ONLINE STRUCTURED EDUCATION FOR PEOPLE NEWLY DIAGNOSED WITH TYPE 2 DIABETES

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Thesis submitted for the degree of PhD
DECLARATION

I, Shoba Poduval 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.

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Shoba Poduval
ACKNOWLEDGEMENTS

The Man in the Arena

By Theodore Roosevelt

The credit belongs to the man who is in the arena, whose face is marred by dust and sweat and blood; who strives valiantly; who errs, who comes short again and again, because there is no effort without error and shortcoming; but who does actually strive to do the deeds; who knows great enthusiasms, the great devotions; who spends himself in a worthy cause; who at the best knows in the end the triumph of high achievement, and who at the worst, if he fails, at least fails while daring greatly, so that his place shall never be with those cold and timid souls who neither know victory nor defeat.

I am so grateful for the opportunities I have been given. Thank you to everyone who got in the arena and fought with me.

First and foremost, I’d like to thank my supervisors Elizabeth Murray and Fiona Hamilton for their guidance and encouragement, for teaching me determination, and that if you don’t see a clear path to what you want, you have to make it yourself. My research was part-funded by the National School for Primary Care Research and the Claire Wand Fund, and I am extremely grateful to both organizations for making it possible for me to do this PhD. Thank you to everyone in the HeLP-Diabetes team, especially the Starting Out team Orla O’Donnell, Fiona Giles, Rebecca Owen, Helen Gibson and Kingshuk Pal. Thank you to the patients and professionals who gave up their time to participate in my research. Thank you to my friends, colleagues and fellow PhD students at the UCL Department of Primary Care and Population Health, especially Emma, Paulina, Hamad, Deepani, Marie-Laure, Lorraine, Jamie and Nathan, who I have shared the journey with, and from whom I have learnt so much.

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Robin, Shaz, Vics, Afsh and Durga, for your love and patience through every stage of my career, and for giving me the courage to chase my dreams.

Finally, I dedicate this work to Henry, Jayan and Amiya. You have made me stronger and wiser, you have made me do better and be better. This is for you.
ABSTRACT

Background

More people than ever have type 2 diabetes (T2DM) and the number is growing. Structured education reduces the risk of complications, and it is National Health Service (NHS) policy that newly diagnosed patients are referred to a structured education programme. Uptake to group-based courses is low. The internet could help surmount barriers to accessing courses. HeLP-Diabetes: Starting Out is an online structured education programme for T2DM.

Aim

The overall aim of the thesis was to develop, optimise and formatively evaluate an online structured education programme for people newly diagnosed with T2DM called HeLP-Diabetes: Starting Out.

Methods

The thesis was guided by the Medical Research Council guidance for complex interventions, and human-computer interaction theory. The thesis aim was achieved through a series of four empirical studies, addressing the development and evaluation of the intervention. A theoretically-informed first iteration of the programme was developed, and evaluated. The results informed the optimisation of the programme, and the development of a second iteration. The second iteration of the programme was evaluated using mixed methods, during its implementation in NHS primary care.

Additionally, I developed and evaluated strategies for reducing patient dropout between registration and completion of the programme. In order to look for evidence of a digital divide, I analysed usage data to compare webpage visits of patients with different demographic characteristics.
Results

Evaluation of the programme demonstrated that online structured education was feasible, and that different demographic groups were able to use the programme. Patients who completed the programme improved their self-efficacy and emotional distress. Problems with uptake and patient dropout were identified.

Discussion

The results have informed recommendations for a fully optimised programme, suitable for evaluation in a Phase 3 randomised controlled trial, to compare online with face-to-face structured education.
IMPACT STATEMENT

Diabetes is the fastest growing health crisis of our time. The number of adults living with type 2 diabetes has more than doubled in the last twenty years, and the number of children with the disease has increased by 40% in just three years. Diabetes can lead to devastating complications like blindness and amputations, and shorten lives. As well as the human cost, diabetes results in a substantial economic cost to the NHS. Treating the disease and its complications amounts to £10 billion a year, or £1 in every £10 spent by the NHS.

It’s crucial that people with type 2 diabetes are supported to make changes which reduce their risk of complications, and structured self-management education is an evidence-based way of doing this. The government has recognised the importance of improving diabetes care and outcomes, and £40 million has been invested in services including self-management education.

My PhD consisted of the development and evaluation of an online structured self-management programme called HeLP-Diabetes: Starting out, which complemented a larger web-based diabetes self-management package called HeLP-Diabetes. HeLP-Diabetes has been licensed for national rollout, and will be the first digital diabetes self-management intervention to be implemented nationally by the National Health Service (NHS) in England. My research on HeLP-Diabetes: Starting Out has added a structured pathway to the package, which makes it compliant with National Institute for Health and Care Excellence (NICE) requirements and Quality and Outcomes Framework (QoF) targets for good practice for General Practitioners (GPs). My findings are being used by NHS England to develop the rollout plan for HeLP-Diabetes. National rollout means that GPs and health professionals will be able to offer patients across England an online option for learning about type 2 diabetes, and accessing support for making crucial lifestyle changes.

One of my studies involved an analysis of the demographic features of people visiting HeLP-Diabetes and HeLP-Diabetes: Starting Out, and I found that our users were representative of people with type 2 diabetes, including older
people, people with less education and people from ethnic minorities. This is one of the first studies to provide evidence that a digital health intervention can be integrated into routine health services without widening health inequalities, and will shortly be published in the Journal of Medical Internet Research (Diabetes). I have disseminated my findings on the feasibility of online structured education for type 2 diabetes to clinicians and academics at national conferences and international research exchange visits. I have used my learning from my PhD to contribute to clinical guidance on diet advice for patients with diabetes which will be published by the British Medical Journal (BMJ). This will be available to help guide and improve the practice of GPs and other health professionals.
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ABBREVIATIONS

APPG All-Party Parliamentary Group

BAME Black, Asian and Minority Ethnic

BCT Behaviour Change Theory

BMI Body Mass Index

CCG Clinical Commissioning Group

CIC Community Interest Company

DESMOND Diabetes Education and Self-Management for Ongoing and Newly Diagnosed

DHI Digital Health Intervention

DSME Diabetes Self-Management Education

DSN Diabetes Specialist Nurse

DUK Diabetes UK

DVLA Driver and Vehicle Licensing Agency

GP General Practitioner

HbA1c Glycated Haemoglobin

HCI Human-Computer Interaction

HCP Healthcare Professional

HDSO HeLP- Diabes: Starting Out

HeLP- Diabetes Health Eating for People with type 2 Diabetes

ISO International Organization for Standardization

IEC International Electrotechnical Commission
MCID Minimal Clinically Important Difference
MRC Medical Research Council
MOST Multiphase optimisation strategy
NICE National Institute for Health and Care Excellence
NPT Normalization Process Theory
NHS National Health Service
NIHR National Institute for Health Research
PPI Public and Patient Involvement
PRIME Process modelling in implementation research
QOF Quality and Outcome Framework
QISMET Quality Institute for Self-Management Education and Training
RCT Randomised controlled trial
STP Sustainability and Transformation Plan
SDT Self Determination Theory
SCT Social Cognitive Theory
SRT Self-Regulation Theory
SMART Specific Measurable Achievable Realistic Time-Bound
T2DM Type 2 Diabetes Mellitus
UK United Kingdom
WHO World Health Organization
GLOSSARY

Cardiovascular: Of, relating to, or involving the heart and blood vessels.

Digital Health Intervention: Interventions delivered via digital technologies such as smartphones, website, and text messaging.

Digital Divide: The concern that the groups who suffer the highest health burden are the least likely to access the internet and benefit from web-based interventions.

Hypoglycaemic: One affected by a decrease in the level of sugar in the blood.

Hyperglycaemia: An increase in the level of sugar in the blood.

‘In the wild’ study: A study in which users are observed using products or prototypes within their everyday context.

Iterative: Doing something again and again, usually to improve it.

Nephropathy: An abnormal state of the kidney.

Neuropathy: Damage, disease, or dysfunction of one or more nerves, typically causing pain, numbness of tingling.

Retinopathy: A disorder of the lining of the eye, which can cause blindness.

Spiral model: Lifecycle model used in software engineering to illustrate the stages of development in a sequential but iterative pattern.

User-centred design: An iterative design process in which designers focus on the users and their needs in each phase of the design process.

Waterfall model: Lifecycle model used in software engineering to illustrate the stages of development in a rigid sequential pattern.

Usability testing: Measuring users’ performance on various tasks in an interactive product.
User experience: A person’s perceptions and responses that result from the use or anticipated use of a product, system or service

X-PERT: Face-to-face self-management course for diabetes.
Chapter 1.  Introduction to the thesis

1.1 Chapter summary

In this chapter I have presented the background to the thesis. The diabetes pandemic is a public health crisis for nearly every country in the world (1). 1 in 11 adults (425 million) have diabetes globally (2). I have described the condition, its prevalence, and its management to set the scene for the extent of the challenge to health systems. I have then discussed diabetes self-management, and self-management education, and the need for improved uptake of self-management education in the UK. I have presented online self-management education as an alternative to face-to-face courses, the evidence for this and the challenges for online interventions. Finally, I have described how the thesis focuses on an online structured education intervention called HeLP-Diabetes: Starting Out, and listed the thesis aim and objectives.

1.2 Background

1.2.1 Type 2 Diabetes Mellitus

Diabetes Mellitus is a serious, lifelong condition where a gland in the body called the pancreas cannot produce the hormone insulin, or the body cannot use insulin properly (insulin resistance) (3). Insulin regulates the blood sugar (glucose) levels in the body, and raised blood sugar resulting from poorly controlled diabetes leads to damage to nerves and blood vessels (4). Over time this can cause long-term complications such as retinopathy (eye disease), cardiovascular disease (heart disease), nephropathy (kidney disease), neuropathy (nerve damage), and can shorten life (5).

More people than ever have diabetes. An estimated 422 million were living with diabetes globally in 2014, compared with 108 million in 1980. The age-standardised global prevalence of diabetes has nearly doubled in adults from 4.7% to 8.5%. This increase reflects the rise in prevalence of risk factors such as obesity and physical inactivity (4). In 2012 diabetes caused 1.5 million deaths worldwide, making it the eighth leading cause of death in both sexes.
The number of deaths from diabetes is expected to double between 2005 and 2030 (4).

About 90% of people with diabetes have Type 2 Diabetes Mellitus (T2DM) which results from the ineffective use of insulin (4). Risk of developing T2DM depends on a combination of genetic and metabolic factors. Black, Middle Eastern or South Asian ethnicity, family history of diabetes and previous history of gestational diabetes combine with older age, cardiovascular disease, raised cholesterol, being overweight, and physical inactivity to increase risk (4, 6).

The other 10% of people with diabetes mostly comprises of people with Type 1 Diabetes Mellitus, which is characterised by a deficiency in insulin production by the pancreas (6). Gestational diabetes also exists. This affects pregnant women and is caused by the pregnancy hormones making it difficult to use insulin effectively. Glucose levels in the blood rise and cause gestational diabetes. Women with gestational diabetes do not have diabetes before their pregnancy, and it usually goes away after giving birth. But this leaves women with an increased risk of gestational diabetes in future pregnancies, and lifelong type 2 diabetes. Women are at increased risk of developing gestational diabetes if they are overweight, have had gestational diabetes before, have had a large baby in a previous pregnancy, have a family history of diabetes or are of South Asian, Black of Middle Eastern ethnicity (7).

Most patients do not have symptoms, and are diagnosed on screening blood tests (6). One of the screening blood tests that is used is called HbA1c. This is a term which refers to glycated haemoglobin, which accumulates when the protein in red blood cells (haemoglobin) joins with glucose and becomes ‘glycated’ (8). HbA1c is a good measure of persistent hyperglycaemia (an increase in the level of sugar in the blood) as it reflects a person’s average blood glucose over a period of 8-12 weeks (9).

In the UK T2DM affects an estimated 3.8 million people over the age of 16 (8.6% of the population of this age group) (10). This figure includes those who are diagnosed and undiagnosed and is predicted to rise to 4.9 million (9.7% of
the population of this age group) by 2035 (10). Diabetes places a considerable economic burden on the National Health Service (NHS). Approximately £10 billion a year is spent on diabetes and its complications, which is 10% of the total NHS budget. Less than a quarter of the £10 billion spent on diabetes is spent on treatment and ongoing management of diabetes, and the rest is spent on treating complications like those listed above (11).

There is evidence that treatment can improve outcomes in T2DM. The United Kingdom Prospective Diabetes Study (UKPDS) is the largest prospective observational study of diabetes. It has provided evidence that intensive glucose-lowering therapy in newly diagnosed patients can significantly reduce the risk of complications (12). Although these results were encouraging, the ten year follow-up data showed that blood glucose steadily worsened (13) and questions have been raised about whether drug treatment alone is sufficient to achieve long-term control (14).

The National Institute for Health and Care Excellence (NICE) has published guidance on the management of T2DM in adults. This guidance, which was updated in 2017, recommends patient education, dietary advice, blood glucose management, blood pressure management, antiplatelet therapy and detection and treatment of complications (15). General Practices (GP practices) in England receive payments for meeting treatment targets listed in the Quality and Outcomes Framework (QoF). QoF is a voluntary annual reward and incentive programme for all GP surgeries in England which aims to reward quality care and standardise improvements in the delivery of primary care (16, 17). QoF indicators for diabetes include keeping a diabetes register of all patients aged 17 or over with diabetes, and achieving a recommended set of targets for a threshold percentage of patients on this register. These targets correspond to blood glucose control, blood pressure control, cholesterol control, identification and treatment of nephropathy, influenza immunization, foot examination and referral to structured education (17).

