσκα/ σαλάτα
1/2 φ χόρτα μαγειρεμένα
1/2 φ χυμό λαχανικών
(Όλα τα χόρτα/λαχανικά εκτός το μπιζέλι, καλαμπόκι, γλυκοκόλοκο, κολοκάσι. Τα πιο πάνω επιτρέπονται μόνο όταν αντικαθιστούν το ψωμί).

Παραδείγματα λαχανικών:
αγκινάρα
φασολάκι (φρέσκο)
χυμός ντομάτας
κοκκινογούλια (βραστά)
κραμπί
κρεμμύδι
ντομάτα (1 μεγαλη)
κολοκύθι (άσπρο)
λάχανα
σπανάκι
πιπεριά (πράσινα)
καρότα

Γενικά όλα τα φυλλώδη πράσινα χόρτα

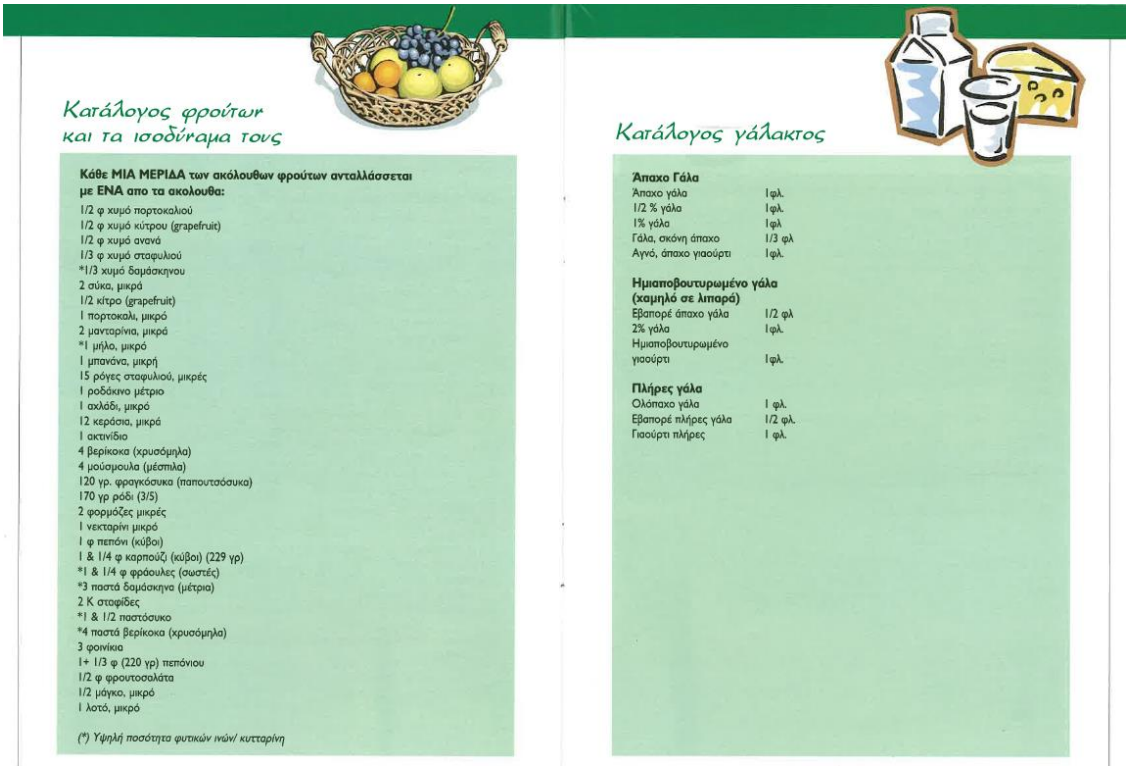
Κατάλογος κρέατος*

Κάθε ΜΙΑ ΜΕΡΙΔΑ κρέατος/ισοδύναμα ανταλλάσσεται με ΕΝΑ απο τα ακόλουθα:

30 γρ τυρί, χαμηλό σε λιπαρά
**30 γρ. τυρί
**30 γρ χαλούμι ή φέτα
**35 γρ. αναρή
**2 Κ αναρή/χαλούμι τριμμένο
**30 γρ. χαμ/λούντζα
1/4 φ. cottage cheese, χαμηλό σε λιπαρά
1/4 φ τόνο (χωρίς λάδι)
2 σαρδέλες
6 κανονικά στρείδια
30 γρ. γαρίδες
30 γρ. καβούρι
30 γρ. αστακό
30 γρ. κοτόπουλο (χωρίς το δέρμα)
30 γρ. κουνέλι
30 γρ. ψάρι
30 γρ. στρουθοκάμηλος
**1 αυγό (ΟΧΙ περισσότερα απο 3 την εβδομάδα)
2 ασπράδια
**30 γρ. κιμά
**30 γρ. χοιρινό
**30 γρ. βοδινό
** 30 γρ συκώτι
120 γρ. (1/2) τοφού
2Κ φυστικοβούτυρο
1 φλ. γάλα σόγιας
**3 φέτες μπέικον
**30 γρ. σιεφταλιές

*** Παραδείγματα τροφών με μέτριο ή αυξημένο κορεσμένο λίπος*

- Αφαιρείτε το λίπος πριν τα μαγειρέψετε
- Ζυγίζετε/μετράτε μαγειρεμένα
- Οι ποσοτητες πιο πάνω είναι στη σχάρα ή χωρίς λάδι



Κατάλογος φρούτων και τα ισοδύναμα τους

Κάθε ΜΙΑ ΜΕΡΙΔΑ των ακόλουθων φρούτων ανταλλάσσεται με ΕΝΑ απο τα ακολουθα:

1/2 φ χυμό πορτοκαλιού
1/2 φ χυμό κύτρου (grapefruit)
1/2 φ χυμό ανανά
1/3 φ χυμό σταφυλιού
*1/3 χυμό δαμάσκηνου
2 σύκα, μικρά
1/2 κίτρο (grapefruit)
1 πορτοκάλι, μικρό
2 μανταρίνια, μικρά
*1 μήλο, μικρό
1 μπανάνα, μικρή
15 ρόγες σταφυλιού, μικρές
1 ροδάκινο μέτριο
1 ακλάδι, μικρό
12 κεράσια, μικρά
1 ακτινίδιο
4 βερίκοκα (χρυσόμηλα)
4 μούσμουλα (μέσπιλα)
120 γρ. φραγκόσυκα (παπουτσόσυκα)
170 γρ ρόδι (3/5)
2 φορμόζες μικρές
1 νεκταρίνι μικρό
1 φ πεπόνι (κύβοι)
1 & 1/4 φ καρπούζι (κύβοι) (229 γρ)
*1 & 1/4 φ φράουλες (σωστές)
*3 ποστά δομάσκηνα (μέτρια)
2 Κ στοφίδες
*1 & 1/2 ποστόσυκο
*4 ποστά βερίκοκα (χρυσόμηλα)
3 φοινίκια
1+ 1/3 φ (220 γρ) πεπόνιου
1/2 φ φρουτοσαλάτα
1/2 μάγκο, μικρό
1 λοτό, μικρό

(*) Υψηλή ποσότητα φυτικών ινών/ κυτταρίνη

Κατάλογος γάλακτος

Άπαχο Γάλα

Άπαχο γάλα	1 φλ.
1/2 % γάλα	1 φλ.
1% γάλα	1 φλ
Γάλα, σκόνη άπαχο	1/3 φλ
Αγνό, άπαχο γιαούρτι	1 φλ.

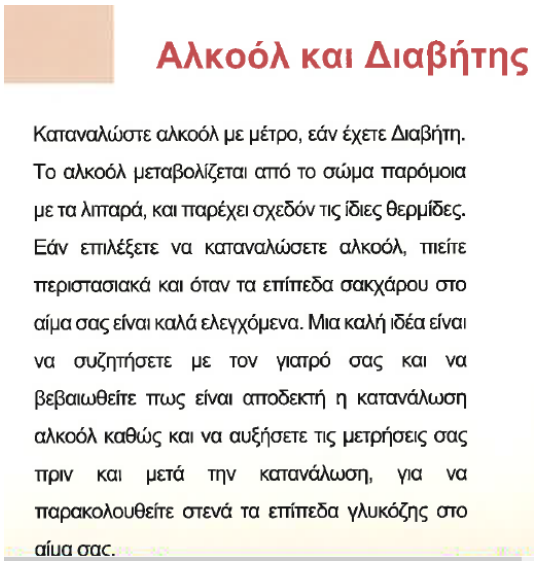
Ημιαποβουτυρωμένο γάλα (χαμηλό σε λιπαρά)

Εβαπορέ άπαχο γάλα	1/2 φλ
2% γάλα	1 φλ.
Ημιαποβουτυρωμένο γιαούρτι	1 φλ.

Πλήρες γάλα

Ολόπαχο γάλα	1 φλ.
Εβαπορέ πλήρες γάλα	1/2 φλ.
Γιαούρτι πλήρες	1 φλ.

Examples of educational leaflets for alcohol and diabetes



Αλκοόλ και Διαβήτης

Καταναλώστε αλκοόλ με μέτρο, εάν έχετε Διαβήτη. Το αλκοόλ μεταβολίζεται από το σώμα παρόμοια με τα λιπαρά, και παρέχει σχεδόν τις ίδιες θερμίδες. Εάν επιλέξετε να καταναλώσετε αλκοόλ, πιείτε περιστασιακά και όταν τα επίπεδα σακχάρου στο αίμα σας είναι καλά ελεγχόμενα. Μια καλή ιδέα είναι να συζητήσετε με τον γιατρό σας και να βεβαιωθείτε πως είναι αποδεκτή η κατανάλωση αλκοόλ καθώς και να αυξήσετε τις μετρήσεις σας πριν και μετά την κατανάλωση, για να παρακολουθείτε στενά τα επίπεδα γλυκόζης στο αίμα σας.

Examples of educational leaflets for hypoglycaemia

Τι είναι υπογλυκαιμία;

Υπογλυκαιμία είναι η κατάσταση κατά την οποία τα επίπεδα της γλυκόζης (σακχάρου) αίματος πέφτουν κάτω από 70mg/dl με ή χωρίς συμπτώματα. Τα επίπεδα γλυκόζης σε άτομα με διαβήτη μπορεί να είναι απρόβλεπτα και μερικές φορές πολύ χαμηλά λόγω της φαρμακευτικής αγωγής (δισκία ή ινσουλίνη). Η υπογλυκαιμία είναι δυνητικά επικίνδυνη για τη ζωή του ατόμου. Γι' αυτό, η πρόληψή της με την έγκαιρη αναγνώριση και αντιμετώπιση των συμπτωμάτων είναι πολύ σημαντική.

Τι προκαλεί την υπογλυκαιμία;

- Καθυστέρηση ή παράληψη γευμάτων
- Υπερβολική δόση ινσουλίνης ή δισκίων σε σχέση με το φαγητό
- Κατανάλωση αλκοόλ σε υπερβολική ποσότητα ή χωρίς συνοδεία φαγητού
- Μη προγραμματισμένη ή έντονη σωματική δραστηριότητα
- Ακραίες θερμοκρασίες, ζεστό μπάνιο ή σάουνα
- Λήψη άλλων φαρμάκων

Ποια είναι τα συμπτώματα της υπογλυκαιμίας;

Η σοβαρή υπογλυκαιμία, αν δεν αντιμετωπιστεί άμεσα, μπορεί να οδηγήσει σε κώμα.

Πώς να αντιμετωπίσετε την υπογλυκαιμία;

Για άμεση αντιμετώπιση μπορείτε να πάρετε **ΕΝΑ** από τα ακόλουθα:

- ½ κουτάκι κανονικού αναψυκτικού (όχι διαίτης ή χωρίς ζάχαρη)
- ½ ποτήρι ή ένα μικρό κουτάκι χυμό πορτοκάλι
- 3 ή 4 δισκία γλυκόζης (διατίθενται στα φαρμακεία)
- 2-3 φακελάκια ή 1 κουταλιά σούπας ζάχαρη
- 1 κουταλιά σούπας μέλι ή μαρμελάδα
- 5-6 σκληρές καραμέλες (με ζάχαρη)

Εάν δεν αισθάνεστε καλύτερα ή αν τα επίπεδα γλυκόζης είναι ακόμη χαμηλά μετά από 15 λεπτά, επαναλάβετε **ΕΝΑ** από τα πιο πάνω μέτρα.

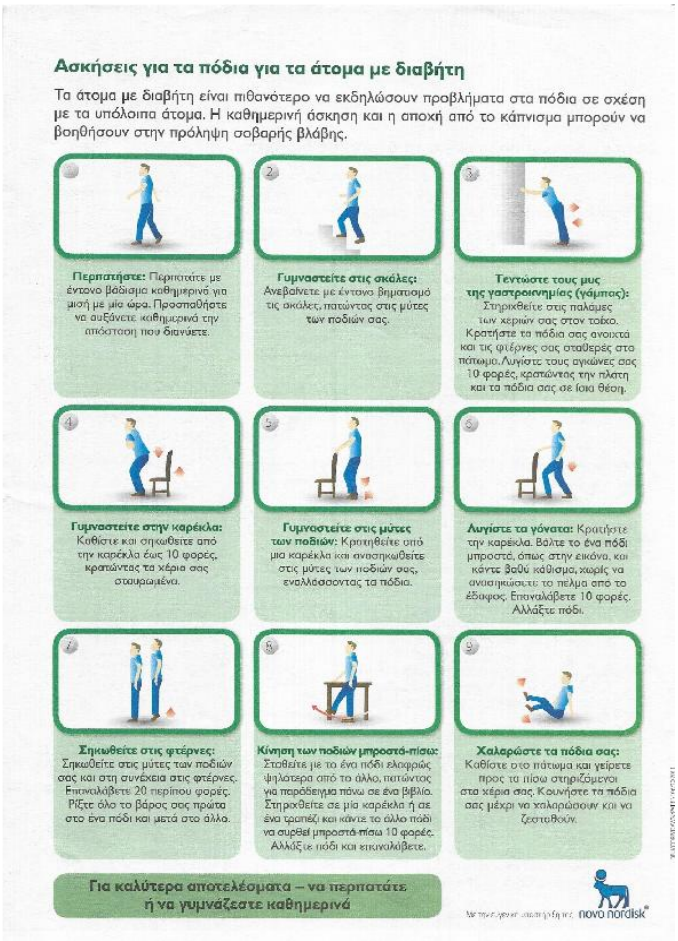
Όταν αρχίσετε να αισθάνεστε καλύτερα, φάτε λίγο αμυλούχο φαγητό όπως ένα σάντουιτς, μια μπανάνα ή ένα ποτήρι γάλα, ή το κανονικό σας γεύμα, εάν αυτό θα ακολουθήσει σε λιγότερο από 1 ώρα.

Να προτιμάτε τα πιο πάνω μέτρα και να αποφεύγετε την κατανάλωση σοκολάτας (κυρίως σε μεγάλες ποσότητες) ή γλυκών με κρέμα ή βούτυρο για να διορθώσετε την υπογλυκαιμία.

Πώς να αποφύγετε την υπογλυκαιμία;

- Να τηρείτε το πρόγραμμα των γευμάτων σας όπως έχει καθοριστεί από τον ιατρό σας
- Να παίρνετε τα φάρμακα σας σύμφωνα με τις οδηγίες του ιατρού σας
- Σε περίπτωση κατανάλωσης αλκοόλ, να γίνεται με μέτρο και με συνοδεία φαγητού
- Να τρώτε περισσότερους υδατάνθρακες (αμυλούχες τροφές) πριν και μετά από σωματική άσκηση
- Να ελέγχετε τα επίπεδα γλυκόζης του αίματός σας με την συχνότητα που σας έχει συμβουλέψει ο ιατρός σας ή αν παρουσιάσετε ένα από τα συμπτώματα της υπογλυκαιμίας που αναφέρονται πιο πάνω

Examples of educational leaflets for exercise and foot care and diabetes



Ασκήσεις για τα πόδια για τα άτομα με διαβήτη

Τα άτομα με διαβήτη είναι πιθανότερο να εκδηλώσουν προβλήματα στα πόδια σε σχέση με τα υπόλοιπα άτομα. Η καθημερινή άσκηση και η αποχή από το κάπνισμα μπορούν να βοηθήσουν στην πρόληψη σοβαρής βλάβης.

1

Περπατήστε: Περπατάτε με έντονο βάδισμα καθημερινά για μισή με μία ώρα. Προσπαθήστε να αυξάνετε καθημερινά την απόσταση που διανύετε.