NICE recommends that dietary advice, weight loss and increasing physical activity are integrated within a personalised diabetes management plan. Blood glucose levels should be monitored at 3-6 monthly intervals until the HbA1c is
stable. The target for people managed with lifestyle and diet, or lifestyle and diet with a single drug not associated with hypoglycaemia (low blood sugar) is 48mmol/mol (15).

There is growing interest in the role of diet and weight loss, not only in diabetes management, but also potentially in causing remission. The underlying disease mechanism of T2DM involves genetics and ageing (18), as discussed above, but it is also strongly related to weight gain in adult life and accumulation of fat in the liver and pancreas (19). Pathophysiological studies have shown that restricting calories can produce a total biochemical remission of T2DM, by normalising liver and pancreas fat content, reducing liver insulin resistance and restoring the function of beta cells in the pancreas which produce insulin (18, 20, 21). A trial of intensive weight management within primary care (the Diabetes Remission Clinical Trial, or DiRECT trial) has achieved diabetes remission in almost half of participants who underwent complete withdrawal of antidiabetic medication, total diet replacement (825-853 kcal/day formula diet for 3-5 months), stepped food reintroduction over 2-8 weeks and structured long-term weight management support (19).

1.2.2 Diabetes self-management education

Self-care has been defined in the literature on the management of long-term conditions (conditions that cannot, at present be cured; but can be controlled by medication and other therapies) as the actions individuals take “to lead a healthy lifestyle; to meet their social, emotional and psychological needs; to care for their long-term condition; and to prevent further illness and accidents” (22). The potential benefits of self-care in the management of long-term conditions is stated in ‘The Chronic Care Model’, a comprehensive model which has been developed to summarise the community, organization, practice and patient level components for improving care in health systems (23). The model states that “all patients with chronic illness make decisions and engage in behaviours that affect their health (self-management). Disease control and outcomes depend to a significant degree on the effectiveness of self-management” (23). Self-management can improve physical functioning, patient experience, and adherence to medication (24). Supporting self-care is
increasingly important in the NHS due to the rise in prevalence of long-term conditions (which now consume about 70% of the NHS budget (25)), alongside a growing patient preference to be more involved in their care (26). Effective self-care has been identified as essential in NHS strategy reports such as the Wanless report into NHS resource requirements (27), and the NHS Five Year Forward View (28).

Patient self-care is particularly important in T2DM because people predominantly have to take care of their illness themselves, when they are outside of a healthcare setting (14). It has been estimated that people with diabetes spend an average of only three hours a year with a healthcare professional. For the remaining 8,757 hours they manage their diabetes themselves (29). What people eat, how much they exercise, and how much they follow medical advice in everyday life is a leading determinant of their health and their need for health care (30). As discussed above, T2DM results from a combination of genetic and metabolic factors (including obesity and physical activity). Self-care behaviours in T2DM have been defined by the American Association of Diabetes Educators as healthy eating, physical activity, blood glucose monitoring, medication adherence, problem-solving skills, coping skills and risk-reduction behaviours (31). Learning about these self-care behaviours is pivotal for effective self-management (14). Despite this, a healthcare professional-centred approach is still favoured in the NHS which does not address psychological and emotional aspects of the disease. There is increasing evidence from the work of Lorig in the Unites States and Barlow in the UK, that people have improved self-efficacy (self-confidence in self-management) and general health when they are empowered to manage their long-term condition (32, 33). People are empowered when they have the relevant knowledge, skills, attitudes and self-awareness to improve the quality of their lives (34). Diabetes self-management education (DSME) aims to give people with T2DM the knowledge and skills they need to improve their health and quality of life.

The World Health Organization (WHO) defines health education as “any combination of learning experiences designed to help individuals and
communities improve their health, by increasing their knowledge or influencing their attitudes” (35). Elsewhere, individual patient education has been described as a “planned learning experience using a combination of methods, such as teaching, counselling and behaviour modification techniques which influence patients’ knowledge and health and illness behaviour” (36).

‘Empowerment’ is becoming more common as an aim of patient education, rather than simply dispensing information in a didactic way (37).

The aim of patient education for T2DM is to improve people’s knowledge, skills and confidence to take control of their condition and integrate self-management into daily life (38). In the UK standards for diabetes education have been set by the Diabetes UK (DUK) Patient Education Working Group in collaboration with the Department of Health in 2015 (38). These standards have four key criteria headings: a structured written curriculum; trained educators; quality assurance; and audit. Structured patient education is recommended by NICE for everyone with T2DM (and/or their carers) at and around the time of diagnosis (15). The recommended components reflect the standards set by the DUK Patient Education Working Group listed above. NICE also recommends that education should be evidence-based, theory-driven, and have specific aims and objectives (15).

Systematic reviews of structured self-management education suggest that structured education is effective at improving patient knowledge, self-care behaviours, metabolic control, psychological outcomes and healthcare costs (39-42). There are limitations in the research carried out on structured education, which are common to many of the reviews. These include heterogeneity in quality and type of intervention; and incomplete or inadequate descriptions of the interventions. Most reviews recommended further research with better-designed long-term studies (43).

Educational interventions are more prone to being heterogeneous and difficult to evaluate, due to having multiple component parts, any of which could be the ‘active ingredient’ (14). There can be differences in the way education is provided, who provides it, the duration and nature of sessions, the setting, and the demographic and the clinical characteristics of participants. This has been
identified as a hindrance to meta-analysis (43). The Medical Research Council (MRC) guidance (44) on developing and evaluating complex interventions has helped improve the rigor of research on complex interventions like health education programmes, and this guidance will be discussed in more detail in Chapter 2.

Of the most recent systematic reviews of DSME, one examined the effectiveness of group-based interventions compared to individual interventions or usual care on outcomes for people with T2DM (45). The review found that group-based education was more effective at reducing HbA1c, fasting blood glucose, body weight, waist circumference, triglycerides and diabetes knowledge than controls, but not at all time points (45). Any reduction in HbA1c is clinically meaningful, but a change in HbA1c of 11mmol/mol (1%) has been found to lower the risk of complications by 25% in UKPDS studies (46).

Theory-based self-management educational interventions for patients with T2DM have also been reviewed recently (47). The review found significant improvements in HbA1c, self-efficacy, and diabetes knowledge, but not in body mass index (BMI) (47). However, due to differences in the duration and format of the teaching, no conclusions could be drawn about which theory-based intervention was most-effective (47).

A 2017 review looked at reduction in all-cause mortality and found that DSME significantly reduced all-cause mortality in patients with T2DM (48). There was no heterogeneity in the included studies and meta-analysis was carried out. However, no sub-group analyses were conducted on diabetes duration, diabetic complications, education levels, and socioeconomic status, and more research is needed on the effect of these characteristics (48).

An economic evaluation of self-management support for diabetes has been carried out (49) to determine cost-effectiveness of these interventions. The review found that the best evidence for cost-effectiveness was from education programmes, but there was limited evidence for telemedicine interventions and behaviour therapy. The telemedicine interventions focused on sending test
results and enabling remote interaction. The behaviour therapy included motivational enhancement therapy and cognitive behavioural therapy. The majority of studies were of low quality (49).

Synthesizing the results from reviews of DSME, there seems to be evidence for improvements in glycaemic control, diabetes knowledge and psychological outcomes. However reviews of the evidence have been limited by heterogeneity in the interventions and inadequate description of interventions.

As described above, structured education is offered to all patients who are diagnosed with T2DM at or around the time of diagnosis (15). General practices are incentivised to refer patients to structured education within 9 months of their diagnosis (17). Currently most courses that are offered are face-to-face.

The market leaders in structured education for T2DM in the UK are DESMOND and XPERT which both offer face-to-face group-based sessions. DESMOND (Diabetes Education and Self-Management for Ongoing and Diagnosed patients) consists of six hours of group education over one day or two half-days (50). XPERT consists of weekly two and a half hour group sessions for six weeks (51). Some areas also offer locally-designed courses including the borough of Tower Hamlets in London where the local diabetes centre and community-based charities work together to provide Bengali speaking link workers, and patient activation measures are used to identify what type of education or support is most suitable for the patient (52).

Uptake of diabetes structured education is poor. Data from the National Diabetes Audit for 2016-17 shows that despite the recorded percentage of patients with T2DM who were offered structured education within one year of diagnosis increasing to 76.6% in 2015, the recorded percentage of patients who attended structured education within one year of diagnosis was only 7.1% (See Figure below) (53).
Figure 1-1: Percentage of people diagnosed with diabetes that have a recorded structured education programme attendance, by year of diagnosis and diabetes type, 2016-17*

<table>
<thead>
<tr>
<th>Year of diagnosis</th>
<th>Type 2 and other</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>3.3</td>
</tr>
<tr>
<td>2011</td>
<td>4.2</td>
</tr>
<tr>
<td>2012</td>
<td>4.6</td>
</tr>
<tr>
<td>2013</td>
<td>6.3</td>
</tr>
<tr>
<td>2014</td>
<td>6.7</td>
</tr>
<tr>
<td>2015</td>
<td>7.1</td>
</tr>
</tbody>
</table>


*The percentage of patients who attended structured education within 2 years of diagnosis’ data was not reported for people diagnosed with diabetes in 2015 because the 2016-17 NDA data (latest audit period) ends in March 2017, meaning that anyone diagnosed after March 2015 would not have the full 2 year opportunity to attend structured education.

Recording of attendance at structured education is believed to be poor, and the low attendance rates are likely to be an underestimate. In 2017 an initiative was developed by Diabetes UK to improve communication between General Practices and education providers to help provide more reliable data for the 2017-18 audit (53). There is also greater incentive for practices to more accurately record attendance at structured education because attendance now forms one of the indicators in the CCG improvement and assessment framework (54). The intention of the framework is to encourage CCGs to deliver the improvement in services needed to achieve the vision laid out in the NHS Five Year Forward View (54). Diabetes is one of the six clinical priority...
Areas listed in the Five Year Forward View where transformation is necessary (28).

Reasons for poor attendance at structured education have been explored. A review of barriers to attendance in diabetes education found that personal difficulties (work, family, travel); perceptions and attitudes of patients (perceptions about the nature of diabetes, perceptions about the benefits of the sessions); communication (inability to speak English, lack of awareness of the sessions); and motivation (lack of time or lack of interest) were the barriers that were identified (55). A systematic review of reasons why patients referred to diabetes education chose not to attend identified similar barriers (56). Themes were grouped into two broad categories: reasons for not being able to go, and reasons for not wanting to go. Of the reasons for not being able to go, people listed issues such as the venue being too far away, timing of programmes, disabilities preventing them from attending, family or work commitments and not being able to afford travel to the course. The reasons why they did not want to go included not feeling any benefit would be gained, not feeling it is a high enough priority, feeling satisfied with the care already being received, feeling they have enough knowledge already, lack of information on programmes, negative feelings towards diabetes education or group education, not wanting anyone to know about their diabetes, and literacy or language problems. There were also participants who did not know why they would not go (56).

Some of the barriers to attending structured education identified in the review are a result of courses being face-to-face and in groups. These barriers are surmountable by offering patients alternative options.

It is a NHS priority to improve uptake of diabetes structured education courses. Building on plans in the Five Year Froward View, the NHS Shared Planning Guidance for 2017-2019 ring-fenced £44 million of transformation funding to improve the treatment of people with type 1 and type 2 diabetes (T2DM), including the uptake of structured education (57). Reports by Diabetes UK and the All Party Parliamentary Group (APPG) on Diabetes have called for more flexibility than is currently offered by face-to-face courses so that people with
diabetes can learn about the illness in different ways and at times that are convenient to them (58, 59). One of the recommendations from DUK was for commissioners to provide a ‘menu’ of options (59). The APPG for diabetes called for more flexibility of content and delivery, to allow for education that fits better into people’s lives and reaches more people. This included online options (60). Online diabetes self-management support is a thriving area of research, due to the compelling case for providing patients with online support. I have next described the case for online diabetes self-management support, and the evidence for its effectiveness. Following that I have described the challenges to successfully implementing online diabetes self-management support.

1.2.3 Online diabetes self-management

We live in an increasingly “connected” society. Over 90% of United Kingdom (UK) adults were internet users in 2018 (61). Yet the NHS is a decade behind other industries, like banking and retail, in the use of technology (62). Digital health interventions (DHIs) are interventions which are delivered via digital technologies like smartphones, websites or text-messaging, and have the potential to provide safe, effective ways to improve health and healthcare (63).

Digitalisation has been proposed as a strategy for improving the quality and efficiency of care within a tightly controlled NHS budget (28). The goal of digitisation is to promote what is known as healthcare’s ‘Triple Aim’: better health, better healthcare and lower cost (64). Technology offers a number of different opportunities for patients and health professionals. There is the potential to empower patients to take the lead in their care by providing access to information and support. Technology could also help clinicians to monitor patients more easily, support clinical decision making, allow data capture and sharing, and improve service planning (65).

DHIs can be delivered to large numbers of people and have the potential to be highly cost-effective due to the minimal marginal cost per user. Evidence for cost-effectiveness is emerging. Systematic reviews of internet interventions for mental health provide preliminary evidence of cost-effectiveness when
compared to treatment as usual or attention control (66). More broadly, an economic analysis by McKinsey estimates that modern health systems can save 7-11.5% of health expenditure by implementing digital systems, including behaviour change interventions (67).

Significant investment has been made in the digitisation of the NHS. In 2016 £4.2 billion was allocated by the government to digital projects (65). The Wachter Report stated that the NHS cannot afford to remain largely non-digital, and offered a series of recommendations for implementation, including a national engagement strategy for educating and involving stakeholders in the creation of digital strategies and systems (68). Local implementation has been prioritised and a framework for delivery of local "Digital Roadmaps" was set out in the National Information Board report “Personalised Health and Care 2020”. These are led by Clinical Commissioning Groups (CCGs) to drive implementation of digital services locally (69), and have been aligned with NHS sustainability and transformation plans (STPs). STPs are ‘place-based plans’ put together by NHS organizations and local authorities in different parts of England to improve quality of care, health and wellbeing and efficiency of services in each area (70). As mentioned in the previous section, around £44 million of transformation funding has been allocated for the improvement of diabetes care (71).

There is evidence from systematic reviews that online diabetes self-management interventions can improve clinical and behavioural outcomes (72-75), and allow interaction and tailoring of behaviour change interventions (76). A 2013 Cochrane systematic review found that computer-based diabetes self-management interventions had a small effect on glycaemic control, and the effect was larger in the mobile phone app sub-group (72). In a 2015 systematic review by Pereira et al, internet-delivered DSME were found to result in significantly improved glycaemic control and clinic attendance, compared to usual care (73). Some studies also found improvements in self-efficacy (77), diabetes knowledge (78-81), exercise behaviours (82, 83), and self-care behaviours (82, 84). Fourteen studies were reviewed and eight of these were randomised controlled trials. Only two studies compared internet
education with face-to-face education. A 2017 systematic review of reviews looking at technology-enabled diabetes self-management and support found that eighteen of twenty-five reviews reported a significant reduction in HbA1c. However, a meta-analysis was not conducted, and there was heterogeneity of the interventions and study designs. The most effective interventions incorporated two-way communication with health professionals, tailored education and individualised feedback (85).

The data from online diabetes self-management support interventions are promising, but further evidence is needed of the relative clinical- and cost-effectiveness of online compared to group-based NICE-compliant structured education. There are also challenges facing DHIs, including adherence and the digital divide, that need further research. These are discussed below.

**1.2.3.1 Challenges with online diabetes self-management**

**1.2.3.1.1 Adherence**

A challenge common encountered by many DHIs is poor adherence. There is evidence of a decrease in use over time from interventions for panic disorder (86), depression (87), weight loss (88, 89), smoking cessation (90-92), problem drinking (93), and diabetes self-management (94). This is a concept known as attrition, and this poses a problem because of the need for engagement with the intervention in order for it to achieve its outcomes. However, the relationship between level of use of DHIs and outcomes is complex. Some studies have found an improvement in outcomes despite decrease in use over time (94). It is unclear how much people need to use a DHI in order to bring about meaningful change in behaviours, and it is likely that there are complicating factors like reverse causality. Reverse causality is when the user experiences better outcomes due to some factors other than the intervention and so becomes more engaged with the intervention.

Reasons for poor engagement could include the usability of the site, the acceptability of the intervention, and users’ commitment to change and symptom level, amongst other factors (87). Attrition may not be a problem that is unique to digital interventions, but it may be better reported for digital
interventions than for other complex interventions used in the NHS like physiotherapy and district nursing.

Attrition was a theme throughout this thesis. Engaging users with the intervention was considered in the development of the HeLP-Diabetes: Starting Out intervention which is described in Chapter 3. Attrition was measured in the evaluations of the intervention described in Chapters 4 and 6. Strategies for reducing attrition were developed and tested in Chapter 7. The data were synthesised and the concept of effective engagement was discussed in the final chapter, Chapter 10.

The second challenge for online diabetes self-management interventions is inequalities in use. This is discussed next.

1.2.3.1.2 The digital divide

In the UK internet access has increased to 90% in 2017, but there are still 4 million households without internet access (95). Lack of internet access disproportionately affects older people, people from minority racial and ethnic groups, people with disabilities, rural communities and those with low socioeconomic status (96). This leads to a serious concern that the groups who suffer the highest health burden being the least likely to access the internet and benefit from web-based interventions, a phenomenon known as the “digital divide” (97, 98).

There are arguments both for and against DHIs widening inequalities. On the one hand, digital health has the potential to worsen inequalities for people who do not have internet access (the groups listed above), for people with poor computer and health literacy, and for people with low motivation to use the internet. Both health and computer literacy have been found to be lower in older people, people from black, Asian and minority ethnic (BAME) backgrounds, people with lower incomes and people with lower educational attainment (99-102). This adds to problems with internet access for these groups, and worsens potential inequalities.

On the other hand, digital health provides the opportunity to narrow inequalities by being easily available to large groups of people, and by reaching isolated
and vulnerable groups like the homeless, rural communities and non-English speakers.

The needs of different demographic groups were carefully considered in the design of the intervention (described in Chapter 3), and the demographic characteristics of users were scrutinised in Chapter 7 to look for evidence of a digital divide.

The research contributing to this thesis sought to address remaining questions around online diabetes self-management support, attrition, and the digital divide. The thesis aims and objectives are listed below, following a description of the thesis rationale and context.

1.3 Thesis rationale

As described above, improving uptake of structured self-management education for T2DM is an NHS priority (103), and systematic reviews have examined reasons for poor uptake (55, 56). Recommendations for improving uptake have been made, and this includes offering patients online courses (56, 59, 60). Systematic reviews of online self-management support have been conducted suggesting evidence of improvements in glycaemic control and self-care behaviours (72-75). However, evidence for relative effectiveness clinical- and cost-effectiveness of online compared to group-based structured education is still lacking. Engagement with online interventions, and their effect on inequalities, is poorly understood.

A National Institute for Health Research (NIHR) programme grant funded the development of an online self-management resource called HeLP-Diabetes for everyone with T2DM, not just newly diagnosed patients. Randomised controlled trial (RCT) data showed this to be effective and cost-effective, but NICE recommends a structured programme (with specific aims and objectives, and a structured written curriculum). This was lacking from HeLP-Diabetes (15). In order to disseminate and implement HeLP-Diabetes, a social enterprise called the HeLP Digital Community Interest Company (CIC) was set up. Obtaining contracts required certification from the Quality Institute for Self-
Management Education & Training (QISMET), and a structured programme. A structured programme (HeLP-Diabetes: Starting Out) was therefore developed in order to be NICE and QiSMET compliant.

This PhD focuses on the development, optimisation and evaluation of the HeLP-Diabetes: Starting Out (HDSO). This is best practice for determining feasibility and acceptability, and addressing design uncertainties according to Medical Research Council (MRC) guidance (104) and the approach taken to human-computer interaction (HCI) research (105), prior to carrying out a definitive trial. The MRC guidance and relevant HCI theory are described in more detail in Chapter 2.

1.4 Thesis aim and objectives

The thesis aim and objectives are listed below and illustrated in Figure 1-2.

1.4.1 Aim

The overall aim of the thesis was to develop, optimise and formatively evaluate an online structured education programme for people newly diagnosed with T2DM called HeLP-Diabetes: Starting Out.

1.4.2 Objectives

1. To develop an initial version of the programme (iteration 1);
2. To determine the uptake, usage and effect of this initial version;
3. To revise the programme in light of these data (iteration 2);
4. To determine uptake, usage and effect of the 2nd iteration;
5. To describe the demographic characteristics of users, patterns of use, and explore associations between demographics and usage patterns;
6. To consider and evaluate different methods of improving adherence to the programme;
7. To make recommendations on strategies for improving adherence and for a fully optimised programme suitable for evaluating in a phase 3 Randomised Controlled Trial.
8. To make recommendations for the research methods used in a phase 3 randomised Controlled trial.

The thesis aim and objectives were achieved through a series of four empirical studies. This is illustrated in Figure 1-2.

**Figure 1-2: Thesis aim and objectives**

To develop, optimise and formatively evaluate an online structured education programme for people newly diagnosed with T2DM called HeLP-Diabetes: Starting Out

- **Development**
  - Study 1: Evaluation of 1\textsuperscript{st} iteration
  - Study 2: Evaluation of 2\textsuperscript{nd} iteration
  - Study 3: Strategies for reducing attrition
  - Study 4: Exploring the digital divide

Recommendations on strategies for improving adherence and for a fully optimised programme suitable for evaluating in a Phase 3 Randomised Controlled Trial

Recommendations for the research methods to be used in a Phase 3 Randomised Controlled Trial
1.5 Summary

Diabetes prevalence is increasing globally, and presents a significant challenge to health systems. Onset of type 2 diabetes is linked to lifestyle factors like diet and exercise, and evidence suggests that self-management education can reduce the risk of complications. However uptake of face-to-face courses is low, partly due to problems attending group education courses. Online options may help to increase the uptake of self-management education in the UK. In this chapter I have outlined the rationale for developing an online structured education programme for type 2 diabetes, called HeLP-Diabetes: Starting Out. I have also presented the aim and objectives of my thesis and how my four studies were designed to address these objectives. The next chapter explains the methodological standpoint of the four studies.
Chapter 2. Methodological considerations

2.1 Chapter summary

In this chapter I have described frameworks for developing and evaluating digital health interventions, the context and setting for the development and evaluation of HeLP-Diabetes: Starting Out, and theories relevant to its design and implementation in primary care. This provides an introduction to the approach taken to my PhD research.

2.2 Complex interventions

HeLP-Diabetes: Starting Out is a complex intervention, and this had implications for the approach I took to its development and evaluation, for the following reasons. There are many definitions of complex interventions. The Medical Research Council (MRC) guidance for developing and evaluating complex interventions explains that they have multiple interacting components, a number of behaviours required of those delivering or receiving them, they target a number of different groups, they can have a number of different outcomes, and they allow for a degree of flexibility or tailoring (44). Hawe has described complex interventions as being non-standard, having specific theory-driven principles, and having different forms in different contexts (106).

An understanding of context is important for the design and implementation of complex interventions. Contextual factors include the sociodemographic background of the patient, the health system, the prevalence or severity of the condition, and changes in these factors over time. Context influences how the health problem that the intervention is targeting is caused and sustained, whether the problem is amenable to improvement by the intervention, and how the intervention might work. Understanding the context for the intervention is therefore crucial during its development, and assessing whether the intervention will be effective in different settings (107).

Complex interventions are used in housing, transport and education, as well as health. Examples include setting up new healthcare teams, interventions to
get treatment guidelines adopted, and community education interventions (106).

Figure 2-1 is a schematic of a complex home-based cardiac rehabilitation intervention for post-myocardial infarction (MI) patients (108), showing the multiple components which act independently and interdependently to produce the intended outcomes. The components consisted of education, a home-based exercise programme, and an audiotape-based relaxation and stress management programme. Specific self-help treatments were provided for psychological problems commonly experienced by patients who have had an MI. Outcomes included anxiety and distress scores, contacts with general practitioners and hospital admissions (108).

Figure 2-1: Schematic of a complex home-based cardiac rehabilitation intervention

2.3 Digital health interventions and interdisciplinary research

Digital health interventions (DHIs) are another example of complex interventions which use multiple interacting components to bring about the intended outcome. Research on DHIs brings together two different areas of expertise: Human-Computer interaction (HCI) (which includes software engineering), and health (encompassing biomedical science and psychology) (109).

The term human-computer interaction arose in the 1980s, and has its roots in computer science, psychology, sociology, communication, human factors engineering, and many other disciplines (110, 111). HCI concerns the design, implementation and evaluation of interactive systems, in the context of the user’s task. The user could be an individual, or a group of individuals, working within an organization to accomplish something using technology (111). The task is often goal-oriented, such as sending an email, programming a thermostat, or entering a destination into a global positioning system (GPS) (112).

The research methods used in HCI originated in computer science, psychology and engineering, and (like health research) are largely empirical e.g. experimental designs, surveys and focus groups. Empirical research contributions are highly scientific, and arise from descriptive discovery-driven activities (science). However, in contrast to health research, HCI also involves design-driven activities (invention) e.g. development and design of new interfaces, accompanied by data on feedback or usage (110, 113).

Both HCI and health research can inform the approaches used in development, evaluation and implementation of DHIs (109). Historically many DHIs have been developed and evaluated by those from a “health” background, using an approach based on the sequential model used in drug development, which culminates in a randomised controlled trial (RCT) to determine effectiveness. HCI research, in contrast, does not solely focus on distal health outcomes. It is also concerned with the proximal (interaction)
outcomes, and the need to iteratively design and test an intervention until it is deemed by the user to be ‘accessible and useful’ (109, 114, 115).

The commitment to RCTs in health research has been criticised (116, 117), and new methods have been sought for the development and evaluation of complex interventions, which emphasise the need for a more iterative approach. These methods and their frameworks are described in more detail next, along with a discussion of the merits and challenges of RCTs.

2.4 Frameworks for developing and evaluating complex interventions from health research

The nature of complex interventions influences the methods needed to investigate them effectively. Complex interventions have a close relationship with context, and key questions in their evaluation are (44):

(i) can the intervention work (efficacy);
(ii) how it works (mechanism of action)
(iii) whether ineffectiveness can be attributed to intervention failure or implementation failure;
(iv) for whom do they work and under what circumstances;
(v) in ideal circumstances what effect do they have; and
(vi) can that effect be replicated in routine practice, and what is needed to enable that to happen

Intervention efficacy should be distinguished from intervention effectiveness. Efficacy is the expected result in ideal circumstances, and effectiveness is effect in “real world” clinical circumstances (118). Traditional methods used in health research are not well suited to answering the questions listed above. To explain this further, I have next discussed the hierarchy of evidence in health research, the role of RCTs, their pros and cons in researching complex interventions, and newer models of research for complex interventions which have been developed.