2

Γυμναστείτε στις σκάλες: Ανεβαίνετε με έντονο βηματισμό τις σκάλες, πατώντας στις μύτες των ποδιών σας.

3

Τεντώστε τους μυς της γαστροκνημίας (γάμπος): Στηριχθείτε στις παλάμες των χεριών σας στον τοίχο. Κρατήστε τα πόδια σας ανοικτά και τις φτέρνες σας σταθερές στο πάτωμα. Λυγίστε τους αγκώνες σας 10 φορές, κρατώντας την πλάτη και τα πόδια σας σε ίσια θέση.

4

Γυμναστείτε στην καρέκλα: Καθίστε και σηκωθείτε από την καρέκλα έως 10 φορές, κρατώντας τα χέρια σας σταυρωμένα.

5

Γυμνοστείτε στις μύτες των ποδιών: Κρατηθείτε από μια καρέκλα και ανασηκωθείτε στις μύτες των ποδιών σας, εναλλάσσοντας τα πόδια.

6

Λυγίστε τα γόνατα: Κρατήστε την καρέκλα. Βάλτε το ένα πόδι μπροστά, όπως στην εικόνα, και κάντε βαθύ κάθισμα, χωρίς να ανασηκώσετε το πέλμα από το έδαφος. Επαναλάβετε 10 φορές. Αλλάξτε πόδι.

7

Σηκωθείτε στις φτέρνες: Σηκωθείτε στις μύτες των ποδιών σας και στη συνέχεια στις φτέρνες. Επαναλάβετε 20 περίπου φορές. Ρίξτε όλο το βάρος σας πρώτα στο ένα πόδι και μετά στο άλλο.

8

Κίνηση των ποδιών μπροστά-πίσω: Σταθείτε με το ένα πόδι ελαφρώς ψηλότερα από το άλλο, πατώντας για περάδειγμα πάνω σε ένα βιβλίο. Στηριχθείτε σε μία καρέκλα ή σε ένα τραπέζι και κάντε το άλλο πόδι να σύρθει μπροστά-πίσω 10 φορές. Αλλάξτε πόδι και επαναλάβετε.

9

Χαλαρώστε τα πόδια σας: Καθίστε στο πάτωμα και γείρετε προς τα πίσω στηριζόμενοι στα χέρια σας. Κουνήστε τα πόδια σας μέχρι να χαλαρώσουν και να ζεστεθούν.

Για καλύτερα αποτελέσματα – να περπατάτε ή να γυμνάζεστε καθημερινά

novo nordisk

ΟΜΑΔΑ ΜΕΛΕΤΗΣ ΘΕΡΑΠΕΥΤΙΚΗΣ ΕΚΠΑΙΔΕΥΣΗΣ

Φροντίδα των ποδιών για τα άτομα με διαβήτη

Τα άτομα με διαβήτη πρέπει να προσέχουν ιδιαίτερα τα πόδια τους. Θα πρέπει να πραγματοποιούν πλήρη εξέταση ποδιού κάθε χρόνο. Η σελίδα αυτή δείχνει ορισμένα πράγματα που μπορείτε να κάνετε για να διατηρείτε τα πόδια σας υγιή.

Πλένετε τα πόδια σας με χλιαρό νερό καθημερινά.

Φοράτε καθαρές, μαλακές κάλτσες σωστού μεγέθους.

Στεγνώνετε καλά τα πόδια σας, ειδικά ανάμεσα στα δάχτυλα.

Κρατάτε τα πόδια σας ζεστά και στεγνά. Φοράτε πάντα παπούτσια σωστού μεγέθους.

Διατηρείτε το δέρμα σας μαλακό με ενυδατική κρέμα, αλλά μην εφαρμόζετε την κρέμα ανάμεσα στα δάχτυλα.

Μην περπατάτε ξυπόλυτοι μέσα ή έξω από το σπίτι.

Παρατηρείτε καθημερινά τα πόδια σας για κοψίματα, μώλωπες, φουσκάλες ή οίδημα. Ενημερώστε αμέσως τον γιατρό σας εάν κάτι δεν σας φανεί φυσιολογικό.

Εξετάζετε τα παπούτσια σας καθημερινά για σκισίματα, χαλίκια, νύχια ή οτιδήποτε άλλο θα μπορούσε να πληγώσει τα πόδια σας.

Ρωτήστε την ομάδα θεραπείας του διαβήτη σας για τον τρόπο φροντίδας των νυχιών των ποδιών.

Φροντίζετε τα πόδια σας. Κινηθείτε. Ο καθημερινός περίπατος με έντονο βάδισμα θα σας κάνει καλό.

Οι παραπάνω οδηγίες είναι ενδεικτικές, για συγκεκριμένες οδηγίες επικοινωνήστε με το θεράποντα ιατρό σας.

Appendix 4.10 Templates of message conversations between the pharmacist and a participant.

Occasion	Template of message
To schedule the next appointment.	Good morning/ afternoon, Mr/Mrs (name). My name is Mrs. (name of the pharmacist), the researcher from the DC. Hoping you are doing well. Please let me know whenever you wish and if you are available to schedule our next appointment. Have a nice day, Antria.
To inform the participants that the educational leaflets were sent to them (via different media).	**Viber application/ Email** Good morning/good afternoon, Mr/Mrs (name). Hoping you are doing well. Below you can find the education leaflet regarding (relevant topic). For anything needed you need regarding diabetes, I am at your disposal. Have a nice day, Antria.
	(If educational leaflets were sent via Post/Fax) Good morning/good afternoon, Mr/Mrs (name). Hoping you are doing well. I have sent you the education leaflet regarding (relevant topic) through post/fax today. For anything needed you need regarding diabetes, I am at your disposal. Have a nice day, Antria.
To respond to participants' queries.	Good morning/good afternoon, Mr/Mrs (name). Hoping you are doing well. I am sending you (a service for the relevant query). For anything needed you need regarding diabetes, I am at your disposal. Have a nice day, Antria.
When the participant was not responding to the pharmacist's messages/calls.	Good morning/good afternoon, Mr/Mrs (name). I was calling you to see how you are going with diabetes management. There is no problem if you wish to stop this research. If you are interested and available, we could have a final appointment regarding your experience in this intervention. It will only take a few minutes. For anything needed you need regarding diabetes, I am at your disposal. Have a nice day, Antria.
The messages should be written as personalized as possible, avoiding generalization. For example, "hoping you are doing well" can be replaced by "hoping you are enjoying your vacation" or "hoping you are feeling better."	

Appendix 4.11 Template of the communication between the pharmacist and the General Physician (GP) regarding a recommendation made for a review of patients' medications.

Dear Dr/diabetes nurse (name)

My name is Andria Pavlidou, and I am conducting my PhD at the diabetes clinic of the Nicosia General Hospital, which we discuss with the rest of the healthcare professionals at the diabetes clinic.

I thought it would be appropriate to inform you about one of your patients (patient's name, identity, date of birth, and date of visit). During my appointment with the patient, she/he informed me that (the issue of the patient)/ As I reviewed the patient's pharmacotherapy, I found that (the problem identified).

The recommendation was made with relevant justification/evidence and links as agreed between the pharmacist and the GPs.

Thank you very much for your time.

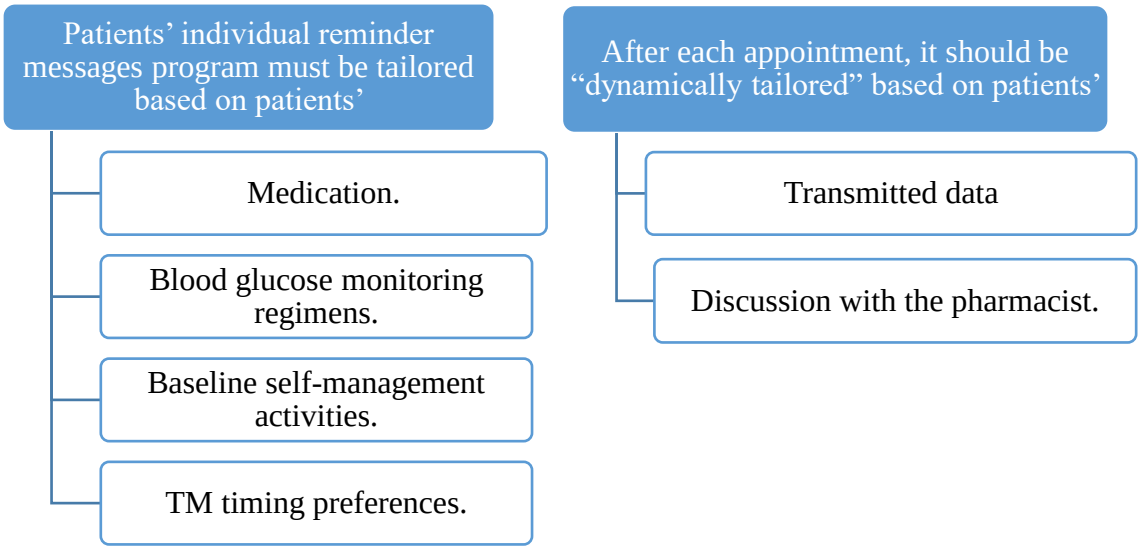
I am at your disposal for any clarification and information.

Kind regards,
Antria Pavlidou
PhD Candidate, UCL
MSc Clinical Pharmacy, International Practice, and Policy, UCL
antria.pavlidou.15@ucl.ac.uk

Appendix 4.12 Instructions for the pharmacist to follow to develop patients' individual reminder messages program and examples of reminder messages in English and Greek.

Adopted by Nundy et al., 2014a and Nundy et al., 2014b

Instructions for the pharmacist to follow to develop patients' individual reminder messages program



For example, individuals who reported low medication adherence or requested more frequent reminders, should receive more medication reminders than those with high adherence preferring fewer reminders.

Examples of reminder messages	
English language	**Greek language**
Time to check your blood sugar	Ώρα να ελέγξετε το σάκχαρό σας
Time to take your diabetes medication (name of drug brand/active substance)	Ώρα να πάρετε το φάρμακο (όνομα εμπορικής ονομασίας / δραστικής ουσίας
Do not forget to refill your medication	Μην ξεχάσετε να ξαναγεμίσετε τα φάρμακά σας
Time to arrange your next appointment with	Ώρα να οργανώσετε το επόμενο ραντεβού σας με
Do not forget your appointment on	Μην ξεχάσετε το ραντεβού σας

Request patients' responses on whether they have taken their medication.

Appendix 4.13 Education required for the provision of this intervention and education of the pharmacist who delivered the intervention.

Education required for the provision the intervention	Education of the pharmacist who delivered the intervention	Date
Motivational Interview techniques	Online Introductory 4-hour Virtual Training) by Motivational Interviewing Network of Trainers (MINT)	11/2019
Clinical background in diabetes	Diabetes and CVD IDF SCHOOL OF DIABETES	04/2018
	Diabetic Retinopathy IDF SCHOOL OF DIABETES	04/2018
	Prevention of type 2 Diabetes IDF School of Diabetes	12/2017
	Diabetes - a Global Challenge Coursera Course Certificates Credential ID 339GYDWTFB6J	01/2017
Clinical background of review of patients' medications	MSc Clinical Pharmacy, International Practice, and Policy, UCL	09/2015-09/2016

Appendix 4.14 Approval from the hospital.

Andria Pavlidou

From:
Sent: Πέμπτη, 5 Δεκεμβρίου 2019 9:16 πμ
To: 'Andria Pavlidou'
Cc: antria.pavlidou.15@ucl.ac.uk
Subject: RE: Αίτηση για γραπτή συγκατάθεση για πρόσβαση σε ιατρικά αρχεία ασθενούς της Διαβητολογικής Κλινικής του Γενικού Νοσοκομείου Λευκωσίας & αποστολή μηνύματος στους ασθενείς για την εκπόνηση διδακτορικής έρευνας

Καλημέρα,

Πέραν του πιο κάτω ηλεκτρονικού μηνύματος, θέλω να προσθέσω ότι οι ιατρικοί φάκελοι δεν επιτρέπεται να μετακινηθούν εκτός νοσοκομείου.

Αθηνά Ιερείδου

From: Athina Ieridou
Sent: Wednesday, December 4, 2019 2:16 PM
To: 'Andria Pavlidou'
Cc: 'antria.pavlidou.15@ucl.ac.uk' <antria.pavlidou.15@ucl.ac.uk>
Subject: RE: Αίτηση για γραπτή συγκατάθεση για πρόσβαση σε ιατρικά αρχεία ασθενούς της Διαβητολογικής Κλινικής του Γενικού Νοσοκομείου Λευκωσίας & αποστολή μηνύματος στους ασθενείς για την εκπόνηση διδακτορικής έρευνας

Αγαπητή κα Παυλίδου,

Σχετικά με το πιο πάνω θέμα, σας ενημερώνω ότι το αίτημα προεγκρίνεται εκ μέρους του νοσοκομείου μόνο για σκοπούς στατιστικών στοιχείων κι όχι για προσωπικά δεδομένα. Νοείται ότι η τελική έγκριση θα δοθεί από την Επιτροπή Ερευνών του Υπουργείου Υγείας.

Αθηνά Ιερείδου
Λειτουργός Υπηρεσιών Υγείας
Γενικό Νοσοκομείο Λευκωσίας

From: Andria Pavlidou
Sent: Wednesday, November 27, 2019 1:07 PM
To:
Cc: antria.pavlidou.15@ucl.ac.uk
Subject: Αίτηση για γραπτή συγκατάθεση για πρόσβαση σε ιατρικά αρχεία ασθενούς της Διαβητολογικής Κλινικής του Γενικού Νοσοκομείου Λευκωσίας & αποστολή μηνύματος στους ασθενείς για την εκπόνηση διδακτορικής έρευνας

Προς Εκτελεστικό & Επιστημονικό Διευθυντή: Κυριάκο Γεωργίου & Δρ Μάριος Λοΐζου

Αίτηση για γραπτή συγκατάθεση για πρόσβαση σε ιατρικά αρχεία ασθενούς της Διαβητολογικής Κλινικής του Γενικού Νοσοκομείου Λευκωσίας & αποστολή μηνύματος στους ασθενείς για την εκπόνηση διδακτορικής έρευνας
(απαραίτητη για την αίτηση μου για άδεια διεξαγωγής έρευνας από την Επιστημονική Επιτροπή Προώθησης Ερευνών του Υπουργείου Υγείας)

1

Appendix 4.15 Employment of the TIDieR (Template for Intervention Description and Replication) Checklist for reporting the developed intervention.

Item number	Item	**Where located in the thesis** (chapter, section, and appendix)
	BRIEF NAME	
1.	Provide the name or a phrase that describes the intervention.	A community pharmacy intervention to support self-management of patients with type 2 diabetes in Cyprus.
	WHY	
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	Chapter 4, sections: 4.2 The theoretical approach to the intervention development process and 4.3 The theoretical framework of the intervention.
	WHAT	
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	Appendices 4.1, 4.4 – 4.13 and 4.16.
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	Chapter 4, section 4.11 The delivery of the intervention.
	WHO PROVIDED	
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	The pharmacist delivered the intervention with continual communication with the other HCPs working at the DC (Figure 4.4 Flowchart for the service "pharmacist online advice to patient queries".). Chapter 4, section 4.5 training for the pharmacist to deliver this type of intervention and Appendix 4.13 the education required for the provision of this intervention and education of the pharmacist who delivered the intervention.
	HOW	
6.	Describe the modes of delivery (e.g., face-to-face or by some other mechanism, such as internet or telephone) of	The intervention was individualized, and each participant could choose the services and frequency of intervention they preferred. Chapter 4, section 4.11 The delivery of the intervention; the media

	the intervention and whether it was provided individually or in a group.	for intervention delivery and operational aspects of the intervention and the flowchart followed by the pharmacist can be found in Figure 4.5.
	WHERE	
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	Initial appointment at the diabetes clinic of the Nicosia General Hospital and thereafter through different media employed for the intervention delivery (Chapter 4, section 4.11 The delivery of the intervention; study location of the intervention, the media for intervention delivery, and operational aspects of the intervention).
	WHEN and HOW MUCH	
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	The flowchart followed by the pharmacist can be found in Figure 4.5, chapter 4.
	TAILORING	
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	All intervention procedures were individually driven (Chapter 4, section 4.11 The delivery of the intervention).
	MODIFICATIONS	
10.	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	No refinements were identified during the pilot period (Chapter 4, section 4.12 The pilot period and the final design of the intervention).
	HOW WELL	
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	To maintain/ improve the intervention's fidelity, data collection forms and instruments were agreed upon beforehand, piloted, and refined before the intervention's delivery (see chapter 5, section 5.6 Data collection forms and instruments). Chapter 9 evaluates the workability of the intervention.
12.	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	Chapter 9 Workability of the intervention, and Chapter 10, section 10.2 Key findings from the combined datasets.