RCTs are regarded as the ‘gold standard’ methodology for evaluating the efficacy of interventions, but cannot always answer the other key questions relevant to complex interventions listed above. A randomised trial is an experiment in which a sample of the population group of interest is randomly
assigned to one of two or more clinical interventions, and followed up over a period of time (119). The groups are treated in the same way, apart from the intervention, and at the end of the study any difference in outcomes is attributed to the intervention (119).

**Figure 2-2: The basic structure of a randomised trial (119)**

![Diagram of a randomised trial](image)

Randomisation is the key to ensuring the treatment groups are equivalent apart from the intervention being tested. This limits potential confounding variables, and the risk of bias (120). Confounding is caused when a factor independently associated with the outcome and exposure of interest (and not on the causal pathway), influences the association between the two. Two common confounders are age and socioeconomic status. Bias refers to a source of error in estimating the association between the exposure and outcome (121). Other study designs can detect associations between exposure and outcome, but cannot rule out that the association is caused by a confounding factor (122).

There are other important features of the RCT. One such feature is that patients and trialists should remain unaware of the treatment until the end of the study (blinding) to reduce information bias, although double blinding of both patients and trialists is sometimes unfeasible. Patients are analysed within the group to which they were allocated, even if they did not experience the treatment because they withdrew or were lost to follow-up (intention to treat analysis). This means that the outcome is compared between participants according to the groups to which they were allocated, ensures comparability...
between intervention arms and limits selection bias from different levels of participation (121, 122).

Systematic reviews of RCTs, with or without meta-analysis, and RCTs are considered the ‘gold-standard’ in the ‘hierarchy of evidence’ (see Figure 2-3). This hierarchy evolved due to the recognition that some study designs have greater accuracy for determining effectiveness of interventions than others due to less susceptibility to bias (123, 124). A pyramid shape is used to illustrate the decrease in risk of bias, from observational studies to RCTs (119). Observational studies compare the frequency of an outcome in individuals with and individuals without the exposure of interest (121). Examples of observational study designs are cohort and case control studies. RCTs are considered to have greatest accuracy for determining effectiveness, and effect size, due to randomisation, which limits the risk of confounding. Findings from an RCT are therefore more likely to be closer to the true effect of the intervention (119).

Figure 2-3: Hierarchy of evidence for questions about the effectiveness of an intervention or treatment (119)

Hierarchies of evidence have been used, and criticised, for decades. One criticism is that they ignore the limitations of randomised trials, including that they may be unnecessary, inappropriate, impossible or inadequate (125). For example in the case of complex interventions, the multiple component parts can interact to influence outcomes in ways that are not expected. RCTs are inadequate for detecting whether lack of intervention effect is due to implementation failure or genuine ineffectiveness (117). RCTs are also limited in the evaluation of DHIs due to their failure to permit iterative improvements to design and updates to technology (126).

Various frameworks and guidelines have been developed which suggest optimisation of complex interventions and evaluation processes, prior to a RCT. The goal is to undergo iterative development of the intervention until they are stable, usable, acceptable, and appear likely to be effective. Only then should a costly and time-consuming RCT be conducted (63). The key phases of the main frameworks are listed in a 2016 review of strategies used to optimise complex health interventions (117), and include the Medical Research Council (MRC) framework (127), the Process Modelling in Implementation Research (PRIME) (128) approach, the Multiphase Optimisation Strategy (MOST) (129), and the Normalisation Process Theory (NPT) (130, 131). They all emphasise testing whether and how an intervention works prior to embarking on a full-scale RCT. I used aspects of the MRC guidance as a framework for my research on HeLP-Diabetes: Starting Out, and so I have described this next.

2.4.1 MRC guidance on developing and evaluating complex interventions

In 2000, the MRC published a framework to help researchers adopt appropriate methods to researching complex interventions (132). A number of limitations to the framework were subsequently identified, including the use of a linear model which is commonly used in drug development; limited guidance on development and implementation phase studies; and lack of attention to the social and geographical context of the intervention. Updated guidance was published in 2006, which identified a more flexible and iterative process with
more emphasis on development and implementation phases, and using a range of different methods (104).

The 2006 framework suggested a non-linear approach to development and evaluation of complex interventions, with four key stages listed below and illustrated in Figure 2-4 (104).

1. **Development**: interventions should be developed based on relevant evidence and theory. Modelling the intervention can identify weaknesses in the intervention and evaluation, and lead to refinements.

2. **Feasibility and piloting**: this involves testing the intervention and procedures to identify problems with acceptability, compliance, delivery, recruitment, retention and smaller-than-expected effect sizes. Pilot studies should address key uncertainties identified in the development stage. A mixture of quantitative and qualitative methods help to identify barriers to participation. A series of pilot studies may be needed prior to a full-scale evaluation.

3. **Evaluation**: complex interventions can be evaluated with a number of different study designs. Randomisation should be considered as this limits selection bias, but randomisation may be unnecessary or impractical in certain conditions. For example, randomisation may be impractical if the intervention is already in widespread use and methods of implementation have already been decided.

4. **Implementation**: translation of findings into practice is aided by active dissemination, involving stakeholders and with specific recommendations. Long-term follow-up can provide data on whether changes persist.
The MRC guidance defines best practice as: using evidence and theory to develop complex interventions, then testing them with a series of pilot studies aimed at key design uncertainties, before moving on to an exploratory and then a definitive evaluation (104). A definitive evaluation should only be undertaken once the intervention and its delivery package reach a degree of stability, any further development would be relatively minor, there is reasonable confidence that the intervention could be implemented with high fidelity, and there is a reasonable likelihood that the intervention will lead to improved health outcomes or equivalent outcomes at lower cost (63). By determining whether the intervention has potential for effectiveness, optimization allows a decision to be made about whether to proceed to a definitive randomised trial.
The MRC, MOST, PRIME and NPT frameworks have the common feature of emphasising an iterative development and evaluation process. This is a feature that is also seen in HCI development lifecycles which are discussed next.

2.5 Frameworks for software development from HCI

Within HCI and computer science there is a large discipline that addresses the development of software systems (computer programmes), called software engineering. One of the foundations of software engineering is the software ‘lifecycle’. This is the sequence of activities that occurs from initial concept, through to eventual phasing out and replacement (111). There are many lifecycle models in the field of software engineering. The models guide the design and testing of products to ensure they are fit for purpose in the appropriate setting (133).

The requirements of an interactive system cannot be specified at the beginning of the lifecycle. The features of a potential design are built and tested on real users, and the design can subsequently be modified after any uncertainties are addressed and corrected. These are the principles of ‘iterative design’, a purposeful design process which cycles through several designs, incrementally improving the design until the final product is reached (111). A key aspect of the design process is understanding “user experience”, which means designing interactive products to support the way people use them in their everyday lives (134). The design process involves the following four activities: (i) establishing requirements; (ii) designing alternatives; (iii) prototyping; and (iv) evaluating. These processes inform each other, and are repeated in each iterative design cycle. Designing interactive products should be user-centred and designers should seek to involve users throughout the design process. It is also important in a user-centred design process, to understand people in the contexts in which they live, work and learn. This allows designers to understand how to design products which fit easily into users’ everyday lives.
Evaluation (the fourth activity in the design process listed above) is integral as it enables designers to check their design is acceptable to users. Evaluation methods depend on the goals of the evaluation. Usability testing is one method of evaluation. Usability testing involves using a combination of observations, interviews and questionnaires. The goal is to determine if a product is usable by the intended population, to carry out the tasks for which it was designed. Usability testing can take place in a controlled setting like a laboratory, or in a setting natural to the user. Findings from usability testing enable developers to make changes to the design of a product and then implement them, for further testing (134).

Design lifecycle models are useful in digital health research due to these iterative design principles, and because they emphasise the co-dependency of development and evaluation. Pagliari has highlighted lifecycle models as an exemplar from software engineering in a paper about the challenges of interdisciplinary working across HCI and health (133). Some of the commonly used lifecycle models identified in the Pagliari paper are the Waterfall, Spiral and Star models (135-137) (see Figure 2-5). Their names refer to their sub stages, which run in sequences or patterns. The Star model in particular rejects the rigid sequential nature of the Waterfall model, and instead suggests that the essential stages of development can take place in various orders depending on the needs of the project, and stages can be repeated or skipped over if necessary (138). Each stage should be accompanied by thorough evaluation and analysis. Evaluation is positioned at the centre of the star, since it guides all the other steps (138).
Figure 2-5: Key software life cycle models: the Waterfall, Spiral and Star models

Sequential phases
1. Requirements specification
2. Design
3. Construction (implementation or coding)
4. Integration
5. Testing and debugging (verification)
6. Installation
7. Maintenance

Sequential but iterative
- Risk analysis
- Prototyping
- Iterative framework allowing ideas to be checked and evaluated
- Explicitly encourages alternatives to be considered

Flexible
- Evaluation central
- No particular ordering of activities; development may start in any one
- Alternating analytic (top-down) and synthetic (bottom-up) design steps
- Derived from empirical studies of interface designers
A comprehensive range of international standards have been developed to support user-centred design in the field of HCI. These standards represent the leading edge of good practice, and are used as an authoritative reference for both experienced and inexperienced practitioners of user-centred design. Standards for HCI and usability are developed by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). The ISO and IEC comprise of national standards committees from member states, who nominate working groups of independent experts. ISO standard number 13407 characterises the essential user-centred design activities needed to produce usable products. Usability in the ISO standards is defined as “the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use” (139). ISO 13407 is illustrated in Figure 2-6. The recommendation is that user-centred design requires a repetitive design process to improve the efficiency and effectiveness of a system interface, with an emphasis on continuous identification of user requirements, testing the intervention against these, re-specifying user requirements and retesting (105, 140).
Many health researchers are not aware of HCI lifecycle models like ISO 13407, but the models do have a resemblance to iterative health research models like the MRC framework, which also recommend a cycle of assessing user needs, developing the intervention, identifying problems, and making changes to the intervention or its delivery method (133). There are also important differences. The entire HCI development lifecycle is contained within the ‘Development’ phase of the MRC framework, whilst the other three phases of the MRC framework focus on testing (with an RCT) and roll-out if the intervention has been shown to be clinically effective (implementation) (44, 109). Other differences are the lack of emphasis on controlled trials in software design, the more rapid identification of user needs and responses, and the less structured and more iterative nature of the design process (133). In addition, health research processes are governed by ethics and it is not possible to test several iterations of a prototype on users.

As a digital health researcher, I learnt from HCI that the iterative development of the HDSO programme should be conducted as research itself, and not just the summative evaluation. As HDSO was an interactive product, it was

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Figure 2-6: ISO 13407 User-Centred Design Cycle (105)

![Diagram of ISO 13407 User-Centred Design Cycle]

important to understand the user experience and to design the product to support use in everyday life. The user-centred design principles and usability testing described above were incorporated into the development and evaluation process for HDSO. The value of this was that I had the opportunity to optimise the intervention prior to planning a large-scale RCT, thereby increasing the likelihood of a successful trial. I was also able to explore user interaction and engagement, and the influence of context, so that I could understand if and how success could be replicated (109). I also learnt from HCI about the need for formative testing, rapid identification of user needs and responses, and the importance of testing HDSO in its final context of use (in NHS primary care) to investigate its feasibility, acceptability and impact ‘in the wild’ (109). My chosen approach was therefore guided by these lessons, and integrated both HCI and health research principles, as discussed below.

2.6 Integrated models

I examined hybrid models from the interdisciplinary world of digital health research to see how I could incorporate the lessons from HCI and health research. I found that hybrid models include a longitudinal evaluation process with a number of overlapping iterative stages. Three broad phases of activity have been identified (133) and are listed below and represented diagrammatically in Figure 2-7:

1. **Concept and prototype evaluation**: developing new interventions by testing theory with experts and users to ensure stakeholder needs are fulfilled;
2. **Outcomes evaluation**: formative testing to assess the impact of interventions on processes and outcomes of care in targeted settings;
3. **Pragmatic evaluation**: evaluating interventions after rollout in final context of use to assess outcomes, including variations in uptake and stakeholder satisfaction.
I subsequently developed my own model borrowing principles from the MRC framework, and the life cycle models used in software development.
framework for the approach used in the studies of HDSO is illustrated in Figure 2-8.

Figure 2-8: The framework for the approach used in the development and optimization of HDSO

The next section of this chapter focuses on the context in which the research took place, and the relevant theory that I explored in order to develop my research and evaluation plan.
2.7 Context of the research

2.7.1 HeLP-Diabetes programme grant

HDSO was a structured education course for people newly diagnosed with type 2 diabetes. The content was based on the content of the HeLP-Diabetes website, which was developed and evaluated prior to HDSO, as part of an NIHR programme grant from 2011 to 2016, which I was not involved in. HDSO was added to the HeLP-Diabetes website. The Chief Investigator of the programme grant and co-supervisor for my PhD was Elizabeth Murray.

The aim of the programme grant was to develop, evaluate and implement a web-based self-management programme for people with type 2 diabetes at any stage of their illness. There were five constituent studies in the programme grant: three focusing on the development of the intervention, an individually randomised controlled trial in primary care to determine effectiveness and cost-effectiveness, and an implementation study to explore how HeLP-Diabetes could best be implemented into routine NHS care.

The HeLP-Diabetes website consisted of eight sections containing evidence-based information on what diabetes is and how it is treated, possible complications and how lifestyle changes can improve health, how diabetes affects emotions, relationships and work (141). Content was based on the Corbin and Strauss model for living with long-term conditions described below (142). The website was developed with considerable user input from patients with type 2 diabetes and health professionals looking after patients with type 2 diabetes (141). In contrast to HDSO, people could use the programme flexibly by looking at pages in any order and as little or often as they wanted.

The HeLP-Diabetes RCT was a multi-centre individually randomised controlled trial of HeLP-Diabetes conducted in 21 general practices in England to evaluate the programme’s effectiveness and cost-effectiveness (143). In the implementation study, HeLP-Diabetes was offered to patients attending GP surgeries and diabetes clinics in two boroughs in London which were not included in the RCT (141).
The structured education programme, HeLP-Diabetes: Starting Out was developed and added to the HeLP-Diabetes website in response to policy drivers, which are described in more detail below.

2.7.2 Rationale for HDSO

2.7.2.1 Policy drivers

It is NHS policy to refer people newly diagnosed with T2DM to structured education programmes. In 2001 the NHS set out its policy and standards of diabetes care in the National Service Framework (NSF) for diabetes. The NSF listed twelve standards and key interventions needed to improve diabetes care. One of these standards was empowering people with diabetes. The provision of information, education and psychological support was identified as the “cornerstone of diabetes care”. Structured education was recognised as a key intervention for improving knowledge, blood glucose control and psychological well-being (144).

Structured education is recommended for patients newly diagnosed with T2DM by the National Institute for Health and Care Excellence (NICE), the Quality and Outcomes Framework (QoF) for General Practitioners (GPs), and the Quality Institute for Self-Management Education (QISMET) which gives accreditation for self-management education programmes.

NICE has developed guidance on the management of patients with type 2, suggesting that patients should be referred to a structured education programme within 9 months of diagnosis (15). NICE define structured education as having specific aims and learning objectives, having an evidence-based curriculum, being quality assured and being regularly audited (15).

Referral to structured education was incentivised through QoF. QoF is a voluntary reward and incentive programme, which rewards practices with points for the quality of care they provide (including referrals to structured education) which turn into payment (17). This helps to standardise improvements in care. Referral to programmes which are accredited by QISMET is preferred by QoF. In order to gain QISMET approval, a programme
with a structured curriculum and clear learning goals was needed, and the HeLP-Diabetes website did not satisfy these requirements (145).

2.7.2.2 Patient views

There is inconsistency between patient views on when they want structured education, and the NICE and QoF recommendations that patients should receive structured education within 9 months of diagnosis, as the following explains. The qualitative data from the HeLP-Diabetes implementation study suggested that newly diagnosed patients had a greater need for information (141). Similar findings have been reported from other studies of information-seeking in people with type 2 diabetes (146, 147). A qualitative study with patients from diabetes clinics in the US found that patients accessed diabetes information differently at different times. Patients reported an increased need for information initially, and lapses in information-seeking or a more selective appraisal of health information later on, depending on other factors including life experiences and changes in health status (147).

But not all studies of information needs of patients with T2DM support the view that the time of diagnosis is the appropriate time for education. A 2018 systematic review of information needs in people with diabetes mellitus (148) found only one study of information or knowledge needs in patients with T2DM, T1DM or prediabetes that focused on stage of the disease. This study looked at the information needs of patients recently started on oral antidiabetic medications, to investigate the opportunity for pharmacists to provide information. The authors reported that people who had recently been started on medication, felt they needed information on drug-related issues such as adherence, but not on other aspects of diabetes management such as lifestyle changes (149).

A qualitative study looking at newly diagnosed patients experiences and views of diabetic care provision, found that some patients felt that information additional to that provided by their GP or nurse was for people who had started to deteriorate, and that they were not ready to acknowledge that they had a potentially serious disease (150). A qualitative study of patient explanations for non-attendance at structured diabetes education sessions for newly diagnosed
Type 2 diabetes (151), also found that patients did not perceive any benefit from education at the time of diagnosis, or felt that they needed more support after the time of diagnosis. Lack of acceptance of the diagnosis, or failure to recognise the risks of an asymptomatic condition, have also been identified as barriers to diabetes self-management in several other studies (152-155). Denial has been described as a key factor for inhibiting adherence to self-management interventions, as well as failure to accept the consequences of the disease will affect them (153). One study categorised patients according to ‘diabetic identity’ into four groups: (i) accepters; (ii) identity accepters and consequence resisters; (iii) identity resisters and consequence accepters; and (iv) resisters. The authors found that some patients accepted the diagnosis but did not prioritise managing their diabetes, and others found it difficult to accept their diagnosis as they did not feel any different physically, and consequently did not make any changes to their lifestyle (154).

The data do not confirm that structured education at the time of diagnosis is what newly diagnosed patients want, but the policy on structured education for newly diagnosed patients is clear, and this drove the development of HDSO. Work on the development of the programme began in 2014 and is described in detail in Chapter 3.

2.7.3 Intervention setting

As discussed above, HDSO was developed in response to NHS policy which states that people newly diagnosed with T2DM should be referred to structured education from primary care. The intervention was therefore aimed at patients who were diagnosed with T2DM in primary care and referred to structured education by their GP or nurse.

At the time that HDSO was being developed, the HeLP-Diabetes implementation study was coming to an end. GP practices in Camden and Islington Clinical Commissioning Groups (CCGs) were involved in the implementation study and were interested in continuing to refer patients to HeLP-Diabetes, and to start referring patients to HeLP-Diabetes: Starting Out. A social enterprise called the HeLP-Digital Community Interest Company (CIC)
was set up to disseminate and implement HeLP-Diabetes and HeLP-Diabetes: Starting Out to other CCGs in the NHS. The HeLP-Digital CIC successfully got HeLP-Diabetes and HDSO commissioned in Lewisham, Lambeth and Haringey. Therefore all five CCGs were able to refer patients to HeLP-Diabetes and HDSO, and were included in the evaluation studies of HDSO (See Chapters 3, 6 and 7).

In order for the GPs and nurses in the five CCGs to refer patients to the programme, it required the clinicians and managers involved in commissioning, and the HeLP-Digital CIC, to disseminate details of the programme to them. GPs, nurses and commissioners were all crucial in the implementation of the programme, and this was taken into account during the development of the programme.

Theory relevant to the development, evaluation and implementation of the programme is discussed below.

2.8 Use of theory

According to Glanz et al, theory presents “a systematic way of understanding events, behaviours, and/or situations. A theory is a set of interrelated concepts, definitions, and propositions that explain or predict events or situations by specifying relations among variables.” (156). Theories can guide an understanding of why people practice certain health behaviours, and how to design an effective intervention to improve health behaviours (157).

There are a number of existing theories which relate to the aim of my thesis. It was important to review relevant theory at the start of the thesis in order to understand how theory could inform and guide the methods of my research and analysis, and the design of the intervention.

The key concepts in my research were the development and evaluation of a complex health intervention for the self-management of type 2 diabetes. Development and evaluation of complex interventions has been discussed above in relation to the MRC guidance and HCI development lifecycles, and
will be reviewed again in Chapters 4-6 in the description of the evaluations and optimisation of the programme.

In addition, the intervention is a self-management education intervention with behaviour change components, and its development therefore relates to education theory and behaviour change theory. The delivery of the intervention within the NHS relates to implementation theory. This is illustrated in Figure 2-9. I have considered each theory and its alignment with my research below.

**Figure 2-9: Key concepts and relevant theory**

![Diagram of key concepts and relevant theory]

### 2.8.1 Education theory

Educating patients is different to educating students because the aim is not only to impart knowledge and skills, but also to empower and encourage behaviour change. The components of an education intervention should not therefore be limited to knowledge acquisition (158). Increasingly, learning has been construed as being multidimensional and involving the body, emotions and spirit as well as the mind (159). The content of HeLP-Diabetes (and consequently HeLP-Diabetes: Starting Out) was developed using the Corbin and Strauss model for the work of living with a long-term condition, which also emphasises the need to address the emotional aspects of disease and identity issues. Corbin and Strauss undertook qualitative work on the perception of patients about their long-term conditions, and delineated three sets of tasks involved in self-management (160). These are conceptualised as follows (142), and in Figure 2-10:
1. **Medical management**: adopting healthy behaviours (e.g. not smoking, exercising regularly, eating healthy food), working with health professionals (e.g. keeping appointments, following instructions), and taking medicines.

2. **Emotional management**: addressing the negative emotions associated with being diagnosed with a long-term condition.

3. **Role management**: coming to terms with the disruption to one’s sense of self, including adjusting to the “patient” role and managing the impact of one’s diagnosis on relationships with friends, family and colleagues.

**Figure 2-10: Corbin & Strauss theory on living with long-term conditions**

The content of HeLP-Diabetes and HDSO addressed all three domains, and covered topics including eating well for diabetes, handling feelings, and having a social life. The intervention curriculum is described in more detail in Chapter 3.

In addition to content, components of the intervention were developed using theory. Self-assessment questionnaires were included at the start and end of the programme. These were included due to education theory which states
that self-assessment is central to the three key processes in learning and teaching (161, 162):

1. Establishing where the learners are in their learning
2. Establishing where they are going
3. Establishing what needs to be done to get them there

Both the teacher and the learners are responsible for these processes. The teacher is responsible for providing learning tasks that elicit evidence of student understanding, and providing feedback that moves learners forward, whilst the learner is responsible for owning their own learning (161). Change begins with the learner's pre-existing understanding, and the learner must be actively involved in the learning for it to be effective (163). This, along with feedback, can help shift learners away from ego-involvement (comparing favourably to others) towards task-involvement (focusing on learning) (164). Self-assessment is key to enhancing metacognition (thinking about thinking) and self-direction (managing one’s own motivation towards learning). It also requires learners to exercise autonomy as the judge of the quality of their learning (163).

Personalised feedback was provided for everyone who completed the self-assessment questionnaires. Feedback has been described in both management theory and education theory as the information about the gap between the actual level and the reference level of a parameter (such as knowledge or skills) which is used to alter that gap (162, 165). For feedback to be effective, data about the reference level of the parameter, the actual level, and a mechanism for generating information about the gap between the two, is needed. The information needs to be utilised to alter the gap, and not just stored (162). Ramaprasad emphasises this utilisation of information, in contrast to information simply being provided without any mechanism for utilizing it (162). Sadler builds on Ramaprasad’s theory about the conditions that are needed to provide good feedback by suggesting that learners need (1) knowledge of the standards that need to be applied; (2) to compare these standards to their own work; and (3) to take action to close the gap between
the two (166). This requires the student to actively engage with the feedback. Newer views of feedback encompass the need for an appropriate curriculum and a conducive learning environment in order to shift feedback from a notion of telling to a process of utilisation (167).

As mentioned earlier, one of the aims of patient education is to encourage behaviour change. The principles of patient education are based on behavioural models from the synthesis of several theories of health behaviour (158). I have discussed the behaviour change theories used in the development of the intervention below.

2.8.2 Behaviour change theory

As discussed in Chapter 1, behavioural factors like diet and exercise are prominent contributors to the onset and management of type 2 diabetes. Patient education has been discussed in the previous section with regard to education theory, and the need for education to help empower patients, encourage behaviour change and impart information. Effective public health programmes require behaviour change at many levels (e.g. individual, organization and community). Interventions to improve health behaviours can be designed based on relevant behaviour change theories, and there is growing evidence to suggest that interventions with a theoretical foundation are more effective, particularly in the field of digital health (168).

A full discussion of behaviour change theory is beyond the scope of this thesis, but in summary “theory provides a helpful basis for designing interventions to change behaviour but offers little guidance on how to do this” (169). Theories of behaviour change summarise the constructs involved in the process of change, and attempt to predict how and when behaviour change occurs (169). Behaviour change techniques (BCTs) are the strategies used in an intervention to promote behaviour change (170). By predicting how behaviour change occurs, theories of behaviour change can be used to design BCTs used in interventions.

The behaviour change wheel is a model for classifying behaviour change interventions, which incorporates the conditions for behaviour change,
intervention functions, and policy categories that enable the interventions. The three essential conditions for behaviour change are: capability, opportunity and motivation (termed the COM-B system). They form the centre (or ‘hub’) of the model. The nine intervention functions aimed at addressing deficits in these conditions sit around the centre. Around the nine intervention functions sit seven policy areas which could enable these interventions to occur (171). The behaviour change wheel is illustrated in Figure 2-11.

**Figure 2-11: The behaviour change wheel**

Interventions that use more theory-based BCTs have been found to have larger effects compared to interventions that use fewer techniques ($P < .001$) in studies of digital health behaviour change interventions (172).
In light of the evidence for the increased effectiveness of online interventions incorporating the use of theory-based BCTs, theories identified as effective for changing the behaviours relevant to type 2 diabetes were adopted in the development of the components of the HDSO programme. Dozens of behaviour change techniques and models have been used to develop public health interventions, and systematic reviews have identified the most commonly used theories (168, 173). One review looking at health behaviour research from 2000-2005 identified the most commonly used theories as the Trans theoretical model (Stages of change), Social Cognitive Theory, and Health Belief Model (173).

The HeLP-Diabetes programme, on which the content of HDSO is based, did not adopt one specific theory but instead used the Abraham and Michie taxonomy of behaviour change techniques (174) to target key health behaviours relevant to type 2 diabetes: smoking, diet, exercise, medication and alcohol (141). The taxonomy defines a set of theory-linked BCTs which are associated with effective behaviour change within and across behavioural domains, and can be used to facilitate design of interventions (174).

The work of developing the content of HeLP-Diabetes was completed by the HeLP-Diabetes programme grant team, prior to my involvement with the HDSO structured programme, and so I have summarised how the taxonomy was used and why this is relevant to HDSO here. A more detailed description of the development work on HeLP-Diabetes is given elsewhere (141). Selected content was chosen from HeLP-Diabetes to be included in the HDSO structured programme following my joining the HDSO team.