Appendix 4.16 The completion form for each appointment with the participant.

Initial Appointment					
Please complete the form for each participant.					
Date of the appointment:			**Participant ID**		
Contact Information			**Participant's GP**		
Gender	☐ Male ☐ Female	**District**	☐ Nicosia ☐ Larnaca ☐ Limassol ☐ Paphos	**Area**	☐ Urban ☐ Rural
Baseline blood glucose		**Baseline Hba1c**	☐ Less than <7% ☐ Between 7-8%	☐ Above than >8% ☐ Data missing	
Medication regimen	**Antidiabetic pharmacotherapy**	☐ Oral medication only ☐ Oral medication and insulin			
	Other pharmacotherapy	☐ Cholesterol-lowering ☐ Cardiovascular ☐ Anticoagulants		☐ Antiplatelet ☐ Other conditions ☐ Data missing	
	Name/active ingredient			**Dose**	**Frequency**
Frequency of the monitoring regimen per:		Day:		Week:	
Topics identified from the questionnaire		☐ Education ☐ Healthy eating ☐ Physical activity		☐Medication ☐Self-monitoring of Blood Glucose	
Participant's preference		☐ Education ☐ Healthy eating ☐ Physical activity		☐Medication ☐Self-monitoring of Blood Glucose	
Goals agreed		☐ Education ☐ Healthy eating ☐Physical activity		☐Medication ☐Self-monitoring of Blood Glucose	
Services agreed		Reminders: ☐ Medication taking ☐ Medication refill ☐Self-monitoring blood glucose ☐ Appointment.		☐Tracking of blood glucose ☐ Graphic reports ☐ Education ☐Review of patients' medications	
Media of delivery		☐ At the clinic ☐ Viber messages		☐ Fax ☐ Emails	☐ Posts
Date of next appointment					

Subsequent Appointments			
Please complete the form for each participant.			
Please write the number of the appointment (e.g., 1st, 2nd, 3rd, etc.):			
Date of the appointment:		**Participant ID**	
Contact Information		**Participant's GP**	
Changes in monitoring regimen			
Changes in medication regimen			
Changes in goals/plan			
Topics identified from the questionnaire	☐ Education ☐ Healthy eating ☐ Physical activity	☐Medication ☐Self-monitoring of Blood Glucose	
Change on Services			
Goals agreed	☐ Education ☐ Healthy eating ☐Physical activity	☐Medication ☐Self-monitoring of Blood Glucose	
Services agreed	Reminders: ☐ Medication taking ☐ Medication refill ☐Self-monitoring blood glucose ☐ Appointment.	☐Tracking of blood glucose ☐ Graphic reports ☐ Education ☐Review of patients' medications	
Media of delivery	☐ At the clinic ☐ Viber messages	☐ Fax ☐ Emails	☐ Posts
Date of next appointment			

Appendix 5.1 Employment of the World Health Organization (WHO) checklist (for reporting and evaluating digital health interventions (DHIs)) to present the proposed intervention.

WHO checklist on reporting digital health interventions	Proposed Study
Infrastructure	• Phone device / Smart mobile phone device. • Internet access. • Viber application. • Post. • Fax.
Technology platform	• Viber application[1] is a cross-platform instant messaging application that enables calls, video calls, messages, videos, photographs, messages with videos or voice, etc. Publicly available application from iOS, Android, Blackberry, Windows, Mac, etc.
Interoperability/ Health Information Systems (HIS) context	• Description of how digital health intervention can integrate into existing health information systems.
Intervention delivery	• Detailed description of the delivery of the digital health intervention (including the delivery media, timing, and duration).
Intervention content	• Details of the content of the intervention were described. Source and any modifications of the intervention content are described (Source of information about Cyprus educational leaflet and regulations and laws about participants' pathways, use of available theories).
Usability/content testing	• Usability testing with the target group (participants) was evaluated.
User feedback	• Acceptability evaluation.
Access of individual participants	• Acceptability evaluation.
Cost assessment	• Cost estimation for the intervention delivery.
Adoption inputs/programme entry	• Description of how people were informed about the program and demonstration of the intervention.
Limitations for delivery at scale	• Limitations for delivery at scale were described.
Contextual adaptability	• Evaluation of implementation issues, refinement of data collection procedures, outcome measures, and workability of the proposed intervention.
Replicability	• Intervention was detailed and explained to support replicability.
Data security	• Data security procedures/ confidentiality protocols were described prior to the start of the intervention.
Compliance with national guidelines or regulatory statutes	• Description of how national and international guidelines/protocols influence the intervention was discussed.
Fidelity of the intervention	• Description of fidelity of the intervention is discussed (Was the intervention delivered as planned?).

Appendix 5.2 Ethical approvals.

ΚΥΠΡΙΑΚΗ ΔΗΜΟΚΡΑΤΙΑ

ΕΘΝΙΚΗ ΕΠΙΤΡΟΠΗ ΒΙΟΗΘΙΚΗΣ ΚΥΠΡΟΥ

Αρ. Φακ.: ΕΕΒΚ ΕΠ 2019.01.202
Αρ. Τηλ.: 22809038/039
Αρ. Φαξ: 22353878

27 Νοεμβρίου, 2019

Κυρία Άντρια Παυλίδου
Ποσκιδώνος 16Α
2303 Αγλαντζιά
Λευκωσία

Αγαπητή κυρία Παυλίδου,

Αίτηση γνωμοδότησης για την πρόταση με τίτλο:
«Feasibility pilot study and potential impact of a mobile app intervention led by pharmacist, to support and improve self-management of diabetes, in collaboration with other healthcare professionals, in Cyprus»

Αναφέρομαι στην αίτηση σας ημερομηνίας 21 Νοεμβρίου 2019 για το πιο πάνω θέμα, και επιθυμώ να σας πληροφορήσω ότι από τη μελέτη του περιεχομένου των εγγράφων που έχετε καταθέσει, που αφορούν την πιο πάνω έρευνα, η Εθνική Επιτροπή Βιοηθικής Κύπρου (ΕΕΒΚ) **γνωμοδοτεί υπέρ της διεξαγωγής της εν λόγω έρευνας.**

2. Η Επιτροπή επιθυμεί να τονίσει ότι παραμένει ευθύνη δική σας η διεξαγωγή της έρευνας με τρόπο που να τηρούνται οι πρόνοιες του νέου Ευρωπαϊκού Γενικού Κανονισμού Προστασίας Προσωπικών Δεδομένων (2016/679) και του περί της Προστασίας των Φυσικών Προσώπων Έναντι της Επεξεργασίας των Δεδομένων Προσωπικού Χαρακτήρα και της Ελεύθερης Κυκλοφορίας των Δεδομένων αυτών Νόμος του 2018 (Ν. 125(Ι) /2018).

3. Σας ενημερώνουμε ότι για σκοπούς καλύτερου συντονισμού και αποφυγής επανάληψης ερευνών με το ίδιο θέμα ήδη υπό εξέταση πληθυσμό μέσα σε σύντομο σχετικά χρονικό διάστημα, η ΕΕΒΚ δημοσιεύει στην ιστοσελίδα της το θέμα της έρευνας, τον φορέα και τον υπό εξέταση πληθυσμό.

4. Κατά τη διάρκεια εκπόνησης της έρευνας, ο συντονιστής / επιστημονικός υπεύθυνος θα ενημερώνει την ΕΕΒΚ για κάθε τροποποίηση των αρχικά κατατεθειμένων εγγράφων (πρωτόκολλο ή άλλα ερευνητικά έγγραφα) και θα υποβάλλει τις απαιτούμενες έντυπες τροποποιήσεις στην Επιτροπή.

5. Σε περίπτωση διακοπής της έρευνας, ο συντονιστής/ επιστημονικός υπεύθυνος θα ενημερώσει γραπτώς την Επιτροπή κάνοντας αναφορά και στους λόγους διακοπής της έρευνας.

.../2

Andria Pavlidou

From:
Sent: Κυριακή, 5 Απριλίου 2020 8:13 μμ
To: apavlidou@phs.moh.gov.cy; antria.pavlidou.15@ucl.ac.uk
Subject: Application for conducting research at SHSO

Importance: High

SHSO Protocol No *01/20*

Dear Antria,

this is to formally inform you that your application to the Scientific Council of SHSO for conducting your research project with title:

'Feasibility pilot study and potential impact of a mobile app intervention led by pharmacist, to support and improve self-management of diabetes, in collaboration with other healthcare professionals, in Cyprus'

was approved.

Wishing you every success with your project,

Best regards

Dr Carolina Stylianou
Coordinator for Approval of Research Projects
Scientific Council
State Health Services Organisation

Cyprus

20200428 Email confirm Z6364106 2020 04 129

Crouch, Spenser <s.crouch@ucl.ac.uk>
on behalf of
Finance.Data Protection <data-protection@ucl.ac.uk>
Tue 28/04/2020 10:35

To: Pavlidou, Antria <antria.pavlidou.15@ucl.ac.uk>

Cc: ISD.IG-Lead <ig-lead@ucl.ac.uk>

4 attachments (6 MB)

ANNEX- A- Ethical approval from Cyprus Research Committee.pdf; ANNEX B - Information leaflet (including reply slip) (English and Greek version).pdf; ANNEX-C-Consent-Form-English-and-Greek-Version.pdf; Antria Pavlidou research_registration_form_for_ucl_rec_approval_v1 3.doc;

Hi,

Thank you for your application to register with the Data Protection Office. I think the participant information sheet should by a default also include a link to a relevant privacy notice. Otherwise the requirements of Articles 13/14 will not going to be met and the researchers expose themselves to the possibility of a complaint. Please consider, update and return for our records,

With this action in mind, I am pleased to confirm that this project is now registered under, reference No Z6364106/2020/04/129 health research in line with UCL's Data Protection Policy.

You may quote this reference on your Ethics Application Form, or any other related forms,

When all essential documents are ready to archive, contact the UCL Records Office by email records.office@ucl.ac.uk to arrange ongoing secure storage of your research records unless you have made specific alternative arrangements with your department, or funder. Please note the UCL Records Office does not store student research data.

For data protection enquiries, please contact the data protection team at data-protection@ucl.ac.uk

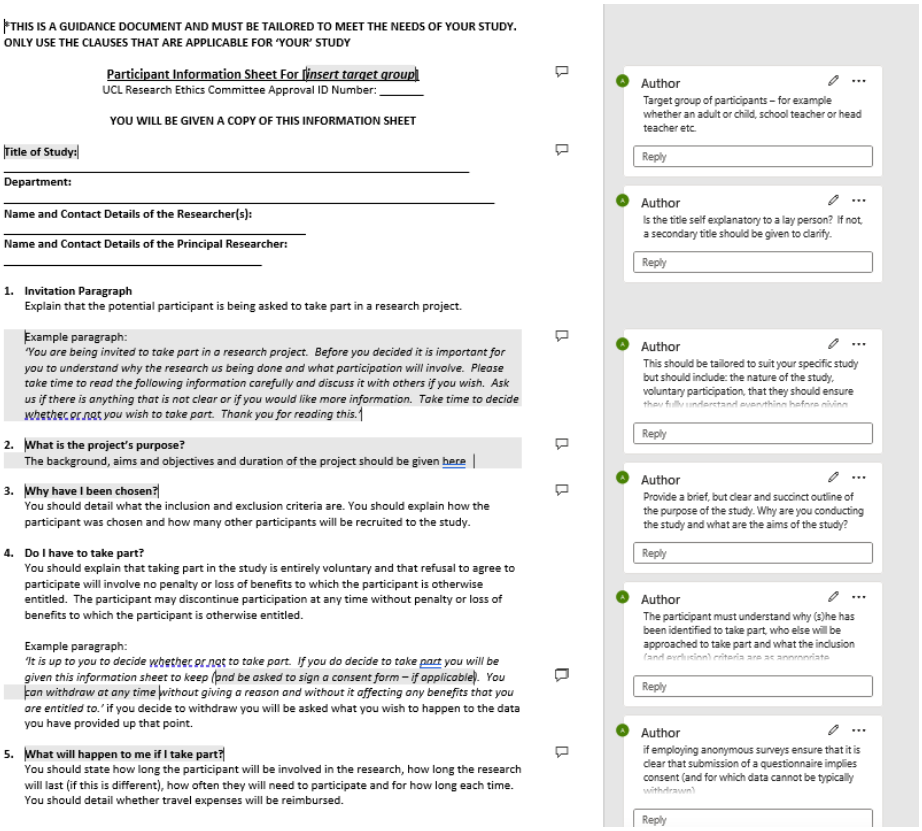
For ethics enquiries, please contact the ethics team at ethics@ucl.ac.uk.

Regards,

Spenser Crouch
Data Protection & Freedom of Information Administrator & Chief Web Editor
Legal Services, UCL | Gower Street | London | WC1E 6BT
Internal Address: 6th floor | Bidborough House | 38- 50 Bidborough Street | Kings Cross | London | WC1H 9BT
Email: s.crouch@ucl.ac.uk Data Protection: data-protection@ucl.ac.uk FOI: foi@ucl.ac.uk.
Telephone: 0203 108 8764 (internal 58764)

Please note my office working days are Tuesday and Thursday 7.30am – 3.30pm;
Home working days are Monday, Wednesday and Friday.

Appendix 5.3 The UCL Template Participant Information Sheet.



*THIS IS A GUIDANCE DOCUMENT AND MUST BE TAILORED TO MEET THE NEEDS OF YOUR STUDY. ONLY USE THE CLAUSES THAT ARE APPLICABLE FOR 'YOUR' STUDY

Participant Information Sheet For *[insert target group]*
UCL Research Ethics Committee Approval ID Number: _____

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of Study:

Department:

Name and Contact Details of the Researcher(s):

Name and Contact Details of the Principal Researcher:

1. **Invitation Paragraph**
   Explain that the potential participant is being asked to take part in a research project.

   Example paragraph:
   'You are being invited to take part in a research project. Before you decided it is important for you to understand why the research us being done and what participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.'

2. **What is the project's purpose?**
   The background, aims and objectives and duration of the project should be given here

3. **Why have I been chosen?**
   You should detail what the inclusion and exclusion criteria are. You should explain how the participant was chosen and how many other participants will be recruited to the study.

4. **Do I have to take part?**
   You should explain that taking part in the study is entirely voluntary and that refusal to agree to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled. The participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

   Example paragraph:
   'It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep (and be asked to sign a consent form – if applicable). You can withdraw at any time without giving a reason and without it affecting any benefits that you are entitled to.' if you decide to withdraw you will be asked what you wish to happen to the data you have provided up that point.

5. **What will happen to me if I take part?**
   You should state how long the participant will be involved in the research, how long the research will last (if this is different), how often they will need to participate and for how long each time. You should detail whether travel expenses will be reimbursed.