Existing behaviour change modules were used to target alcohol (Down Your Drink), weight loss (Positive Online Weight Reduction) and smoking (Stop Advisor). Existing modules could not be identified for eating healthily, being more active, or taking medications. Therefore BCTs from the Abraham and Michie taxonomy that have been shown to be effective were selected and used to develop relevant modules. The resulting modules included “Goal-setting”; “Action planning”; “Review behavioural goals”; “Problem solving”; “Prompt self-monitoring” and “Provide feedback on performance” (141). These modules are
based on self-regulation theory, which states our major self-regulative mechanism functions through (i) self-monitoring of behaviour, its determinants, and its effects; (ii) judgement of behaviour in relation to person and place; and (iii) affective self-reaction. Self-regulation theory also encompasses self-efficacy (people’s beliefs about their capabilities to exercise control over their level of functioning), which has a strong impact on thought, affect, motivation, and action (175).

The theory-linked behaviour change technique that was used in HDSO was goal-setting (176). Goal-setting was incorporated because of its basis in social cognitive theory (highlighted above as one of the most commonly used behaviour change techniques in reviews of public health interventions). Social cognitive theory has been best characterised by Bandura (177), as a three-way model involving the interaction of personal factors, environmental influences, and behavior. A basic premise of SCT is that people learn through their own experiences, and also by observing the actions of others and the results of those actions (168).

One of the key constructs of social cognitive theory is self-efficacy, defined as “the belief in one’s own capabilities to successfully carry out a course of action”. Self-efficacy is thought to influence effort expenditure, activity choice, and persistence in the face of barriers or failure (178). Goal-setting and self-monitoring seem to be particularly effective techniques for improving self-efficacy (168). Goal-setting helps to increase motivation, by allowing people to compare their performance against personal standards they have set for themselves (179). Setting specific goals is more likely to aid learning because it is easier to monitor progress (180). Achieving goals creates an initial sense of self-efficacy (181), and this is reinforced when learners see they are progressing and increasing their skills (182). Providing feedback on goals also increases self-efficacy (183). Feedback is another way of notifying people about their progress, and can help people feel a sense of accomplishment and competence (184). Increased self-efficacy results in sustained motivation and skills development (181). Motivation depends on the proximity, specificity and difficulty of the goal (181). Easier, more proximal and specific goals are more
likely to increase motivation, and for this reason the Specific, Measurable, Achievable, Realistic, and Time-Bound (SMART) criteria were used in the programme.

As mentioned above, public health interventions require behaviour change at the level of the organization as well as the individual (168). I described in section 2.7.3 that healthcare professionals were very much involved in the delivery of HDSO as commissioners disseminated information about the intervention to clinicians, and clinicians were able to discuss it and refer type 2 diabetes patients to the programme in consultations. However I did not specifically target the behaviour of health professionals in my research, and so I have not focused on behaviour change theory to change health professional behaviour in my discussion here.

2.8.3 Implementation theory

Understanding how to successfully implement and integrate new treatments into a healthcare system has been a longstanding challenge for health researchers. In particular there has been a lack of theory to guide the adoption of new technologies into routine clinical practice (185). Theories of implementation, such as the Normalization Process Theory (NPT) have been developed in response to this problem (186).

NPT provides an empirically grounded model of the factors that promote or inhibit the routine incorporation of interventions in everyday practice (187). NPT is concerned with making new treatments or interventions routine practices (embedding), and sustaining embedded practices in their social contexts (integration) (188). The starting point to embedding practices is understanding what people do and how they work. The theory operationalises the work of implementation as four constructs: (i) coherence; (ii) cognitive participation; (iii) collective action; and (iv) reflexive monitoring.

Coherence involves sense-making of the intervention. This helps to embed the practice by anchoring it in the experience of the participant (188). For example, when doctors use a videoconferencing system to consult with patients, what do they do to understand the differences between face-to-face consulting and
videoconferencing (189). Cognitive participation requires the investment and commitment of the participant, and this investment promotes or inhibits how legitimate the participant perceives the intervention. Collective action requires investments of effort, and promotes or inhibits the participant utilising an intervention. Reflexive monitoring requires appraisal of the intervention, and how a new set of practices affect them and others around them (187, 189). For example, a nurse working in a falls prevention program will appraise not only the worth of the program, but also its impact on her other tasks (189).

The four constructs are affected by norms and conventions which can promote or inhibit routine embedding (188). The mechanisms, norms and conventions interact dynamically with agents (individuals or organizations), objects (practices employed by agents), and contexts (structures in which agents and objects are implicated) (187).

NPT was considered from the outset of the development of HeLP-Diabetes and HDSO to ensure that they were optimally “implementable” within the NHS (141). This included making sure that the programme was easy to differentiate from other programmes and had clear benefits; fit with professional priorities (such as adhering to NICE recommendations); fit into existing working practices easily; and made consultations between patients and health professionals more productive (141). The principles of NPT also helped in the analysis of my data to explain my findings on uptake and engagement, and are discussed further in Chapters 6 and 10.

2.9 Summary

Developing and evaluating complex interventions presents methodological challenges to researchers. Various frameworks have been developed in health research and in HCI to guide the development of complex health interventions and interactive systems. Integrated models combining aspects of both have also been developed, emphasising the need to use an iterative user-centred approach. In this chapter I have described the frameworks from health research and HCI that guided the development and evaluation of HeLP-Diabetes: Starting Out, and the theoretical frameworks from the fields of
education, behaviour change and implementation science that I consulted to
guide my methods and analysis. In the next chapter I have described the
development of the first iteration of the intervention.
Chapter 3. The development of the first iteration of HeLP-Diabetes: Starting out

3.1 Chapter summary

In this chapter I have provided a description of the initial version of the HDSO intervention, and the theory and processes that went into its design. I have started by describing the HDSO team. I have then described the curriculum and components, and explained where relevant education and behaviour change theories were used.

3.2 The HDSO team

The HDSO team consisted of three academic GPs (myself, an academic GP who acted as technical lead and Elizabeth Murray who provided oversight and leadership), Diabetes Specialist Nurses (DSNs), a project manager, an administrator, a software programmer and two Patient and Public Involvement (PPI) representatives. The HDSO team attending steering group meetings that met four monthly during the first two studies.

The DSNs were trained educators who were experienced in delivering face-to-face structured education courses. They provided clinical expertise for support with content development, and assisted the project manager with recruiting practices to implement the programme. The administrator’s role was to register patients for the programme by telephone. The PPI representatives were members of the public who had a diagnosis of type 2 diabetes. They were integral in the development process, and I have described how this worked in practice in section 3.2.1 and 3.4). The software programmer worked with the GP technical lead on the technical aspects of the programme construction, such as adding videos and images, and managing the server side of the website so that usage data could be downloaded.

I joined the team at the end of 2014, during the first stage of the development process. At that stage, an outline of the curriculum and the content had been developed. My role within the team was to build on the outline curriculum and develop this into a tangible intervention. I did this in several stages. First, the
outline curriculum was developed into a full curriculum and relevant content from the HeLP-Diabetes website was selected. This is described in more detail below. I then developed a pathway of action for the programme in order to identify outcomes, and outcome measures. I used these to select self-assessment questionnaires for users, which were used to evaluate the impact of the programme. I found the appropriate questionnaires, and wrote personalised feedback for users in response to their questionnaire scores (also described in more detail below). I developed an email reminder system. This system meant that email reminders were sent to users who had not logged on for seven days or more. I wrote the content of the emails and have described this below.

3.2.1 Patient and Public Involvement

Patient and public involvement in health and social care research (also known as service-user involvement) is a partnership between patients and the public and researchers, where patient and public representatives are not research participants but advisors and co-researchers (189). Patients and the public can provide insight into living with a condition, and make research more relevant to the needs of service users. PPI is seen as a marker of quality, and research funders including the NIHR require PPI as a condition of funding (189).

The NIHR suggest key areas of the research process where patient and public involvement could take place (189):

1. **Design of the research**: clarify the research question and confirm its importance; ensure methods are appropriate; advise on recruitment strategy and data collection tools, including questionnaires.
2. **Undertaking/management of the research**: advise on patient information sheets and consent forms; assist in conducting interviews and surveys.
3. **Analysis of data**: assist in developing themes from the data; consult on interpretation of the data.
4. **Dissemination of research findings**: help distribute results in local networks; present findings with researchers; write information for local patient groups.

PPI representatives were involved in several stages of the research on HDSO, but there was more involvement in the design and undertaking of the research than the analysis and dissemination. There was also more involvement in the
first two studies, than the second two studies. I have described this and reflected on how I could have ensured more involvement in Chapter 11. PPI in the development of the first iteration of the programme is outlined here and described in more detail in section 3.4.

During the development of the first iteration of the programme, PPI representatives were asked to give their opinions on programme content and layout (see section 3.4). They commented on whether the information in each session of the programme was easy to understand, and if it was easy to complete and click through the sessions without difficulties. This feedback was analysed and changes were made to the programme based on their comments.

In the next section, I have described the curriculum, the programme content with screenshots, and given an explanation of the rationale and theory used in the programme components (including self-assessment questionnaires, feedback, goal-setting tasks and personalised email reminders).

3.3 Description of the intervention

The aim of the HDSO programme was to help people newly diagnosed with type 2 diabetes to improve their knowledge, self-efficacy and emotional wellbeing by learning about living a healthy lifestyle, making the most of the NHS and staying motivated. The curriculum and programme components were developed to meet this aim.

3.3.1 Curriculum

The HDSO curriculum outline was based on selected content from the HeLP-Diabetes website (developed as part of the programme grant described in Chapter 2). Eight core topics which aligned with the programme aims were selected and organised into eight sessions for people to work through in a sequential order. Each session took about 40-50 minutes to complete and people were encouraged to complete one session per week. The eight sessions are listed below in Table 3-1.

Table 3-1: Session titles and parts
<table>
<thead>
<tr>
<th>Session title</th>
<th>Session parts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 1 – Getting Started</td>
<td>Part 1 – Self-assessment</td>
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<tr>
<td></td>
<td>Part 2 – An introduction to diabetes</td>
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<tr>
<td></td>
<td>Part 3 – Eating well for diabetes</td>
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<tr>
<td>Week 2 – Self-management</td>
<td>Part 1 – Taking control</td>
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<tr>
<td></td>
<td>Part 2 – Becoming more active</td>
</tr>
<tr>
<td></td>
<td>Part 3 – Handling feelings</td>
</tr>
<tr>
<td>Week 3 – Improving my health and</td>
<td>Part 1 – Protecting my body and mind</td>
</tr>
<tr>
<td>wellbeing</td>
<td>Part 2 – Making changes</td>
</tr>
<tr>
<td></td>
<td>Part 3 – Understanding my moods</td>
</tr>
<tr>
<td></td>
<td>Part 4 – Working with diabetes</td>
</tr>
<tr>
<td>Week 4 – Taking control of my</td>
<td>Part 1 – Making the most of the NHS</td>
</tr>
<tr>
<td>diabetes</td>
<td>Part 2 – Update my goals and plans</td>
</tr>
<tr>
<td></td>
<td>Part 3 – Managing my moods</td>
</tr>
<tr>
<td></td>
<td>Part 4 – My social life</td>
</tr>
<tr>
<td>Week 5 – Medication and lifestyle</td>
<td>Part 1 – Medication</td>
</tr>
<tr>
<td></td>
<td>Part 2 – Review my goals and plans</td>
</tr>
<tr>
<td></td>
<td>Part 3 – How to fix almost everything</td>
</tr>
<tr>
<td></td>
<td>Part 4 – Driving</td>
</tr>
<tr>
<td>Week 6 – Reducing my risks</td>
<td>Part 1 – Reducing the risks of heart attack and strokes</td>
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<tr>
<td>---------------------------</td>
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</tr>
<tr>
<td></td>
<td>Part 2 – Looking after my feet</td>
</tr>
<tr>
<td></td>
<td>Part 3 – Review my goals and plans</td>
</tr>
<tr>
<td></td>
<td>Part 4 – Living with diabetes</td>
</tr>
<tr>
<td>Week 7 – Working with my healthcare team</td>
<td>Part 1 – Managing illness</td>
</tr>
<tr>
<td></td>
<td>Part 2 – My diabetes review</td>
</tr>
<tr>
<td></td>
<td>Part 3 – review my goals and plans</td>
</tr>
<tr>
<td>Week 8 – Celebrating success and planning for the future</td>
<td>Part 1 – Self-assessment</td>
</tr>
<tr>
<td></td>
<td>Part 2 – Looking after my diabetes</td>
</tr>
<tr>
<td></td>
<td>Part 3 – Moving on: the end of the beginning</td>
</tr>
</tbody>
</table>

The programme followed a spiral curriculum which means that people built on the knowledge they acquired in each session as they proceeded. The spiral model is an evidence-based model for adult education which is based on the Harden and Stamper spiral curriculum model (190). This model proposes that there is an ‘iterative revisiting of topics, subjects or themes throughout the course’ (190). The idea is that topics are not just repeated, but that knowledge and understanding should be deepened each time. There can be increasing levels of difficulty, and new learning should relate to previous learning. The learner’s competence should increase with each visit until the overall aim is achieved.
Figure 3-1: The spiral curriculum (180)

1. The student revisits a topic, theme or subject

2. The complexity of the topic or theme increases with each revisit

3. New learning has a relationship with old learning and is put in context with the old information
Information was presented using text, images and videos, including videos of others living with diabetes. Text was written for people with a reading age of 12 to correspond to with 80% of the UK population (191). The programme is illustrated below with a series of screenshots.

### 3.3.2 Screenshots

#### Week 1- Getting started

![Part 1 - An introduction to type 2 diabetes](image)

*Watch a video*

Click on the image below to watch our 7-minute video that explains what type 2 diabetes is.

To play this video you will need audio and you may need the Flash plug-in. To watch it full screen move your cursor down to the bottom right corner of the video and click the expand button.

Type 2 diabetes is a chronic (ongoing) condition in which there is a high level of glucose (sugar) in the blood. Glucose comes from breaking down the carbohydrates that you eat. High blood glucose levels occur if your body is unable to move the glucose into body cells, where it can be used for energy.

**Figure 3-2: Screenshot of a video introduction to diabetes**

This session contained three parts: a self-assessment, an introduction to diabetes, and information about eating well for diabetes. The self-assessment quizzes are described in detail below. The ‘Introduction to diabetes’ included videos explaining what type 2 diabetes is, accepting the diagnosis, information about how diabetes affects the body and how it is managed, and a BMI calculator. The ‘Eating well for diabetes’ section included information and videos about the important aspects of a healthy diet, a personal daily calorie requirement calculator, an eight step guide to healthier eating, and a diet goal-setting exercise.
Week 2- Self-management

Think about three levels of activity.

**Vigorous** physical activities take hard physical effort and make you sweaty, breathe much harder than normal and get warmer. Examples include running and sports such as swimming or football.

**Moderate** activities take moderate physical effort, make you breathe somewhat harder than normal and make you a bit warm (e.g. bicycling at a regular pace, brisk walking, carrying light loads, or doubles tennis).

**Light** activities take light physical effort, and do not make you breathless or warm such as gentle walking, dusting, or weeding.

Once you have finished answering the questions, click on the **Save button at the bottom of the page**.

<table>
<thead>
<tr>
<th>Activity quiz</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>During the last week, on how many days did you do vigorous physical activities like heavy lifting, digging, aerobics, or fast bicycling?</strong></td>
</tr>
<tr>
<td>Please Select <strong>x</strong></td>
</tr>
<tr>
<td><strong>How much time did you usually spend doing vigorous physical activities on one of those days?</strong></td>
</tr>
<tr>
<td>1-600 Minutes per day or __________ Hours __________ Minutes</td>
</tr>
<tr>
<td><strong>During the last week, on how many days did you do moderate physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis?</strong></td>
</tr>
<tr>
<td>Please Select <strong>x</strong></td>
</tr>
<tr>
<td><strong>How much time did you usually spend doing moderate physical activities on one of those days?</strong></td>
</tr>
<tr>
<td>1-600 Minutes per day or __________ Hours __________ Minutes</td>
</tr>
<tr>
<td><strong>During the last week, on how many days did you do light physical activities like walking, dusting or weeding?</strong></td>
</tr>
<tr>
<td>Please Select <strong>x</strong></td>
</tr>
<tr>
<td><strong>How much time did you usually spend doing light physical activities on one of those days?</strong></td>
</tr>
<tr>
<td>1-600 Minutes per day or __________ Hours __________ Minutes</td>
</tr>
</tbody>
</table>

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**Figure 3-3: Screenshot of physical activity quiz**

Week 2 contained three parts: taking control, becoming more active and handling feelings. ‘Taking control’ included information about monitoring blood glucose levels and healthy behaviours, and quizzes on physical activity, medication use, alcohol intake and diet. ‘Becoming more active’ gave information about recommended activity levels, advice about how to become more active, a physical activity goal-setting task, and videos of people’s stories. ‘Handling feelings’ included information about how diabetes can affect relationships at work and at home, and videos of people with diabetes talking about how they approached these issues.
Week 3- Improving my health and wellbeing

Week 3 contained four parts: protecting body and mind, making changes, understanding moods, and working with diabetes. ‘Protecting my body and mind’ included information about preventing problems with emotions, eyes, feet, infections, kidneys, nerves, sexual function, and abnormal blood sugar levels. ‘Making changes’ provided an exercise for reflecting on the quizzes in Week 2, and setting specific, measurable, achievable, realistic and time-bound (SMART) goals for diet, medication, activity, drinking and other health behaviour changes. ‘Understanding moods’ included videos of people with diabetes explaining how they felt when they found out they had diabetes, and what they did to make themselves feel better. It also included quizzes to help people identify how they were feeling. ‘Working with diabetes’ covered telling employers, employment law, managing abnormal blood sugar levels at work, shift work, and videos of people’s stories. The videos were from healthtalk.org (192), and were used with a license.
Week 4- Taking control of my diabetes

Week 4 contained four parts: making the most of the NHS, update my goals and plans, managing my moods and having a social life. ‘Making the most of the NHS’ explained the essential checks that all people with diabetes should receive, videos of people talking about their interaction with the NHS, and a link to the health record in HeLP-Diabetes where users can record appointments. ‘Update my goals and plans’ allowed people to look back at and review the SMART goals they set in Week 3. ‘Managing my moods’ gave people a chance to look back at the results of their mood quizzes in Week 3, and use a set of “Mood Tools”, including “Living Life to the Full”, a package developed by clinical psychologists using principles from cognitive behavioural therapy (CBT) and specially adapted for people with diabetes (193). This package was used with a license. ‘Having a social life’ contained advice about special occasions, eating out, eating at celebrations, fasting and religious festivals, alcohol and recreational drugs, and videos of people’s stories from healthtalk.org.
Week 5 - Medication and lifestyle

Figure 3-6: Screenshot of videos on the effects of medicines

Week 5 contained four parts: medication, review my goals and plans, how to fix almost everything, and driving. ‘Medication’ included information about the purpose of medication, videos about the challenges and benefits of medications, advice for concerns about medications, a “My medicines” list, and information about commonly used medications in diabetes. ‘Review my goals and plans’ allowed users to review the goals they set in Week 3 and update them. ‘How to fix almost everything’ was an opportunity to revisit the mood tools used in Week 4, and any changes made since then. ‘Driving’ gave information about motor insurance and informing the Driver and Vehicle Licensing Agency (DVLA) about diabetes, and advice about managing low blood sugar when driving.
Week 6- Reducing my risks

Figure 3-7: Screenshot of information about heart disease

Week 6 contained four parts: reducing the risks of heart attacks and strokes, looking after my feet, review my goals and plans, and living with diabetes. ‘Reducing the risks of heart attacks and strokes’ explained the importance of blood pressure, how it is measured, and heart disease and its treatment and prevention. ‘Looking after my feet’ explained types of foot problems, preventing foot problems, foot checks and tests, and foot complications from diabetes and their management. ‘Review my goals and plans’ was a further opportunity to review and update SMART goals. ‘Living with diabetes’ contained videos of people talking about how they got used to having diabetes, and what made them feel better. It also made the suggestion to revisit ‘Managing my moods’ to see if any of the mood tools could be helpful.
Week 7 - Working with my healthcare team

Figure 3-8: Screenshot of information about managing diabetes when ill

Week 7 contained three parts: managing illness, my diabetes review and review my goals and plans. ‘Managing illness’ gave information about eating when ill, and blood glucose levels when ill, and answered questions about taking medicines when ill, and gave information about preventing illness by, for example, getting a yearly flu vaccination. ‘My diabetes review’ included videos about people’s experiences of diabetes care, explained a diabetes care plan, gave users the opportunity to enter important dates such as appointments and health checks, and provided an exercise on preparing for a diabetes review. ‘Review my goals and plans’ allowed users to review and update SMART goals.
Week 8- Celebrating success and planning for the future

Week 8 contained three parts: self-assessment, looking after my diabetes, and moving on: the beginning of the end. ‘Self-assessment’ was an opportunity for users to repeat the quizzes in week 1 of the programme, and see how their scores had changed. The self-assessment quizzes are described in depth below. ‘Looking after my diabetes’ focused on looking forward to the future and gave users the opportunity to prepare a care plan, to take to their next appointment with their doctor or nurse. ‘Moving on: the beginning of the end’ gave advice about staying motivated and how to read information about diabetes in research studies (see Figure 3-9) and in the media, provided useful links to further information and suggested setting new challenges.

3.3.3 Self-assessment questionnaires

Self-assessment questionnaires were included in the programme in Weeks 1 and 8 (pre- and post-programme). These were used to help people recognise their learning needs at the start of the programme, reflect on their learning at
the end of the programme, and to provide evidence of impact of the intervention for my research. Self-assessment has been identified as essential to learning by education theorists (161, 162). Theory about self-assessment was discussed in Chapter 2, and is summarised here. Self-assessment allows acknowledgement of pre-existing understanding, and along with feedback, can help shift learners to task-involvement (focusing on learning) (164). Self-assessment is also key to managing one’s motivation towards learning (163).

3.3.3.1 Formative and summative assessment

The self-assessment questionnaires were used as formative and summative assessments. The Week 1 (pre-programme) questionnaires were formative assessments for learners. Formative practice establishes and interprets student achievement, in order to make decisions about the next steps in instruction. These steps are likely to be better than the steps that would have been taken without the evidence elicited (165). Unless learners understand their strengths and weaknesses, and how they might deal with them, they will not be able to make progress (194). An assessment of current understanding can be used to make opportunities and materials for learning available, and make clear the purposes and goals of the work (195). For an assessment to be formative, it requires feedback which indicates whether there is a gap in learning, and how learning can be improved (196).

In the case of HDSO, users were able to establish their pre-existing level of learning in diabetes self-management with the Week 1 questionnaires, and use this evidence along with the feedback to reflect on the next steps in their learning. The feedback provided for the Week 1 questionnaires made the opportunities and materials for learning available by signposting users to parts of the course that would help them take the next steps. The Week 1 feedback is described in more detail, and examples are given, below.

The Week 8 (post-programme) questionnaires were used as summative assessments. Formative assessment can be seen as helping learning to move forward, whereas summative assessment can be seen as summarizing learning that has taken place (195). Summative assessment is a recording of the overall achievement of the student, and relates to progression in their
learning (194). The Week 8 questionnaires in the HDSO programme were used to demonstrate progression in learning for users. The pre- and post-programme questionnaire scores were given with the feedback to demonstrate progression. The Week 8 feedback is described in more detail, and examples are given, below. The change in questionnaire scores was also used as an outcome measure in my research evaluating the impact of the programme, as described in Chapters 4 and 6.

3.3.3.2 Causal modelling of the intervention

I decided which self-assessment questionnaires to include based on the outcomes I identified for the programme. In order to identify these outcomes, I needed to understand the causal chains linking the theoretical framework (the self-management tasks proposed by Corbin and Strauss) with the components of the intervention, in order to predict their range of effects. Understanding how an intervention works by developing a theoretical framework to predict the likely process of change, is recommended by the Medical Research Council (MRC).

A ‘causal modelling’ approach to framework development can be used (197), which links intervention components and health outcomes in a causal pathway. Theory and evidence are used to guide selection of intervention components and measurement points (197). Using theory to develop a model for how an intervention may alter health outcomes, or affect other links in the causal chain between intervention and outcome, may lead to better-designed interventions and evaluations (127).

The content of HDSO is based on the Corbin and Strauss model of the work of managing a long-term condition described in Chapter 2 (198). I have used Corbin and Strauss’s theory on living with long-term conditions (198) to identify mediators along the hypothesised causal pathways of intervention effects. This is illustrated in Figure 3-10 below.
**Self-management tasks faced by people with chronic conditions**

<table>
<thead>
<tr>
<th>Role management</th>
<th>Medical management</th>
<th>Emotional management</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intervention component</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Information</strong></td>
<td><strong>Goal setting</strong></td>
<td><strong>Changing behaviour</strong></td>
</tr>
<tr>
<td>An introduction to diabetes; protecting my mind and body; reducing the risks of heart attacks &amp; strokes; having a social life, driving.</td>
<td>Self-assessment and feedback; my diet and physical activity goals; update my goals and plans; self-assessment and feedback; review my goals and plans.</td>
<td>Eating well for diabetes; becoming more active; medication; looking after my feet.</td>
</tr>
<tr>
<td><strong>Behavioural pathway</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Want to change (motivation)</td>
<td>Do it (change behaviours)</td>
<td>Increase knowledge</td>
</tr>
<tr>
<td><strong>Outcomes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proximal: improved knowledge</td>
<td>Distal: weight loss, increased physical activity, optimised HbA1c</td>
<td></td>
</tr>
</tbody>
</table>
3.3.3.3 Selection of outcome measures

Impact of the intervention on users’ learning could have been measured in terms of any of the outcomes listed in the causal model above. I chose to measure the proximal outcomes: knowledge, self-efficacy and emotional distress. My process for selecting these is discussed here, including the characteristics of ideal outcomes, contextual constraints, pay-offs and judgements.

The distal outcomes in my causal model were weight loss, increased physical activity and optimised HbA1c. These would have been the ideal outcomes to measure because they improve quality of life, and reduce morbidity, disability, and premature mortality, which are the ultimate aims of health and medical interventions (199). They are also important to clinicians as they influence management choices. However, I was constrained because I did not have face-to-face contact with users so it was not feasible to take weight and HbA1c measurements. Face-to-face contact with people using the programme was only possible via their healthcare providers, but as the programme was being used as an NHS service and not a research study, healthcare providers could not be asked to provide physical measurements (the details of the study design and setting are discussed in Chapters 4 and 6).

Physical activity could have been measured using wearable devices or self-reported questionnaires (such as The International Physical Activity Questionnaire (IPAQ) (200)). However, it would have increased the response burden on users to add another questionnaire to the programme, and it would not have been feasible to provide all programme users with wearable devices or assume smartphone ownership.