Author
Target group of participants – for example whether an adult or child, school teacher or head teacher etc.
Reply

Author
Is the title self explanatory to a lay person? If not, a secondary title should be given to clarify.
Reply

Author
This should be tailored to suit your specific study but should include: the nature of the study, voluntary participation, that they should ensure they fully understand everything before giving
Reply

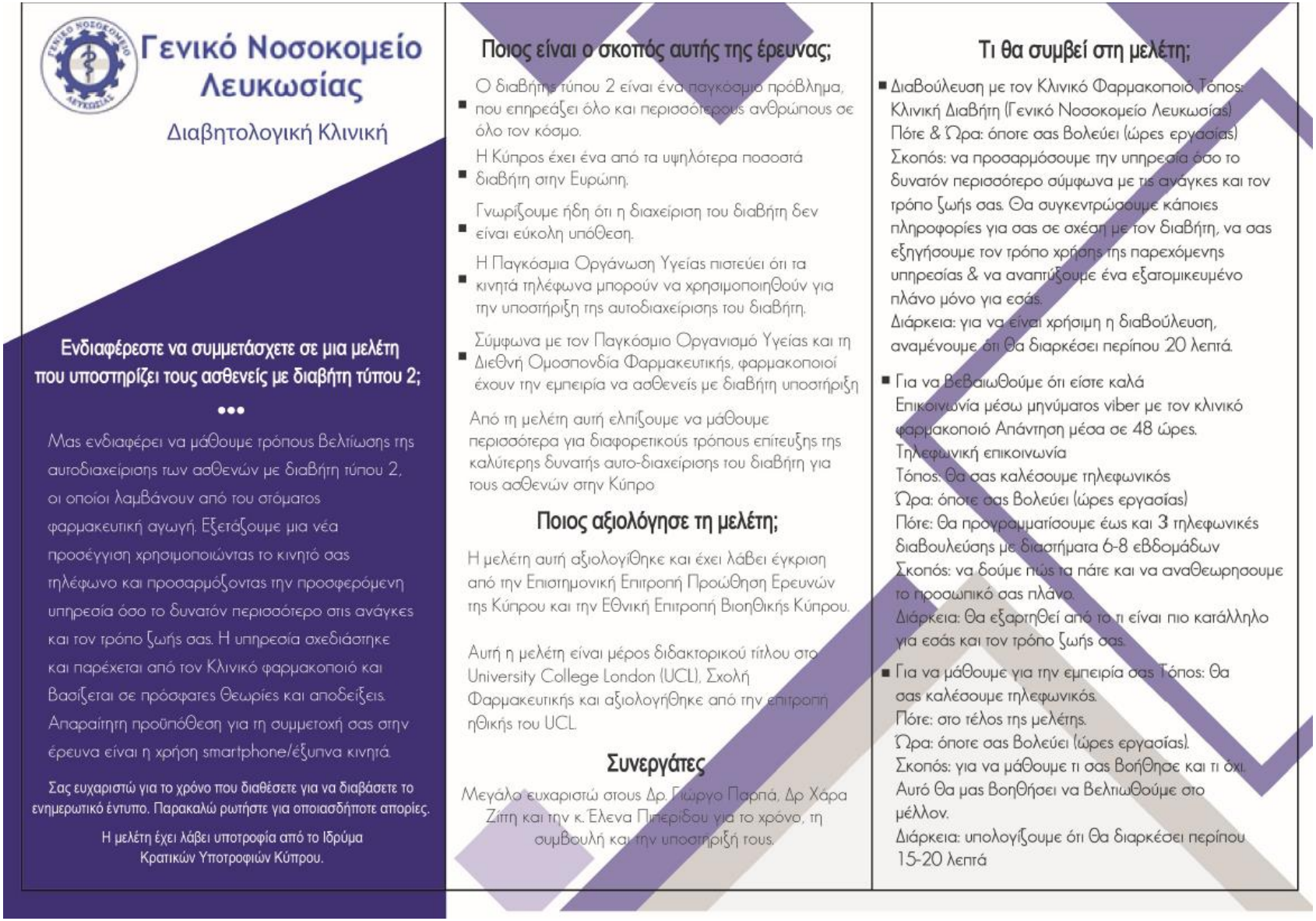
Author
Provide a brief, but clear and succinct outline of the purpose of the study. Why are you conducting the study and what are the aims of the study?
Reply

Author
The participant must understand why (s)he has been identified to take part, who else will be approached to take part and what the inclusion (and exclusion) criteria are as appropriate
Reply

Author
if employing anonymous surveys ensure that it is clear that submission of a questionnaire implies consent (and for which data cannot be typically withdrawn)
Reply

Appendix 5.4 Information leaflet, with the patients' expression of interest reply slip and consent form

Information Leaflet



Γενικό Νοσοκομείο Λευκωσίας

Διαβητολογική Κλινική

Ενδιαφέρεστε να συμμετάσχετε σε μια μελέτη που υποστηρίζει τους ασθενείς με διαβήτη τύπου 2;

•••

Μας ενδιαφέρει να μάθουμε τρόπους Βελτίωσης της αυτοδιαχείρισης των ασθενών με διαβήτη τύπου 2, οι οποίοι λαμβάνουν από του στόματος φαρμακευτική αγωγή. Εξετάζουμε μια νέα προσέγγιση χρησιμοποιώντας το κινητό σας τηλέφωνο και προσαρμόζοντας την προσφερόμενη υπηρεσία όσο το δυνατόν περισσότερο στις ανάγκες και τον τρόπο ζωής σας. Η υπηρεσία σχεδιάστηκε και παρέχεται από τον Κλινικό φαρμακοποιό και βασίζεται σε πρόσφατες θεωρίες και αποδείξεις. Απαραίτητη προϋπόθεση για τη συμμετοχή σας στην έρευνα είναι η χρήση smartphone/έξυπνα κινητά.

Σας ευχαριστώ για το χρόνο που διαθέσετε για να διαβάσετε το ενημερωτικό έντυπο. Παρακαλώ ρωτήστε για οποιασδήποτε απορίες.

Η μελέτη έχει λάβει υποτροφία από το Ιδρύμα Κρατικών Υποτροφιών Κύπρου.

Ποιος είναι ο σκοπός αυτής της έρευνας;

- Ο διαβήτης τύπου 2 είναι ένα παγκόσμιο πρόβλημα, που επηρεάζει όλο και περισσότερους ανθρώπους σε όλο τον κόσμο.
- Η Κύπρος έχει ένα από τα υψηλότερα ποσοστά διαβήτη στην Ευρώπη.
- Γνωρίζουμε ήδη ότι η διαχείριση του διαβήτη δεν είναι εύκολη υπόθεση.
- Η Παγκόσμια Οργάνωση Υγείας πιστεύει ότι τα κινητά τηλέφωνα μπορούν να χρησιμοποιηθούν για την υποστήριξη της αυτοδιαχείρισης του διαβήτη.
- Σύμφωνα με τον Παγκόσμιο Οργανισμό Υγείας και τη Διεθνή Ομοσπονδία Φαρμακευτικής, φαρμακοποιοί έχουν την εμπειρία να ασθενείς με διαβήτη υποστήριξη

Από τη μελέτη αυτή ελπίζουμε να μάθουμε περισσότερα για διαφορετικούς τρόπους επίτευξης της καλύτερης δυνατής αυτο-διαχείρισης του διαβήτη για τους ασθενών στην Κύπρο

Ποιος αξιολόγησε τη μελέτη;

Η μελέτη αυτή αξιολογήθηκε και έχει λάβει έγκριση από την Επιστημονική Επιτροπή Προώθηση Ερευνών της Κύπρου και την Εθνική Επιτροπή Βιοηθικής Κύπρου.

Αυτή η μελέτη είναι μέρος διδακτορικού τίτλου στο University College London (UCL), Σχολή Φαρμακευτικής και αξιολογήθηκε από την επιτροπή ηθικής του UCL

Συνεργάτες

Μεγάλο ευχαριστώ στους Δρ. Γιώργο Παρπά, Δρ Χάρα Ζίπη και την κ. Έλενα Πηερίδου για το χρόνο, τη συμβουλή και την υποστηριξή τους.

Τι θα συμβεί στη μελέτη;

- Διαβούλευση με τον Κλινικό Φαρμακοποιό Τόπος: Κλινική Διαβήτη (Γενικό Νοσοκομείο Λευκωσίας) Πότε & Ώρα: όποτε σας βολεύει (ώρες εργασίας) Σκοπός: να προσαρμόσουμε την υπηρεσία όσο το δυνατόν περισσότερο σύμφωνα με τις ανάγκες και τον τρόπο ζωής σας. Θα συγκεντρώσουμε κάποιες πληροφορίες για σας σε σχέση με τον διαβήτη, να σας εξηγήσουμε τον τρόπο χρήσης της παρεχόμενης υπηρεσίας & να αναπτύξουμε ένα εξατομικευμένο πλάνο μόνο για εσάς. Διάρκεια: για να είναι χρήσιμη η διαβούλευση, αναμένουμε ότι θα διαρκέσει περίπου 20 λεπτά.
- Για να βεβαιωθούμε ότι είστε καλά Επικοινωνία μέσω μηνύματος viber με τον κλινικό φαρμακοποιό Απάντηση μέσα σε 48 ώρες. Τηλεφωνική επικοινωνία Τόπος: Θα σας καλέσουμε τηλεφωνικός Ώρα: όποτε σας βολεύει (ώρες εργασίας) Πότε: Θα προγραμματίσουμε έως και 3 τηλεφωνικές διαβουλεύσης με διαστήματα 6-8 εβδομάδων Σκοπός: να δούμε πώς τα πάτε και να αναθεωρησουμε το προσωπικό σας πλάνο. Διάρκεια: Θα εξαρτηθεί από το τι είναι πιο κατάλληλο για εσάς και τον τρόπο ζωής σας.
- Για να μάθουμε για την εμπειρία σας Τόπος: Θα σας καλέσουμε τηλεφωνικός. Πότε: στο τέλος της μελέτης. Ώρα: όποτε σας βολεύει (ώρες εργασίας). Σκοπός: για να μάθουμε τι σας βοήθησε και τι όχι. Αυτό θα μας βοηθήσει να βελτιωθούμε στο μέλλον. Διάρκεια: υπολογίζουμε ότι θα διαρκέσει περίπου 15-20 λεπτά

Χρησιμες πληροφοριες:

- Εάν αποφασίσετε να λάβετε μέρος θα σας ζητηθεί να υπογράψετε μια φόρμα συγκατάθεσης, στην πρώτη συνάντηση και θα σας δωθεί ένα αντίγραφο για να φυλάξετε μαζί με αυτό το έντυπο.
- Με την άδεια σας, για να μας βοηθήσετε να δημιουργήσουμε το προσωπικό σας πλάνο και να αξιολογήσουμε την υπηρεσία, θα συλλέξουμε συνήθεις πληροφορίες σχετικά με τη διαχείριση του διαβήτη σας, όπως γλυκόζη του αίματος, HbA1c και τη φαρμακευτική αγωγή του διαβήτη σας.
- Για να μεγιστοποιήσουμε τα οφέλη σας, θα θέλαμε να κάνουμε μέρος της υπηρεσίας τον γιατρό σας και τη νοσηλεύτρια του διαβήτη που εργάζονται στην διαβητολογική κλινική. Ως εκ τούτου, με την άδεια σας, θα μοιραστούμε μαζί τους μεσικές πληροφορίες που θα αποκτηθούν από την υπηρεσία.
- Θα έχετε χρόνο να κάνετε περισσότερες ερωτήσεις και διευκρινίσεις, αν θέλετε.

Εάν επιθυμείτε περισσότερες πληροφορίες ή να συμμετάσχετε στη μελέτη εδώ είναι τα στοιχεία επικοινωνίας:

Άντρια Παυλίδου
Υποψήφια Διδάκτωρ, UCL
MSc Κλινικός Φαρμακοποιός, UCL
Τηλέφωνο επικοινωνίας: (τα SMS είναι ευπρόσδεκτα)
Αριθμός Viber:
Ηλεκτρονική Διεύθυνση:

Πώς μπορώ να συμμετάσχω στη μελέτη;

Αφού διαβάσετε αυτές τις πληροφορίες και αποφασίσατε να συμμετάσχετε στη μελέτη, μπορείτε είτε να επιστρέψετε το επισυναπτόμενο δελτίο απάντησης, να καλέσετε ή να στείλετε email στην ερευνητή (Άντρια Παυλίδου) (στοιχεία επικοινωνίας στην επόμενη σελίδα).

Θα πρέπει να έχετε ένα smartphone και πρόσβαση στο διαδίκτυο για να συμμετάσχετε στη μελέτη.

Η εφαρμογή Viber θα χρησιμοποιηθεί σε αυτή τη μελέτη. Μην ανησυχείτε αν δεν χρησιμοποιείτε / έχετε εφαρμογή Viber. Θα σας βοηθήσουμε να κατεβάσετε την εφαρμογή και θα σας καθοδηγήσουμε πώς να χρησιμοποιήσετε τις υπηρεσίες smartphone που παρέχονται στη μελέτη.

Πρέπει να λάβω μέρος;

- Όχι, εναπόκειται σε εσάς να αποφασίσετε αν θα λάβετε μέρος ή όχι.
- Η επιλογή να μην συμμετέχετε δεν θα σας φέρει σε μειονεκτική θέση με οποιονδήποτε τρόπο.
- Είστε ελεύθεροι να αποσυρθείτε οποιαδήποτε στιγμή και χωρίς να δώσετε κάποιο λόγο. Η απόφασή σας δεν θα επηρεάσει το επίπεδο φροντίδας που λαμβάνετε.

Θα πληρωθώ για την συμμετοχή μου;

- Όχι, δεν μπορούμε να σας πληρώσουμε για τη συμμετοχή σας, αλλά δεν θα σας κοστίσει τίποτα.
- Τα SMS και οι τηλεφωνικές κλήσεις που θα κάνετε είναι μέσω του Viber, το οποίο είναι μια δωρεάν εφαρμογή.
- Ωστόσο, δεν θα χρηματοδοτούνται κανονικές τηλεφωνικές κλήσεις, SMS και πρόσβαση στο διαδίκτυο.

Τι θα συμβεί όταν τελειώσει η μελέτη;

Τα αποτελέσματα αυτής της μελέτης θα δημοσιευθούν ως έκθεση και θα είναι διαθέσιμα στο διαδίκτυο και άρθρα περιοδικών. Δεν θα είστε αναγνωρίσιμες σε δημοσιευμένες αναφορές. Μπορούμε να σας παρέχουμε ένα αντίγραφο της έκθεσης μετά την ολοκλήρωση της μελέτης. Αν σας ενδιαφέρει να λαμβάνετε ένα, παρακαλούμε επικοινωνήστε με Άντρια Παυλίδου μέσω τηλεφώνου, μηνύματος ή ηλεκτρονικής διεύθυνσης.

Τα αποτελέσματα της μελέτης θα μας βοηθήσουν να εντοπίσουμε τις ανάγκες και να σχεδιάσουμε μελλοντικές υπηρεσίες για άτομα με διαβήτη τύπου 2.

Τι γίνεται αν υπάρχει κάποιο πρόβλημα;

- Ελπίζουμε ότι δεν θα υπάρξει πρόβλημα. Ωστόσο, εάν έχετε κάποιες ανησυχίες κατά τη διάρκεια της συμμετοχής σας στη μελέτη, μπορείτε να επικοινωνήσετε με την Άντρια ή άλλα μέλη που εμπλέκονται στην έρευνα για να το συζητήσετε (στοιχεία επικοινωνίας στην επόμενη σελίδα).
- Εάν εξακολουθείτε να θέλετε να παραπονεθείτε και να το συνεχίσετε περαιτέρω ή έχετε οποιεσδήποτε ανησυχίες σχετικά με τον τρόπο προσέγγισης ή αντιμετώπισης σας από μέλη του προσωπικού κατά τη διάρκεια της μελέτης, μπορείτε να το κάνετε μέσω του μηχανισμού καταγγελιών του Υπουργείου Υγείας (ηλεκτρονική διεύθυνση: https://www.moh.gov.cy/MOH/MCH.nsf/newcontactform_gr/newcontactform_gr?OpenForm)

Τα δεδομένα σας θα χρησιμοποιηθούν μόνο για τους σκοπούς της μελέτης. Η εμπιστευτικότητα και η ανωνυμία θα διατηρηθούν και δεν θα είναι δυνατή η αναγνώριση σας από οποιεσδήποτε δημοσιεύσεις. Όλα τα δεδομένα συλλέγονται και αποθηκεύονται σύμφωνα με το νόμο περί προστασίας δεδομένων 2018.

Nicosia General Hospital
Diabetes Clinic

Are you interested in participating in a study supporting type 2 diabetes patients?

•••

We are interested in learning ways to improve self-management of type 2 diabetes patients, who take medicines for diabetes. We are assessing a new approach using your mobile phone and tailoring the intervention as much as possible to your needs and lifestyle. This intervention is designed and provided by Clinical pharmacist and based on recent theories and evidence.

You will need to own a smartphone and have internet access in order to participate in the study.

Thank you for taking time to read this.
Please ask any questions if you need to.

This study is funded by the Cyprus State Grant Foundation.

What is the purpose of this study?

- Type 2 diabetes is a global problem, affecting increasing numbers of people all over the world.
- Cyprus has one of the highest rates of diabetes in Europe.
- We already know, that managing diabetes it is not an easy task.
- The World Health Organization believes that mobile phones can be used to support diabetes self-management.
- According to World Health Organization and International Pharmaceutical Federation, Pharmacists have the expertise to support diabetes patients

From this study we hope to learn more about the optimal way of self - management of diabetes for patients in Cyprus.

Who has reviewed the study?

This study has been reviewed and received ethical approval from Cyprus Research Ethics Committee and Cyprus National Bioethics Committee

This study is part of a PhD degree at University College London (UCL), School of Pharmacy and reviewed by UCL ethics Committee..

Collaborators

A big thank you to Dr. George Parpas, Dr. Chara Zitti and Mrs Elena Piperidou for their time, advice and support

What will happen in the study?

- **Consultation, with the Clinical Pharmacist Place:** Diabetes Clinic (General Hospital of Nicosia).
  When & Time: at your convenience (working hours).
  Purpose: to tailor the intervention as much as possible according to your needs and lifestyle. We will gather some information about you and your diabetes, explain how to use the service provided & develop a personalized plan just for you.
  Duration: so that the consultation is helpful, we expect it would take approximately 20 minutes.

- **Ensure you are doing OK**
  Communication through Viber message with the clinical pharmacist Response within 48 hours.
  Telephone communication Place: we will call you
  Time: at your convenience (working hours)
  When: we will schedule up to maximum 3 phone consultations with 6-8 weeks intervals.
  Purpose: to see how you are doing and revise your personal plan.
  Duration: will depend on what is more suitable for you and your lifestyle.

- **Learn about your Experience Place:** we will call you by phone.
  When: by the end of the study.
  Time: at your convenience (working hours)
  Purpose: to find out what worked for you and what did not. This will help us make improvements in the future.
  Duration: We expect that this will take about 15-20 minutes.

Useful Information

- If you decide to take part you will be asked to sign a consent form, at the first meeting, and given a copy to keep with this information sheet.
- With your permission to help us develop your personal plan and evaluate the intervention, we will collect some routine information about your diabetes management such as blood glucose, HbA1c and my diabetes medication from your medical records.
- In order to maximize your benefits, we want to make part of this intervention your doctor and diabetes nurse working at the Diabetes Clinic. Hence, with your permission, some information gained from this intervention will be shared with them.
- You will have time to ask more questions and clarification, if you want to.

If you would like more information or to join the study here are the contact details:

Antria Pavlidou
PhD student - UCL
MSc Clinical Pharmacy UCL
Phone number: (text SMSs are welcomed)
Viber number
Email

How can I participate in the study?

- After you read this information and you decided to participate in the study you can either return the reply slip attached, call or email the researcher (Antria Pavlidou) (contact details overleaf).
- You will need to own a smartphone and have internet access in order to participate in the study.
- Viber application will be used in this study. Do not worry if you are not using/having Viber application. We will help you download the app and guide you how to use the smartphone services provided in the study..

Do you have to take part?

- No, It is up to you to decide whether to take part or not.
- Choosing not to take part will not disadvantage you in any way.
- You are free to withdraw at any time and without giving a reason. Your decision will not affect the standard of care you receive.

Will I be paid?

- No, we cannot pay you for your participation, but it should not cost you anything.
- The SMS and phone calls you make will be through Viber which is a free application. However, regular phone calls, SMS and internet access will not be funded.

What will happen when the study ends?

The results of this study will be published as a report that will be available online and in journal articles. You will not be identifiable in published reports. A copy of the report can be provided for you after the study is completed. If you are interested in receiving one, please contact Antria Pavlidou by phone, text or email.

This study will help us to identify needs and inform future services for people with type 2 diabetes.

What if there is a problem?

- We hope that it will not be any problem. However, if you have any concerns during your participation to the study, you can contact Antria or other members involved in the research to discuss it (contact details overleaf).
- If you still wish to complain and take it further or have any concerns about the way you were approached or treated by members of staff during this study, you can do so through the complaints mechanism through Ministry of Health.

Your data will be used for the purpose of the study only. Confidentiality and anonymity will be maintained and it will not be possible to identify you from any publications. All data will be collected and stored in accordance with the Data Protection Act 2018.

Patients' expression of interest reply slip as attached to the information leaflet

English Version

If you would like to take part in this study, please fill in the information below.

Your name:

Your telephone number:

The best time to call:

Please return this slip to the diabetes nurse at Diabetic Clinic General Hospital.

Thank you for your time.

Greek Version

Αν θέλετε να λάβετε μέρος στη μελέτη αυτή, παρακαλούμε συμπληρώστε τις παρακάτω πληροφορίες.

Το όνομα σου:

Τον αριθμό τηλεφώνου σας:

Η καλύτερη στιγμή για να σας καλέσουμε:

Παρακαλώ όπως επιστραφεί το δελτίο στη νοσοκόμα του διαβήτη στη Διαβητολογική Κλινική του Γενικού Νοσοκομείου Λευκωσίας.

Σας ευχαριστώ για το χρόνο σας.

Consent Form

Participation Identification Number for this study:

Project title: Development and feasibility study of a community pharmacy intervention to support self-management of patients with type 2 diabetes, in Cyprus.

Supervisors: Professor Felicity Smith and Professor Cate Whittlesea

Name of Researcher: Antria Pavlidou (PhD Student)

This study has been approved by the Scientific Committee for Research Promotion and UCL Research Ethics Committee and reviewed by the Cyprus National Bioethics Committee. **Project ID Number:**

		Please initial box
1.	I confirm that I have read the Information Sheet and understand what the study involves. I have had the opportunity to consider the information, ask questions, and have these answered satisfactorily.	
2.	I understand that if I decide at any time that I no longer wish to take part in this project, I can notify the researchers involved and withdraw immediately.	
3.	I understand that the information I will submit may be published as a report, and I will be sent a copy. Confidentiality and anonymity will be maintained, and it will not be possible to identify me from any publications.	
4.	I understand that all interviews may be recorded and transcribed, but that these will not contain my name or any other identifiable information. I give permission for interviews to be recorded.	
5.	I consent to the use of quotes anonymously in any publication.	
	I understand that the study will involve the collection of data regarding my diabetes management, such as blood glucose, glycated haemoglobin, and my diabetes medication, from my medical records to help develop my personal plan and evaluation of the intervention.	
6.	I agree that some information gained from this intervention will be shared with my doctor and diabetes nurse, who are working at the Diabetes Clinic.	
7.	I agree to take part in the above study.	

Name of Participant:	Date	Name of the person taking the consent
Signature of Participant	Date	Signature of the person taking the consent

Έντυπο Συγκατάθεσης

Αριθμός αναγνώρισης συμμετοχής για τη μελέτη αυτή:

Τίτλος Εργασίας: Πιλοτική μελέτη σκοπιμότητας και ο δυνητικός αντίκτυπος μιας υπηρεσίας με χρήση εφαρμογής στο κινητό, υπό την καθοδήγηση του φαρμακοποιού για την υποστήριξη και βελτίωση της αυτοδιαχείρισης του διαβήτη σε συνεργασία με άλλους επαγγελματίες του τομέα της υγείας στην Κύπρο.

Επιστημονικοί Υπεύθυνοι: Professor Felicity Smith and Professor Cate Whittlesea

Ερευνητής: Άντρια Παυλίδου (Υποψήφια Διδάκτωρ)

Η μελέτη αυτή εγκρίθηκε από την Επιστημονική Επιτροπή Προώθησης Ερευνών της Κύπρου, την Επιτροπή Ηθικής Έρευνας της UCL και αναθεωρήθηκε από την Εθνική Επιτροπή Βιοηθικής Κύπρου.

Αριθμός Αναγνωριστικού Έργου:

		Παρακαλώ συμπληρώ-στε με τα αρχικά σας.
1.	Επιβεβαιώνω ότι έχω διαβάσει το έντυπο πληροφόρησης, και κατανοώ τι περιλαμβάνει η μελέτη. Είχα την ευκαιρία να σκεφτώ τις πληροφορίες και να κάνω ερωτήσεις, οι οποίες απαντήθηκαν ικανοποιητικά.	
2.	Κατανοώ ότι εάν αποφασίσω ανα πάσα στιγμή ότι δεν επιθυμώ πλέον να συμμετέχω σε αυτή τη μελέτη, μπορώ να ενημερώσω τους εμπλεκόμενους ερευνητές και να αποσυρθώ άμεσα.	
3.	Κατανοώ ότι οι πληροφορίες που υπέβαλα θα μπορούν να δημοσιεύονται ως αναφορά και να μου αποσταλεί αντίγραφο. Η εμπιστευτικότητα και η ανωνυμία θα διατηρηθούν και δεν θα είναι δυνατή η αναγνώρισή μου από οποιεσδήποτε δημοσιεύσεις	
4.	Κατανοώ ότι όλες οι συνεντεύξεις μπορούν να καταγραφούν και να μεταγραφούν, αλλά ότι αυτά δεν θα περιέχουν το όνομά μου ή οποιαδήποτε άλλη αναγνωρίσιμη πληροφορία. Δίνω την άδεια μου για καταγραφή συνεντεύξεων.	
5.	Συμφωνώ με τη χρήση ανώνυμων αναφορών (αποσπασμάτων) σε οποιαδήποτε δημοσίευση.	
	Κατανοώ ότι η μελέτη θα περιλαμβάνει τη συλλογή δεδομένων σχετικά με τη διαχείριση του διαβήτη μου, όπως η γλυκόζη του αίματος, γλυκιωμένη αιμοσφαιρίνη, και τη φαρμακευτική μου αγωγή για το διαβήτη από τα ιατρικά μου αρχεία για να βοηθήσω στην ανάπτυξη του προσωπικού μου σχεδίου και την αξιολόγηση της υπηρεσίας.	
6.	Συμφωνώ ότι ορισμένες πληροφορίες που θα αποκτηθούν από αυτή την υπηρεσία θα μοιραστούν με τον γιατρό μου και τη νοσηλεύτρια που εργάζονται στην διαβητολογική κλινική.	
7.	Συναινώ να συμμετάσχω στην ερευνητική εργασία.	

Ονοματεπώνυμο συμμετέχοντος	Ημερομηνία	Ονοματεπώνυμο παρατηρητή/ερευνητή
Υπογραφή συμμετέχοντος	Ημερομηνία	Υπογραφή παρατηρητή/ερευνητή

Appendix 5.5 Data collection forms for participants' characteristics.

Participants' characteristics data collection form			
Please complete the form for each participant.			
Participant ID		*Please complete ✓ where applicable*	**Source of data** *(e.g., diabetes nurse notes, participant's file or responses)*
Age, years			
Gender	Male		
	Female		
District	Nicosia		
	Larnaca		
	Limassol		
	Paphos		
Area	Urban		
	Rural		
Baseline BG (mg/dL)			
Baseline HbA1c	Less than <7%		
	Between 7-8%		
	Above than >8%		
	Data missing		
Baseline participants' antidiabetic pharmacotherapy	Oral medication only		
	Oral medication and insulin		
Antidiabetic drugs	Metformin		
	Dipeptidyl peptidase-4 inhibitor (DPP-4)		
	Sulfonamides		
	Insulin glargine		
	Fast-acting insulin		
Baseline participants' pharmacotherapy for other morbidities	Participants taking other medication		
	Cholesterol-lowering medications		
	Cardiovascular medications		
	Anticoagulants or antiplatelet medications		
	Other conditions		
	Data missing		

Appendix 5.6 Data collection forms for recruitment and retention of participants.

Recruitment and retention of participants data collection form		
Please complete the form for each day of recruitment.		
Please write the recruitment day (e.g., 18 May 2020):		
Number of patients booked an appointment at the diabetes clinic.		
Number of patients who attended their appointment.		
Number of information leaflets distributed by	The pharmacist	
	The diabetes nurse	
	The general physicians	
Total number of information leaflets distributed.		
Number of eligible patients identified by	The pharmacist	
	The diabetes nurse	
	The general physicians	
Number of patients referred by	The diabetes nurse	
	The general physicians	
Total number of patients approached by the pharmacist (and when before patients' diabetes nurse or general physicians appointments)		
Total number of eligible patients.		
Number of patients recruited by	The pharmacist	
	The diabetes nurse	
	The general physicians	
Total number of patients recruited.		
Number of patients not recruited.		

Appendix 5.7 Data collection forms for participants studies - Nonresponse rates.

Data collection form on the reasons participants withdraw of the intervention				
Please complete the form by filling in the participant's ID and ticking ✓ the relevant reason for withdrawal.				
Participant ID who withdraw	**Nothing to gain**	**Extra burden**	**Already aware of diabetes management**	**Other** *(Please state the reason)*
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				

Nonresponse rates data collection form								
Please complete the form by filling in the number of participants per appointment and in total.								
	Appointments							**Total**
	First	**Second**	**Third**	**Fourth**	**Fifth**	**Sixth**	**Final**	
Number of participants attended the appointments.								
Number of participants responded to the questionnaire		Not applicable						
Number of participants attended to consultation								
Number of participants responded to the final interviews	Not applicable							
Number of participants withdraw								

Daily log of phone calls				
Please write 1= Rescheduling the interview, 2= Did not respond, 3= The appointment was completed 4= Quick phone call for further information/instructions[1]				
Participant ID	**Appointments**			
	First	**Second**	**Third**	**Fourth**
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				
11.				
12.				
13.				
14.				
15.				
16.				
17.				
18.				
19.				
20.				
21.				
22.				
[1]Re-schedule appointments, instructions for receiving educational leaflets, further instructions after discussing with other HCPs at the diabetes clinic.				

Appendix 5.8 Data collection forms for participants' engagement

Data collection form 1 regarding the services chosen at each appointment.

Data collection form on participants' engagement					
Please complete the form by filling in the participant's ID and ticking ✓on all participant's choices for each appointment.					
Please write the number of the appointment (e.g., 1st, 2nd, 3rd, etc.):					
Participant ID	**Pharmacist online advice to patient queries**	**Tracking and uploading SMBG readings**	**Graphical reports**	**Reminders**	**Education**
1.					
2.					
3.					
4.					
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6.					
7.					
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22.					

Data collection form 2 regarding the goals agreed upon at the initial participant appointment.

Goals agreed upon at the initial participant appointment							
Please complete the form by filling in the participant's ID and ticking ✓on all participant's choices.							
Participant ID	**Medication taking**	**Monitoring blood glucose**	**Knowledge**	**Being active**	**Healthy eating**	**No goals agreed**	**Combination of goals**
1.							
2.							
3.							
4.							
5.							
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10.							
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12.							
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19.							
20.							
21.							
22.							

Data collection form 3 regarding the topic of the educational leaflet sent to the participants.

Topic of the educational leaflets sent									
Please complete the form by filling in the participant's ID and ticking ✓ on all participant's choices.									
Participants ID	**Diabetes and eyes**	**Diabetes and foot care**	**Diabetes and exercise**	**Diabetes and healthy eating**	**Diabetes book**	**General**	**Hypoglycaemia**	**Medication**	**Media of delivery[1]**
1.									
2.									
3.									
4.									
5.									
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7.									
8.									
9.									
10.									
11.									
12.									
13.									
14.									
15.									
16.									
17.									
18.									
19.									
20.									
21.									
22.									
[1]*At the clinic, Viber messages, emails and fax, and posts. If more than one medium was used, please state all media.*									

Data collection form 4 regarding the topics discussed between the pharmacist and the patient during the intervention.

The topics discussed between the pharmacist and the patient during the intervention							
Topics on medication							
Please complete the form by filling in the participant's ID and ticking ✓ on all participant's choices for each appointment.							
Write the number of the appointment (e.g., 1st, 2nd, 3rd, etc.):							
Participants ID	**Symptoms expressed to the pharmacist, which could be due to pharmacotherapy**	**Review of patients' medications**	**Adherence**	**Optimization of pharmacotherapy**	**Information about their medication**	**Media of delivery[1]**	**Comments**
1.							
2.							
3.							
4.							
5.							
6.							
7.							
8.							
9.							
10.							
11.							
12.							
13.							
14.							
15.							
16.							
17.							
18.							
19.							
20.							
21.							
22.							
[1]*Phone calls, Viber messages, text messages, and emails. If more than one medium was used, please state all media.*							

The topics discussed between the pharmacist and the patient during the intervention					
Topics on self-monitoring blood glucose					
Please complete the form by filling in the participant's ID and ticking ✓ on all participant's choices for each appointment.					
Write the number of the appointment (e.g., 1st, 2nd, 3rd, etc.):					
Participants ID	**Facing finger-pricking problems**	**The correct interpretation of blood glucose results**	**When to measure blood glucose**	**Media of delivery[1]**	**Comments**
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					
11.					
12.					
13.					
14.					
15.					
16.					
17.					
18.					
19.					
20.					
21.					
22.					
[1]*Phone calls, Viber messages, text messages, and emails. If more than one medium was used, please state all media.*					

The topics discussed between the pharmacist and the patient during the intervention							
Topics on healthy eating and exercise							
Please complete the form by filling in the participant's ID and ticking ✓on all participant's choices for each appointment.							
Write the number of the appointment (e.g., 1st, 2nd, 3rd, etc.):							
Participants ID	**Food characteristics** (e.g., carbohydrates, protein, etc.)	**Dieting habits on maintaining blood glucose within range**	**Alcohol and diabetes**	**Type of exercise they can do**	**Exercise and hypoglycaemia**	**Media of delivery**[1]	**Comments**
1.							
2.							
3.							
4.							
5.							
6.							
7.							
8.							
9.							
10.							
11.							
12.							
13.							
14.							
15.							
16.							
17.							
18.							
19.							
20.							
21.							
22.							
[1]Phone calls, Viber messages, text messages, and emails. If more than one medium was used, please state all media.							

The topics discussed between the pharmacist and the patient during the intervention					
Topics on foot problems and vaccination					
Please complete the form by filling in the participant's ID and ticking ✓ on all participant's choices for each appointment.					
Write the number of the appointment (e.g., 1st, 2nd, 3rd, etc.):					
Participants ID	**Knowledge about foot care**	**Foot acne**	**Vaccination (influenza vaccine and pneumococcal vaccine)**	**Media of delivery[1]**	**Comments**
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					
11.					
12.					
13.					
14.					
15.					
16.					
17.					
18.					
19.					
20.					
21.					
22.					
[1]*Phone calls, Viber messages, text messages, and emails. If more than one medium was used, please state all media.*					

Data collection form 5 regarding phone calls between the pharmacist and participants.

Duration and number of phone calls between the pharmacist and participants									
Please complete the form by filling in the duration of the phone calls and the total number of phone calls made at the end of the intervention for each participant.									
Participant ID	**Appointments**							**Final phone call[2]**	**Total number of phone calls** *(At the end of the intervention)*
	First[1]	**Second[2]**	**Third[2]**	**Fourth[2]**	**Fifth[2]**	**Sixth[2]**	**Seventh[2]**		
1.									
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4.									
5.									
6.									
7.									
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9.									
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11.									
12.									
13.									
14.									
15.									
16.									
17.									
18.									
19.									
20.									
21.									
22.									
[1]*Including motivational interviews. Recorded by the Qualtrics and mobile phone timer.* [2]*Recorded from the mobile phone.*									

Data collection form 6 regarding the communication between the pharmacist and participant apart from phone calls.

Communication between the pharmacist and participant apart from phone calls						
Please complete the form by filling in the total number of messages sent throughout the intervention for each participant, as recorded by the mobile phone.						
Participant ID	**Number of TMs**	**Number of emails**	**Number of Viber messages**	**Participant did not respond**	**Participant called the pharmacist**	**Comments**
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						
13.						
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21.						
22.						

Appendix 5.9 Data collection forms for participants studies - Participants' reminders.

Data collection form for participants' reminders						
Please complete the form by filling in the participant's ID and ticking ✓on all participant's choices regarding reminders.					**Did the participant respond to the reminder regarding medication taking?** *(Yes/ No)*	**Did the participant take the medication?** *(Yes/ No)*
Participants ID	**Type of reminder**					
	Medication refill	**Self-monitoring blood glucose**	**Appointment**	**Medication taking**		
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
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22.						

Appendix 5.10 Data collection forms for healthcare staff actions on the intervention.

Data collection form for healthcare staff actions on pharmacist's recommendations to the GPs on participants' pharmacotherapy										
Please complete the form for each recommendation using a different line.										
Participant ID	**Nature of the issue[1]**	**Name of healthcare staff**	**Communication between healthcare professionals**			**Outcome of the recommendation**				
			Did the healthcare staff respond? *(Yes/no)*	**Medium**	**Number of phone calls/messages exchanged**	**Was the recommendation accepted?** *(Yes/no)*	**Reasons for not accepting recommendation[2]**	**Number of medications**		**Other** *(please state)*
								Added	**Removed**	
1.										
2.										
3.										
4.										
5.										
6.										
7.										
8.										
9.										
10.										
11.										
12.										
13.										
14.										
15.										
[1]*Pharmacotherapy; adverse event, contraindication, change medication, hypoglycaemia, participants' symptoms (etc.).* [2]*Healthcare professional: refused to make changes, made other changes, issue resolved, monitoring of the issue before proceeding to changes(etc.).*										

Appendix 5.11 Post-intervention interview schedule evaluating patients' perception, based on Theoretical Framework of Acceptability (TFA) (English and Greek version).

(General prompts which might be used are displayed after the interview schedules)

English Version

Introduction

1. The pharmacist should briefly outline the purpose of this interview to the patient. "The aim of this interview is to learn your views about the pharmacist intervention using technology. The aim is not to obtain positive results, but to truly understand the needs of diabetes patients and gain information on how these needs may be supported through a pharmacy service which uses an app."
2. Inform/remind the patient that the interview is audio taped (Review consent) – "The interview will be recorded and transcribed in order to enable the interviewer to listen and focus on conducting the interview rather than writing and ensures that additional details and clarification are addressed for all relevant issues. Some notes might also be taken with the audio recorder to aid the interview process."
3. Inform/remind the patient about confidentiality. "I would like to remind you that confidentiality and anonymity will be maintained, and it will not be possible to be identified in any publications."
4. Inform the patient of an estimate of the interview length.

Section 1: General Views

5. First of all, I would like to ask you if there was anything, in particular, you liked about the intervention. If so, can you explain?
6. Anything you did not like? If so, can you explain?
7. Was there anything you found specifically helpful?
8. Did you have any problems?

If so, can you explain?

(Prompts: online text message, tracking BG, sending BG readings, graphical reports, education, reminder, recommendations to GP, pharmacist contribution- sessions with the pharmacist, setting goals)

Section 2: Burden

Now I would like to ask you some questions about the convenience of the intervention

9. How easy or difficult was the application to follow?
10. How easy or difficult was it for you to attend the consultation?
11. How easy or difficult was it for you to respond to the questionnaire?
12. How easy or difficult was it for you to respond to reminders for medication taking?
13. How easy or difficult was for you to communicate with the pharmacist through Viber text message?

14. How easy or difficult was it for you to send your BG and read your graphical reports?
15. What are your views about the time and duration of the intervention?
16. What are your views about the time and duration of the appointments?
17. What are your views about the time and duration of the questionnaires?
18. To what extent do you feel it was convenient for you to participate in this study?

(Prompts: attend at the clinic, location-setting, respond to questionnaires, use the Services of the intervention; online text messages, face-to-face and telephone, educational leaflets online versus hardcopy)

Section 3: Effectiveness

19. To what extent do you feel the intervention helped manage your diabetes?
20. To what extent do you feel the intervention was helpful in better understanding your diabetes?
21. To what extent do you feel the intervention had any benefit on your diabetes management? In which areas and how?
22. How confident did you feel in self-managing your diabetes when using the services of this intervention?
23. How confident did you feel using the Viber application for this intervention?

Prompts: Online text messages, face-to-face, and telephone, location-setting, educational leaflets online versus hardcopy

Section 4: Future Changes

Now I want to ask you your views on how to improve the intervention in the future.

24. Did you feel that you fully understood what the intervention wanted to achieve? Do you feel that you received all the information needed? (e.g., educational leaflet, demonstration of the Viber app, etc.)
25. In your opinion, do you feel that there are other ways to improve self-management of diabetes? If so, do you have any suggestions?
26. What changes can you suggest improving the intervention?

Prompt: Is there anything you believe must be added or removed from the intervention to make it better in the future? (e.g., educational leaflets, the application used, text messages sent and received, education)

27. What did you feel about the intervention overall?
28. Was this intervention something you would expect in the healthcare system?
29. Would you recommend this to a friend or relative with type 2 diabetes

Greek Version
Introduction

1. The pharmacist should briefly outline to the patient the purpose of this interview. "Στόχος αυτής της συνέντευξης είναι να ακούσουμε την άποψη σας σχετικά με την υπηρεσία του φαρμακοποιού χρησιμοποιώντας την εφαρμογή Viber. Στόχος δεν είναι η επίτευξη θετικών αποτελεσμάτων, αλλά η αληθινή κατανόηση των αναγκών που έχουν οι ασθενείς με διαβήτη. Επιπλέον, η άντληση πληροφοριών αναφορικά με το τρόπο κάλυψης των αυτών αναγκών μέσω των υπηρεσιών φαρμακοποιού και της χρήσης εφαρμογών."
2. Inform/remind patient that the interview is audio taped (Review consent) – "Η συνέντευξη θα καταγραφεί προκειμένου να δοθεί η δυνατότητα στον ερευνητή να εστιάσει στη διεξαγωγή της συνέντευξης, αντι να καταγράφει, και να διασφαλίσει λεπτομέρειες που σχετίζονται με όλα τα θέματα. Ορισμένες σημειώσεις μπορούν επίσης να ληφθούν μαζί με την καταγραφή της συνέντευξη για να βοηθήσουν στη διαδικασία συνέντευξης.''
3. Inform/remind patient about confidentiality. "Θα ήθελα να σας υπενθυμίσω ότι θα διατηρηθούν η εμπιστευτικότητα και η ανωνυμία σας. Επιπλέον, δεν θα είναι δυνατή η αναγνώρισή σας από οποιεσδήποτε δημοσιεύσεις."

Section 1: General Views

4. Αρχικά θα ήθελα να σας ρωτήσω εάν υπήρχε κάτι που σας άρεσε ιδιαίτερα στην υπηρεσία; Αν ναι, μπορείτε να το εξηγήσετε;
5. Κάτι που δεν σας άρεσε? Αν ναι, μπορείτε να το εξηγήσετε;
6. Υπήρχε κάτι που θεωρήσατε ιδιαίτερα χρήσιμο;
7. Αντιμετωπίσατε οποιοδήποτε πρόβλημα; Αν ναι, μπορείτε να το αναφέρετε;

(προτροπές: Viber messages, μέτρηση γλυκόζης στο αίμα, αποστολή μετρήσεων γλυκόζης στο αίμα, γραφικές αναφορές γλυκόζης στο αίμα, ενημερωτικά φυλλάδια, υπενθυμίσεις, ενημέρωση του ιατρού, συμβολή φαρμακοποιού-συνεδρίες με το φαρμακοποιό, καθορισμός στόχων)

Section 2: Burden

Τώρα θα ήθελα να σας θέσω κάποιες ερωτήσεις σχετικά με την ευκολία ή όχι της υπηρεσίας.

8. Πόσο εύκολη ή δύσκολη ήταν η χρήση της εφαρμογής;
9. Πόσο εύκολο ή δύσκολο ήταν να παρευρίσκεστε στη διαβούλευση με τη/ο φαρμακοποιό;
10. Πόσο εύκολο ή δύσκολο ήταν να απαντάτε στο ερωτηματολόγιο;
11. Πόσο εύκολο ή δύσκολο ήταν να απαντάτε στις υπενθυμίσεις για τη λήψη της φαρμακευτικής σας αγωγής;
12. Πόσο εύκολο ή δύσκολο ήταν να επικοινωνείτε με τον φαρμακοποιό μέσω Viber message;
13. Πόσο εύκολη ή δύσκολη ήταν η αποστολή των μετρήσεων γλυκόζης στο αίμα σας; Πόσο εύκολη ή δύσκολη ήταν η μελέτη των γραφικών αναφορών;
14. Ποιές είναι οι απόψεις σας για το χρόνο και τη διάρκεια της υπηρεσίας.
15. Ποιές είναι οι απόψεις σας για το χρόνο και τη διάρκεια των συναντήσεων σας με το φαρμακοποιό;
16. Ποιές είναι οι απόψεις σας για το χρόνο και τη διάρκεια που είχαν τα ερωτηματολόγια;
17. Σε ποιο βαθμό πιστεύετε ότι ήταν εύκολο να συμμετέχετε σε αυτή τη έρευνα;

Προτροπές: να βρίσκεστε στην κλινική, τοποθεσία, να απαντήσετε στο ερωτηματολόγιο, να χρησιμοποιήσει τα χαρακτηριστικά της υπηρεσίας, Viber message έναντι προσωπικής

συνάντησης και τηλεφώνου, εκπαιδευτικά φυλλάδια μέσω Viber εναντίον έντυπου αντιγράφου

Section 3: Effectiveness

18. Σε ποιο βαθμό, σας βοήθησε η υπηρεσία στη διαχείριση του διαβήτη;
19. Σε ποιο βαθμό, πιστεύετε ήταν χρήσιμη για την καλύτερη κατανόηση του διαβήτη σας;
20. Σε ποιο βαθμό πιστεύετε ότι επωφεληθήκατε από τη συμμετοχή σας στη μελέτη; Σε ποιους τομείς και πώς;
21. Πόσο σίγουροι αισθανθήκατε στην αυτοδιαχείριση του διαβήτη σας κατά τη χρήση των υπηρεσιών αυτής της υπηρεσίας?
22. Πόσο σίγουροι αισθανθήκατε όταν χρησιμοποιούσατε την εφαρμογή Viber για τους σκοπούς αυτής της επέμβασης;

Προτοπές: Viber message έναντι προσωπικής συνάντησης και τηλεφώνου, τοποθεσία, εκπαιδευτικά φυλλάδια μέσω Viber εναντίον έντυπου αντιγράφου

Section 4: Future Changes

23. Αισθανθήκατε ότι κατανοήσατε πλήρως τι θέλησε να επιτύχει η υπηρεσία; Πιστεύετε ότι λαμβάνετε όλες τις απαραίτητες πληροφορίες; (π.χ. ενημερωτικό φυλλάδιο, επίδειξη της εφαρμογής Viber κ.λπ.)
24. Κατά τη γνώμη σας, αισθάνεστε ότι υπάρχουν άλλοι τρόποι βελτίωσης της αυτοδιαχείρισης του διαβήτη; Εάν ναι, έχετε κάποιες προτάσεις;
25. Ποιες αλλαγές προτείνετε για τη βελτίωση της υπηρεσίας;

Προτροπή: Υπάρχει κάτι που πιστεύετε ότι πρέπει να προστεθεί ή να αφαιρεθεί από την υπηρεσία για να γίνει καλύτερη στο μέλλον; (π.χ. ενημερωτικό φυλλάδιο, εφαρμογή που χρησιμοποιήθηκε, αποστολή και λήψη μηνυμάτων, εκπαίδευση)

26. Τι αισθανθήκατε για την υπηρεσία συνολικά;
27. Ήταν αυτή η υπηρεσία κάτι που θα περιμένατε στον τομέα της υγείας;
28. Θα το συνιστούσατε σε κάποιον φίλο ή συγγενή σας με διαβήτη τύπου 2;

Appendix 5.12 Post-intervention interview schedule evaluating healthcare professionals' perception, based on Theoretical Framework of Acceptability (TFA) (English and Greek version).

(General prompts which might be used are displayed after the interview schedules)

English version

Introduction:

1. The pharmacist should briefly outline the purpose of this interview. "Thank you for taking part and supporting this intervention. The purpose of the interview is to find your views about a pharmacist's intervention using the technology. This interview is part of the evaluation of the intervention.
2. Inform/remind healthcare professionals that the interview is audio taped (Review consent) – "The interview will be recorded and transcribed in order to enable the interviewer to listen and focus on conducting the interview rather than writing and ensures that additional details and clarification are addressed for all relevant issues. Some notes might also be taken with the audio recorder to aid the interview process."
3. Inform/remind healthcare professional about confidentiality. "I would like to remind you that confidentiality and anonymity will be maintained, and it will not be possible to be identified in any publications."
4. Inform the healthcare professionals of an estimate of the length of the interview.

Section 1: General Views

5. Was there anything, in particular, you liked about the intervention?
6. Was there anything you did not like about the intervention?
7. Did you find something specifically helpful? If so, can you explain?
8. What did you find more useful from the intervention?
9. To what extent do you feel using the service offered in the intervention was easy?
10. Did you feel more confident in managing your diabetes patients when they were using the intervention?
11. Did you feel that the intervention helped you in any way in your daily routine with diabetes patients?

Prompts: use graphical reports of the patient/ pharmacist's recommendations / individual plan

Section 2: Burden

12. Was there any, particular, problem caused by the intervention?

<u>Recruitment period</u>

13. Can you tell me about your thoughts regarding patient recruitment and data collection?
14. Can you tell me about your thoughts regarding the extra time needed for the recruitment and data collection? Any comments on how to change this in the future?
15. Can you please tell me, your thoughts regarding the length of the intervention duration? Comment on convenience.

Only to the nurse: Can you please tell me how much time was required to identify patients and arrange the consultation? Was it difficult to find that time?

Section 2: Future Practice and Ethicality

16. Did you feel that you understood what the intervention aimed to achieve?
17. How does this intervention fit in what you might expect in healthcare services for patients with type 2 diabetes?

18. Can you please tell me your thoughts about the pharmacist's contribution to diabetes management at this diabetes clinic?

Prompt: In your opinion, how pharmacists' contribution should be changed in the diabetes management pathways in Cyprus?

19. In your opinion to what extent do you believe pharmacist involvement in diabetes management could make a difference to current clinical practice?
20. Can you please tell me about your thoughts regarding sharing patient data (laboratory examination, GP notes, etc.) with the pharmacist? Do you think this is vital for the continuity of patient care?

Example: use graphical reports of the patient/ pharmacist's recommendations / individual plan

21. Please can you tell me your thoughts about interventions using applications and how useful they are for patients?
22. In your opinion, interventions using applications should be further investigated for the improvement of the management of diabetes. If yes, in your opinion, do you believe interventions using applications have a fit in Cyprus pathways?
23. In your opinion, to what extent do you believe using applications will make a difference to the current clinical practice of type 2 diabetes management?
24. In your opinion, what alternative solutions could provide the same/better results than the intervention for patients with type 2 diabetes? If so, can you explain? (Areas to change/adjust/remove/add)
25. What did you feel about the intervention overall? Any comments on how to change in the future?

Greek version

Introduction:

1. The pharmacist should briefly outline the purpose of this interview. "Σας ευχαριστώ για τη συμμετοχή και τη στήριξη σας. Σκοπός της συνέντευξης είναι να ακούσουμε τις απόψεις σας σχετικά με την υπηρεσία του φαρμακοποιού με τη χρήση μιας εφαρμογής. Αυτή η συνέντευξη είναι μέρος της αξιολόγησης της υπηρεσίας."
2. Inform/remind healthcare professional that the interview is audio taped (Review consent) – "Η συνέντευξη θα καταγραφεί προκειμένου να δοθεί η δυνατότητα στον ερευνητή να εστιάσει στη διεξαγωγή της συνέντευξης, αντι να καταγράφει, και να διασφαλίσει λεπτομέρειες που σχετίζονται με όλα τα θέματα. Ορισμένες σημειώσεις μπορούν επίσης να ληφθούν μαζί με την καταγραφή της συνέντευξη για να βοηθήσουν στη διαδικασία συνέντευξης. "
3. Inform/remind healthcare professional about confidentiality. "Θα ήθελα να σας υπενθυμίσω ότι η εμπιστευτικότητα και η ανωνυμία θα διατηρηθούν και δεν θα είναι δυνατή η αναγνώρισή μου από οποιεσδήποτε σελίδες δημοσιεύσεις."

Section 1: General Views

4. Υπήρξε κάτι που σας άρεσε ιδιαίτερα στην υπηρεσία;
5. Υπήρξε κάτι που δεν σας άρεσε ιδιαίτερα στην υπηρεσία;
6. Υπήρξε κάτι που θεωρήσατε ιδιαίτερα χρήσιμο; Αν ναι, μπορείτε να το αναφέρεται;
7. Τι βρήκατε πιο χρήσιμο στην υπηρεσία;
8. Πόσο εύκολη ή δύσκολη ήταν η χρήση της υπηρεσία για εσάς;
9. Αισθανθήκατε πιο σίγουροι για τη διαχείριση των ασθενών με διαβήτη όταν χρησιμοποιούσατε την υπηρεσία;
10. Αισθανθήκατε ότι η υπηρεσία σας βοήθησε με οποιονδήποτε τρόπο στην καθημερινότητα σας με τους διαβητικούς ασθενείς;

Προτροπές: Χρήση γραφικών αναφορών του ασθενούς / προτάσεις από τον φαρμακοποιό / ατομικό σχέδιο ασθενούς

Section 2: Burden

11. Υπήρξε κάποιο συγκεκριμένο πρόβλημα που προκλήθηκε από την υπηρεσία;

Recruitment period

12. Μπορείτε να μου πείτε, τις σκέψεις σας σχετικά με τη στρατολόγηση ασθενών και τη συλλογή δεδομένων;
13. Μπορείτε να μου πείτε τις σκέψεις σας σχετικά με τον επιπλέον χρόνο που απαιτείται για την στρατολόγηση και τη συλλογή δεδομένων; Οποιαδήποτε σχόλια/ παρατηρήσεις σχετικά για αλλαγές στο μέλλον;
14. Μπορείτε να μου πείτε, τις σκέψεις σας σχετικά με τη διάρκεια της υπηρεσίας; Σχόλιο σχετικά με την ευκολία.

Προς νοσηλεύτρια: Παρακαλώ, μπορείτε να με ενημερώσετε για το χρόνο που απαιτείται για τον εντοπισμό του ασθενή και την οργάνωση της διαβούλευσης; Ήταν δύσκολο να βρεθεί αυτός ο χρόνος;

Section 2: Future Practice and Ethicality

15. Αισθανθήκατε ότι κατανοήσατε το νόημα της υπηρεσίας; καταλάβατε τι επιδιώκει να επιτύχει η υπηρεσία; (το νόημα της)
16. Πώς η υπηρεσία αυτή ταιριάζει σε αυτό που θα περιμένατε στον τομέα της υγείας;
17. Μπορείτε να μου πείτε τις σκέψεις σας σχετικά με τη συμβολή του φαρμακοποιού στη διαχείριση του διαβήτη στη διαβητολογική κλινική;

Προτροπή: Κατά τη γνώμη σας, πώς πρέπει να αλλάξει η συμβολή του φαρμακοποιού στις τρόπους διαχείρισης του διαβήτη στην Κύπρο;

18. Κατά την άποψή σας σε ποιο βαθμό πιστεύετε ότι η συμμετοχή του φαρμακοποιού στη διαχείριση του διαβήτη θα καταφέρει να επιφέρει διαφορά στην τρέχουσα κλινική πρακτική;
19. Μπορείτε να μου πείτε τις σκέψεις σας σχετικά με την κοινοποίηση των δεδομένων των ασθενών (εργαστηριακές εξετάσεις, σημειώσεις γιατρών κ.α) στο φαρμακοποιό; Πιστεύετε ότι αυτό είναι σημαντικό για τη συνέχεια της περίθαλψης των ασθενών;

Προτροπές: Χρήση γραφικών αναφορών του ασθενούς / προτάσεις από τον φαρμακοποιό / ατομικό σχέδιο ασθενούς

20. Παρακαλώ, μπορείτε να μου πείτε τις σκέψεις σας για τις παρεμβάσεις με χρήση εφαρμογών και πόσο χρήσιμες είναι για τους ασθενείς με διαβήτη τύπου 2;
21. Κατά την άποψή σας, θα πρέπει να διερευνηθεί περαιτέρω η υπηρεσία με χρήση εφαρμογών για τη βελτίωση της διαχείρισης του διαβήτη; Εάν ναι, κατά τη γνώμη σας, πιστεύετε ότι οι υπηρεσίες με χρήση εφαρμογών είναι κατάλληλες για την Κύπρο;
22. Κατά τη γνώμη σας, σε ποιο βαθμό πιστεύετε ότι η χρήση εφαρμογών θα καταφέρει να επιφέρει διαφορά στην τρέχουσα κλινική πρακτική;
23. Κατά τη γνώμη σας, αισθάνεστε ότι άλλες εναλλακτικές λύσεις μπορούν να παρέχουν ίδια / καλύτερα αποτελέσματα από ότι η προσφερόμενη υπηρεσία; Αν ναι, μπορείτε να το εξηγήσετε; (περιοχές για αλλαγή / προσαρμογή / αφαίρεση / προσθήκη)
24. Τι αισθανθήκατε για την υπηρεσία συνολικά; Τυχόν παρατηρήσεις σχετικά με το πώς να αλλάξει στο μέλλον;

Appendix 5.13 The definition of acceptability and of the component constructs in the theoretical framework of acceptability (TFA) proposed by Sekhon et al.'s 2017 study (Sekhon et al., 2017)

The definition of acceptability proposed by Sekhon et al.'s 2017 study (Sekhon et al., 2017)

The definition of acceptability
"Acceptability is a multi-faceted construct that reflects the extent to which people delivering or receiving a healthcare intervention consider it to be appropriate, based on anticipated or experienced cognitive and emotional responses to the intervention. The TFA consists of seven component constructs: affective, attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs and self-efficacy" (Sekhon et al., 2017, page 9)

Definitions of the component constructs in the theoretical framework of acceptability (TFA) (Sekhon et al., 2017, page 12, Additional file 6).

Theoretical framework of acceptability (TFA)	Definition
Ethicality	The extent to which the intervention has a good fit with an individual's value system.
Affective attitude	**Anticipated Affective Attitude:** How an individual feels about the intervention before participating. **Experienced Affective Attitude:** How an individual feels about the intervention after participating.
Burden	**Anticipated burden:** The perceived amount of effort that is required to participate in the intervention. **Experienced burden:** the amount of effort that was required to participate in the intervention.
Opportunity costs	**Anticipated opportunity cost:** The extent to which benefits, profits, or values must be given up to engage in the intervention. **Experienced opportunity cost:** the benefits, profits or values that were given up to engage in the intervention.
Perceived effectiveness	**Anticipated effectiveness:** the extent to which the intervention is perceived to be likely to achieve its purpose. **Experienced effectiveness:** the extent to which the intervention is perceived to have achieved its intended purpose.
Self-efficacy	The participant's confidence that they can perform the behaviour(s) required to participate in the intervention.
Intervention coherence	The extent to which the participant understands the intervention and how it works.

Appendix 5.14 Prompts employed during the interview about the evaluation of the intervention's acceptability

(Adopted by Taylor et al., 2016 and Smith, 2010)

Prompts for more detail/ Prompts to ask for comments on particular aspects	
English Version	**Greek Version**
• Would you say more about…?	• Θα μπορούσατε να πείτε περισσότερα για...
• Please could you explain…?	• Θα μπορούσατε να μου εξηγήσετε…
• What do you think that/about…?	• Τι νομίζετε ότι / σχετικά…
• What do you think are the reasons for…?	• Ποιοι πιστεύεται είναι οι λόγοι ….
• You mentioned your experience of…Could you tell me more about this?	• Αναφέρατε την εμπειρία σας ... Μπορείτε να μου πείτε περισσότερα γι 'αυτό;
• You said this made you feel...Why was that?	• Είπατε ότι αυτό σας έκανε να νιώσετε ... Γιατί ήταν αυτό;

Appendix 5.15 Pharmacist's experience with delivering the intervention.

Pharmacist's experience with delivering the intervention.			
Please complete the form by stating your experience after the provision of each task.			
Positive and negative experiences in regards to	**Pharmacist task**		
	Appointment based on principles of motivational interviewing	**Identify participant information and prepare before each appointment** (hear some recordings, review motivational interview principles and notes, and organize the next appointments)	**Respond to the participant's queries based on principles of motivational interviewing**
Time/workload			
Impact in pharmacist's work			
Impact by participants			
Additional burden caused			
Other comments			

Appendix 5.16 Data collection forms for workability and time estimation for the intervention delivery.

Data collection form for pharmacist's tasks for interventions provision	
Please complete the form for each participant.	
Participant ID:	**Duration** *(In minutes)*
Pharmacist tasks for the preparation for the delivery of the intervention:	
Identify participant information and prepare before the initial appointment.	
Pharmacist tasks for the delivery of the initial appointment:	
Demonstrate the application to patients.	
The adapted DSCAQ – Greek version.	
Initial appointment based on principles of Motivational Interviewing.	
Pharmacist tasks for the delivery of the subsequent appointments:	
Identify participant information and prepare before each appointment (hear some recordings, review motivational interview principles and notes, and organize the next appointments).	
Evaluate the patient's status.	
Phone calls and appointments.	
Scheduling and rescheduling calls, maintaining records (e.g., missed calls).	
Pharmacist tasks during the delivery of the intervention:	
Respond to the participant's queries, prepare messages, and identify and send educational leaflets.	
Review the participant's drug therapy and diabetes management plan.	
Contact and make recommendations to the GP.	

Appendix 5.17 Data collection forms for data form for cost estimation for the intervention delivery.

Costs		**Cost (All costs are based on costs in Cyprus, in Euro)**		
Item		**Description of cost**	**Quantity**	**Cost**
Set-up costs	**Cost of devices needed**	Viber application/ Email		
		Mobile phone		
		Initial phone contracts		
		Office with chair, desk, etc		
		Other please state:		
	Phone contracts			
	Heating and lighting			
	Cleaning service, electricity/water bill/ Internet bill			
	Stationery	Notes, computer, fax machine, printers, pens		
	Books and resources	Educational leaflets and photocopying charges		
Cost for intervention delivery	**Pharmacist's salary cost**			
	Training costs for the pharmacist	Motivational interview training		
	Costs related to promotion	Cost for production of: • Information leaflets for patients. • All documentation required for the delivery of the intervention.		
	Cost of devices needed	**Viber application/ Email** The Viber application and emails are free. Viber is a commonly used application in Cyprus and is available in Greek.		
		Fax machine		
		Audio recorder		
	Books and resources	Photocopying educational leaflets charges		
	Post services	Educational leaflets dispatched via post.		
Other please state:				
Total Costs				

Appendix 5.18 Data collection coding for participants' characteristics and engagement.

Data collection coding for participants' characteristics		
	Variable	**Coding**
1.	**Gender**	Male=1 Female =2
2.	**District**	Nicosia =1 Larnaca =2 Limassol =3 Paphos =4
3.	**Area**	Urban =1 Rural =2
4.	**Baseline HbA1c**[1]	Less than <7% =1 Between 7-8% =2 Above than >8% =3 Data missing =4
5.	**Baseline participants' antidiabetic pharmacotherapy**	Oral medication only =1 Oral medication and insulin =2
6.	**Antidiabetic drugs**	Metformin =1 Dipeptidyl peptidase-4 inhibitor (DPP-4) =2 Sulfonamides =3 Insulin glargine =4 Fast-acting insulin =5
7.	**Baseline participants' pharmacotherapy for other morbidities**	Participants taking other medication =1 Cholesterol-lowering medications =2 Cardiovascular medications =3 Anticoagulants or antiplatelet medications =4 Other conditions =5 Data missing =6

Data collection coding for participants' engagement.		
	Variable	**Coding**
1.	**Services**	Pharmacist online advice to patient queries =1 Tracking and uploading SMBG readings =2 Graphical reports =3 Reminders =4 Education =5
2.	**Goals**	Medication taking =1 Monitoring blood glucose =2 Knowledge =3 Being active =4 Healthy eating =5 No goals agreed =6 Combination of goals =7
3.	**Educational leaflets**	Diabetes and eyes =1 Diabetes and foot care =2 Diabetes and exercise =3 Diabetes and healthy eating =4 Diabetes book General =5 Hypoglycaemia =6 Medication =7
4.	**Media of delivery of educational leaflets**	At the clinic =1 Viber messages =2 Emails =3 Fax =4 Posts =5 More than one medium =6
5.	**Topics on medication**	Symptoms expressed to the pharmacist, which could be due to pharmacotherapy =1 Review of patients' medications =2 Adherence =3 Optimization of pharmacotherapy =4 Information about their medication =5
6.	**Topics on self-monitoring blood glucose**	Facing finger-pricking problems =1 The correct interpretation of blood glucose results =2 When to measure blood glucose =3
7.	**Topics on healthy eating and exercise**	Food characteristics (e.g., carbohydrates, protein, etc.) =1 Dieting habits on maintaining blood glucose within range =2 Alcohol and diabetes =3 Type of exercise they can do =4 Exercise and hypoglycaemia =5
8.	**Topics on foot problems and vaccination**	Knowledge about foot care =1 Foot acne =2 Vaccination (influenza vaccine and pneumococcal vaccine) =3
9.	**Media of delivery of topics discussed between the pharmacist and the patient**	Phone calls =1 Viber messages =2 Text messages =3 Emails =4 More than one medium =5

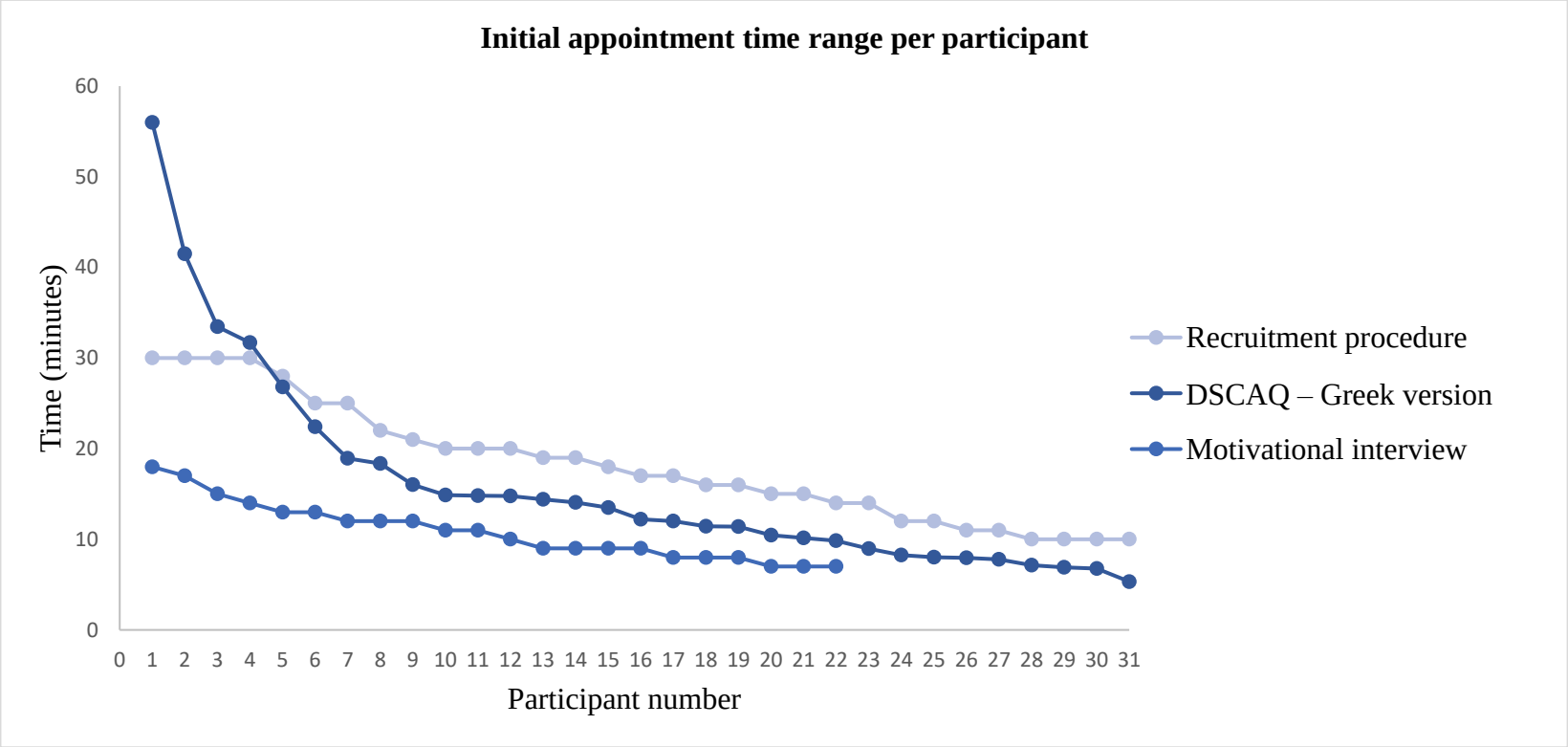
Appendix 5.19 Coding frame designed for participants' interviews.

Coding frame designed for participants' interviews			
Property from the interview schedule	**Open codes**	**Transcript extracts**	**Participants**
First of all, I would like to ask you if there was anything, in particular, you liked about the intervention. If so, can you explain?	• Increased motivation	*"You motivate us to do something we might not have done."*	Participant Number 20, male, 63 years old.
	• Role of education and advice	*"For something I doubt or do not know, I can ask you."*	Participant Number 19, male, 57 years old.
Was there anything you found specifically helpful?	• Role of ongoing support and communication	*"By talking to someone about a problem of yours helps you."*	Participant Number 03, female, 72 years old.
		"You are telling us things that we cannot find by ourselves. A scientist is informing us."	Participant Number 11, male, 68 years old.
		"The kindness, all the calls, good advice, and taking care of me.	Participant Number 21, male, 45 years old.
To what extent do you feel the intervention helped manage your diabetes?	• Enablement of self-management	*"Yes, now I am more responsible."*	Participant Number 09, female, 67 years old.
How confident did you feel in self-managing your diabetes when using the services of this intervention?	• Increased confidence	*"Yes, I am more confident that I will live a life without stress with my diabetes."*	Participant number 03, female, 72 years old.
What changes can you suggest improving the intervention?	• Scheduling - Timing of the phone appointments	*"Usually, the time that you were calling me is generally the time that I am sleeping."*	Participant Number 04, female, 65 years old.

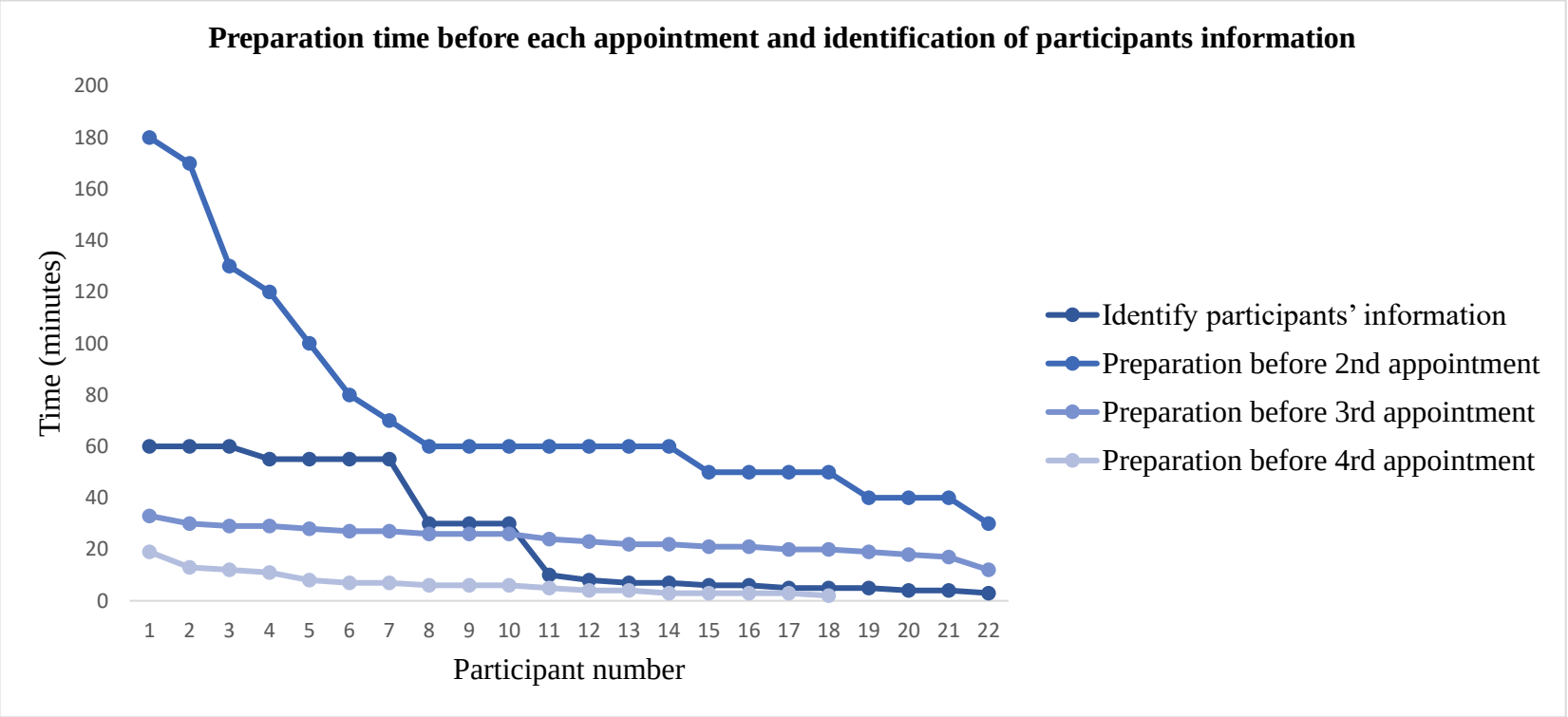
	• Media of delivering the intervention	*"A person feels more comfortable calling you or replying to a text."*	Participant Number 17, family care giver, 77 years old.
	• Frequency of the follow-up appointments	*"There is no need for more phone appointments."*	Participant Number 16, male, 77 years old.
	• Educational leaflets	*"Look, the educational leaflets are good."*	Participant Number 01, male, 81 years old.
	• Valued general physicians (GPs) versus pharmacist	*"Our GP is good but might not give us as much attention."*	Participant Number 12, male, 66 years old.
	• Lack of participants' motivation	*"I understand what I have to do, but I do not do everything as I should."*	Participant Number 06, female, 75 years old.

Appendix 9.1 The pharmacist's workload and time spent per task for delivering the intervention.

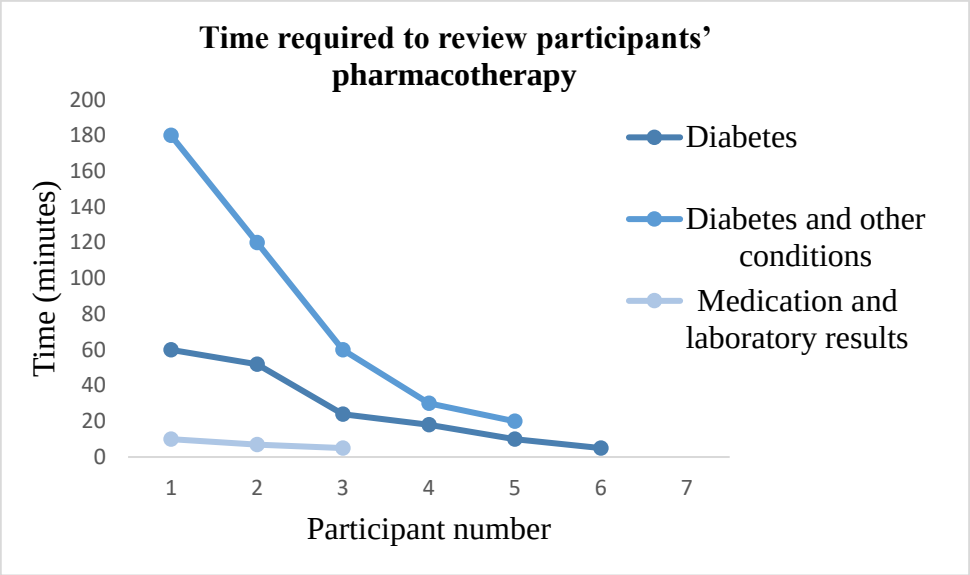
Pharmacist time spent at initial appointment per participant



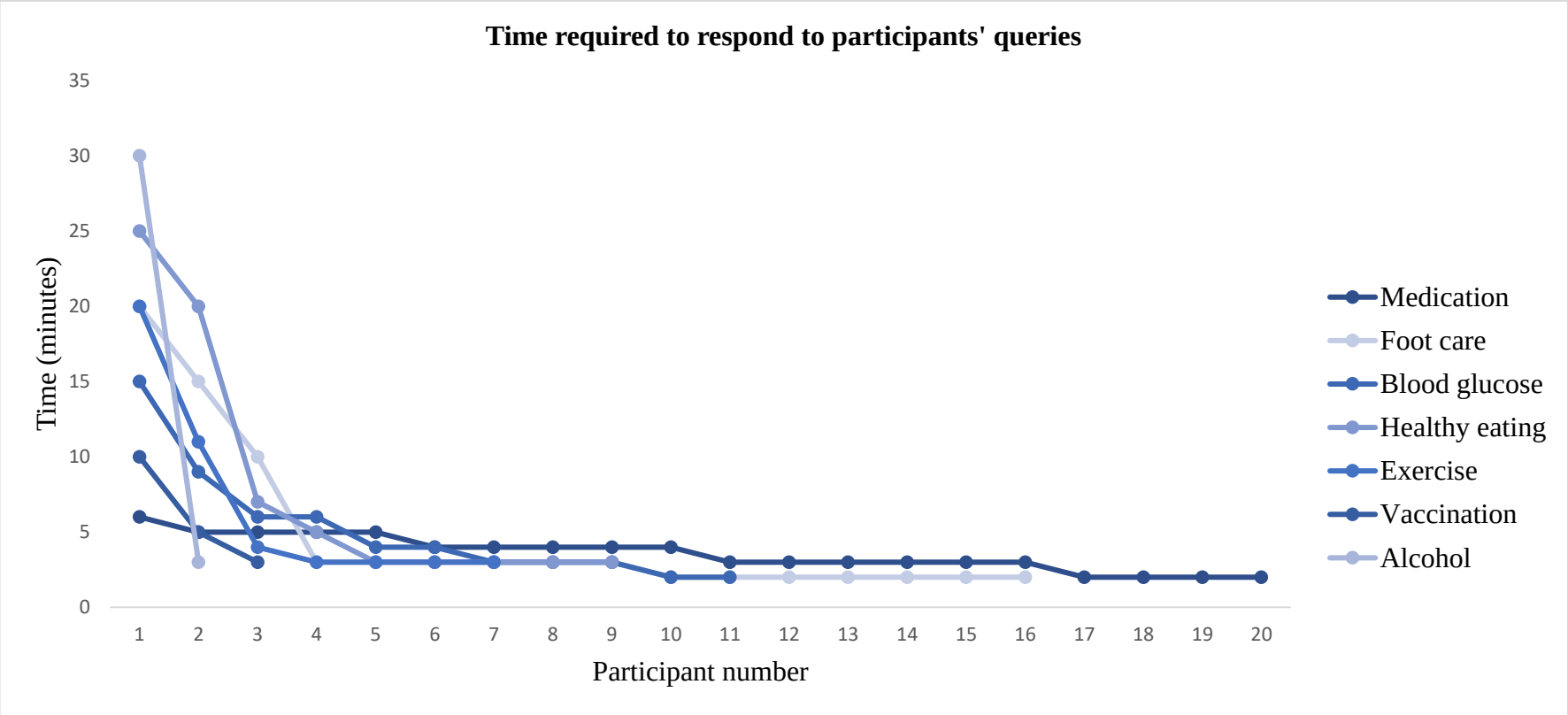
Pharmacist time spent at before each appointment per participant



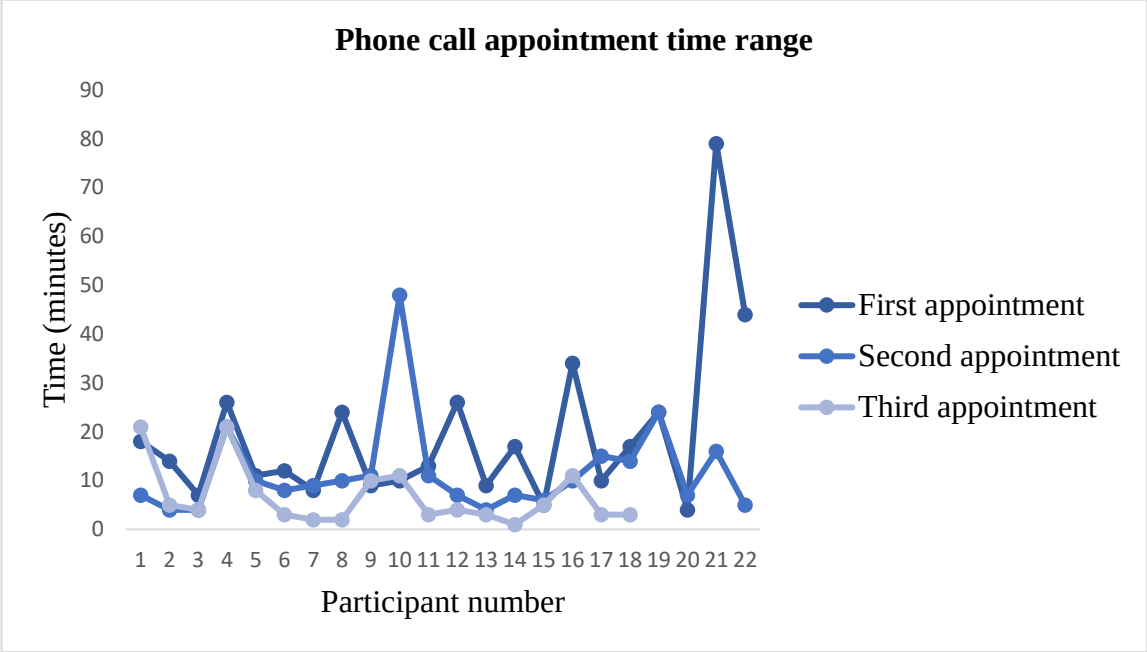
Pharmacist time spent to review participant' pharmacotherapy



Pharmacist time spent to respond to participants' queries



Pharmacist time spent at phone call appointments per participant



Pharmacist time spent to send educational leaflets per media