The HDSO programme has a short duration (8 weeks), and physical and biomedical markers may not be expected to change in such a short timeframe. A longer period of follow-up, such as 3, 6 or 9 months, would be needed to achieve and assess change in these markers. Of equal consideration, was the importance of the proximal markers to the PPI representatives, who considered self-efficacy and emotional distress important outcome measures for patients.
I chose to measure the proximal outcomes: knowledge, self-efficacy and diabetes-related emotional distress because it was more feasible to measure using questionnaires added to Weeks 1 and 8 of the programme; because there were reliable and valid questionnaires available; and because improving these outcomes made it more likely (as predicted by behaviour change theory) that people would be able to change distal outcomes like weight loss and physical activity. In the next section, I have discussed each of these three constructs and why they matter for users of the programme.

Knowledge

Ability to carry out the medical management of diabetes (e.g. exercising regularly and eating healthy food) requires new knowledge about health behaviours, and the information component of the HDSO programme aims to provide this necessary knowledge. An expected outcome of completing the programme would be an increase in knowledge about diabetes self-management.

The relationship between knowledge and glycaemic control may be more complex. There has been concern about the apparent failure of knowledge to predict outcomes (the “knowledge-behaviour” gap) (201, 202). However knowledge may interact with motivation and self-efficacy in the behavioural pathway, which may in turn impact on glycaemic control.

Self-efficacy

Perceived self-efficacy is an individual’s perception of their ability to undertake a task (203). Achieving medical management and role management (e.g. adjusting to the “patient” role and managing the impact of one’s diagnosis on relationships) requires a change in beliefs about one’s capabilities (self-efficacy). Studies suggest that self-efficacy affects health behaviours and their outcomes positively (204, 205). People with high perceived self-efficacy approach difficult tasks as challenges to be mastered, maintain strong commitment to goals, and increase their efforts in response to failure. People with low perceived self-efficacy have low aspirations, weak commitment and dwell on personal deficiencies (206). Diabetes requires a high level of self-
efficacy due to the high number of self-management tasks required to prevent complications (206). Of all the intervention components, the videos, goal-setting and the self-assessment and feedback in particular aimed to improve the user’s beliefs in their capabilities. Goal-setting, self-assessment and feedback are discussed in the next section. Videos help to improve self-efficacy by allowing patients to model themselves on their peers in the videos, making them feel empowered to make similar changes.

Diabetes-related emotional distress

I also chose to measure change in diabetes-related emotional distress because of its role in performing self-care behaviours. Diabetes-related distress is an emotional response to being diagnosed with diabetes (207). It is disease-specific (208), distinct from depression and affects an estimated 40% of people diagnosed with diabetes (209). It has been defined as the distress associated with the burden of self-care; interpersonal issues; emotional burden and worry; relationships with care-givers and health professionals (210). Diabetes-related distress has been found to be significantly related to HbA1c and self-care behaviours in type 1 diabetes (T1DM) (211), and understanding diabetes-related distress may help explain the connection between emotions, coping strategies and illness outcomes in diabetes (207).

3.3.3.4 Description of questionnaires

The questionnaires were added to the programme as quizzes in Weeks 1 and 8, and were the: (1) Audit of Diabetes Knowledge (AdKnowl); (2) Diabetes Management Self-efficacy Scale (DMSES); and (3) Problem Areas in Diabetes (PAID).

AdKnowl

The AdKnowl is designed for use by adults with type 1 or type 2 diabetes, for a range of purposes including evaluating the success of educational interventions. There are 23 item-sets (114 items) relating to treatment, sick days, hypoglycaemia, complication risk, physical activity, smoking, alcohol, foot care and diet. Higher scores indicate greater knowledge and the topic sub-sets allow specific knowledge deficits to be targeted (201).
DMSES

The 20-item Diabetes Management Self-Efficacy Scale (DMSES) measures the individual’s expectations for being able to engage in diabetes self-management activities like daily exercise, and keeping to a healthy eating plan when away from home. Self-efficacy scores of 0 indicate no self-efficacy and scores of 150 indicate very high self-efficacy. The scale was developed for a Dutch/US population, but has been validated for use with a UK population and found to have good internal reliability, criterion and construct validity, and acceptable test-retest reliability (206).

PAID

Problem Areas in Diabetes (PAID) is a psychometric tool which provides a standardised way of measuring the emotional difficulties experienced by people with diabetes. PAID has 20 items focusing on areas that cause difficulty for people living with diabetes, including social situations, food, friends and family and social support. A score of above 40 on the PAID scale indicates increased diabetes-related distress, and is significantly associated with poor lifestyle (diet and exercise) and higher HbA1c. The minimal clinically important difference (MCID) for PAID is 4.0 (212). Psychometric tests have shown that PAID has consistently high internal reliability, sound test-retest reliability, and was a statistically significant predictor of glycaemic control in a one-year study of a managed care population (212, 213).

3.3.4 Personalised feedback

Feedback was sent to users after they completed the above questionnaires. Feedback is used to bridge the gap between the actual and reference level of knowledge (162, 165). Effective feedback provides the actual and reference levels, and the mechanism for generating information about the gap between the two (162). Self-assessment questionnaires were completed in Weeks 1 and 8 (pre- and post-programme). At Week 1, feedback was provided to help move users move forward with their learning, and at Week 8, feedback was provided to summarise the learning that had taken place during the
programme. The feedback and the theory I used in its development are described in more detail below, and illustrated with examples.

3.3.4.1 Week 1 (pre-programme) feedback
After completing the questionnaires in Week 1 of the course, users received an email with their actual score, the total possible score, and lowest scoring topic area (for the DSMES and AdKnowl questionnaires). An example of the feedback given for the DSMES (self-efficacy) questionnaire is given in Tables 3-2 and 3-3.

Table 3-2: Self-efficacy scores

<table>
<thead>
<tr>
<th>DMSES Total Score</th>
<th>Feedback</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-49</td>
<td>You’re not feeling confident to look after your diabetes, but that’s what we hope to improve with this course!</td>
</tr>
<tr>
<td>50-99</td>
<td>You feel confident in managing some areas of your diabetes but not others.</td>
</tr>
<tr>
<td>100-150</td>
<td>Well done! You feel confident in managing your diabetes. There are still areas you can address.</td>
</tr>
</tbody>
</table>

Table 3-3: Topic-specific feedback

<table>
<thead>
<tr>
<th>Lowest scoring area</th>
<th>Feedback</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nutrition specific and weight</td>
<td>Managing my eating and weight. There is plenty of information to help you decide which foods to eat to manage your weight. We will cover some of this in session 1, and you can find more information in the “Staying Healthy” section of the HeLP-Diabetes website. You can also discuss diet with the Practice Nurse at your surgery.</td>
</tr>
<tr>
<td><strong>Nutrition general and medical treatment</strong></td>
<td>Managing diabetes with diet and medicines. It can be confusing to understand how food and medicines affect your diabetes, but we will learn more about this in session 5. You can also find more information in the “Treating Diabetes” section of the HeLP-Diabetes website. It would also be useful to discuss your treatment with your Practice Nurse or GP, particularly if you have a review appointment coming up as this is a great opportunity to ask questions.</td>
</tr>
<tr>
<td><strong>Physical exercise</strong></td>
<td>Physical activity. Have a think about how you could be more active. Have you tried incorporating exercise into your daily routine, for example through walking to work, gardening or cycling? We will cover physical activity in session 2 and you can find more information in “Staying Healthy” on the HeLP-Diabetes website.</td>
</tr>
<tr>
<td><strong>Blood sugar</strong></td>
<td>Managing blood glucose levels. If you do need to check your blood glucose levels regularly, it might be worth discussing your medication with your doctor at your next diabetes review. We will cover medication and lifestyle in Session 5 which should help you with this as well.</td>
</tr>
</tbody>
</table>

The rationale for giving the actual score and total possible score was to provide users with their actual and reference level of knowledge and skills about diabetes self-management, as proposed in the literature by Ramaprasad and Sadler about giving effective feedback. It was also important to give users the opportunity to act upon the gap in their actual level of
knowledge or skills and the reference level. I did this by providing additional information in the feedback signposting users to parts of the programme that would help improve their knowledge and skills, as illustrated in Table 3-3 above. If the user’s lowest scoring area of the DSMES (self-efficacy) questionnaire was ‘Nutrition specific and weight’, I signposted them to the rest of Week 1 of the programme, and to the “Staying Healthy” section of the HeLP-Diabetes website. I included this signposting in order to show users where the opportunities were for improving their knowledge and skills, and narrowing the gap between their actual and the reference level of knowledge and skills. This moved the feedback from simply telling users about this gap, to giving users the opportunity to utilise information about the gap to improve their knowledge and skills.

3.3.4.2 Week 8 (post-programme) feedback
The questionnaires were repeated in Week 8 to provide feedback about the impact of the course on knowledge, self-efficacy and distress. The questionnaires also provided quantitative measures of impact for studies 1 and 2.

I wrote the Week 8 (post-programme) feedback to give users a record of their achievement and progress in their learning (as illustrated in Table 3-4).

Table 3-4: Week 8 feedback

<table>
<thead>
<tr>
<th></th>
<th>Post score&gt; Pre score</th>
<th>Post score = Pre score</th>
<th>Post score &lt; Pre score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-efficacy</td>
<td>Well done! You feel more confident in managing your diabetes. We are glad that the course has been helpful for you.</td>
<td>You have maintained the same level of confidence in managing your diabetes. As you continue to learn about diabetes we hope your</td>
<td>Your confidence in managing your diabetes is not quite as high as before you started. This might be because you are more aware of</td>
</tr>
<tr>
<td>Distress</td>
<td>It appears that your level of distress has increased. Perhaps some of the things on the course surprised you and have you a little worried. Take some time to reflect on what you have learnt and with confidence will grow.</td>
<td>We can see that your level of distress has stayed the same. This should improve over time as you continue to build your knowledge and confidence.</td>
<td>We can see that your level of distress has decreased. That's great! We are glad the course has been helpful for you. And we hope you find the main HeLP-Diabetes website just as helpful.</td>
</tr>
</tbody>
</table>
the right changes, you can turn your diagnosis into something positive. The main HeLP-Diabetes website has lots of hints and tips to help you feel healthier and happier. Please do speak to your GP or nurse about any issues that are concerning you.

<table>
<thead>
<tr>
<th>Knowledge</th>
<th>Well done! We can see that your knowledge about diabetes has improved. That’s wonderful. Over the next few pages we will help you to think about how you can continue to learn about diabetes.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>We can see that you have maintained the same level of knowledge about your diabetes. Learning is a continuous process so over the next few pages we will help you to think about how you can continue to</td>
</tr>
<tr>
<td></td>
<td>We can see that your knowledge about diabetes is not quite as good as before the course. This could be because certain topics have been confusing for you. Don’t worry – there is probably a lot of new material to take in and you</td>
</tr>
</tbody>
</table>
When self-efficacy, distress or knowledge improved, I congratulated users on their achievement. When these parameters stayed the same, I reassured users that their self-efficacy, distress and knowledge would improve as they learned more about diabetes self-management. When the parameters did not improve, I explained why this can occur. In the case of self-efficacy, this can decrease with learning due to being more aware of complications. This can leave people feeling less confident due to the size of the task of preventing complications. Research on self-efficacy suggests that change can be limited by ‘a ceiling effect’ (214). This means that there is little room for improvement when pre-intervention self-efficacy is high. Low self-efficacy is less subject to a ceiling effect (214). The perception of a lack of control over the causes of performance also limit change in self-efficacy. Internal cues like effort can be controlled by the individual, but external cues such as task interdependence may be controlled externally (214). Users of the HDSO programme may see the tasks of diabetes self-management as being outside of their control, and this may limit the change in their self-efficacy during the programme. The feedback I provided for a decrease in self-efficacy included advice that the knowledge and skills that are acquired during the programme will help give them the control to make positive changes. I also advised users to consult their healthcare team about anything they were particularly worried about.

Distress can increase with learning due to, again, a greater awareness of the illness, its implications and the work of self-management. A randomised
controlled trial of the effectiveness of a group education course for type 2 diabetes (DESMOND) found no change in emotional distress (215), but the authors also measured personal responsibility for diabetes, belief in seriousness and understanding of its duration and found these all increased. They were reassured therefore that the increase in these measures led to a lack of improvement in emotional distress (215). I tried to help users understand that lack of improvement in distress can be explained by greater awareness, and that reflecting on learning and making constructive changes, will help generate a more positive outlook on their diabetes.  

A study by Thoolen et al (216) investigated how time since diagnosis and treatment intensity effected diabetes-related distress, self-efficacy and other psychological outcomes in patients with screen-detected type 2 diabetes. They found that most screen-detected patients reported low distress and high self-efficacy, and distress increased with time and treatment intensity. The findings suggest that asymptomatic patients tend to downplay the seriousness of the illness in order to reduce distress, until signs and symptoms develop. This idea is supported by theory on defensive denial and self-regulation of health threats (217). The finding of high-self efficacy suggests the screen-detected patients were overly confident in their ability to self-manage and perhaps do not yet recognise the difficulties of living with diabetes. An increase in distress may not mean that patients are less adaptive, and actually a certain amount of negative arousal is necessary for the appraisal of and coping with problem situations (218). An increase in distress and decrease in self-efficacy could therefore represent a ‘reality check’ of the reality of living with diabetes. Understanding how psychological outcomes change in patients with chronic illnesses, is important for understanding how to intervene (219, 220). Patients who have an increase in distress and less self-efficacy may need more support from clinicians with lifestyle changes (216). 

Knowledge can apparently decrease because the increase in the amount of information the user is exposed to may cause confusion. Participants in a qualitative study of individuals with diabetes and health information-seeking reported that ‘information overload’ can be a hindrance, and a high volume of
information can have a paralyzing effect (147). This finding fits with theory on cognitive overloading, which suggests that performance deteriorates with excessively high cognitive load (221). Learners can feel overwhelmed by a large number of interacting elements of information that need to be processed (222). I reassured users who had a decrease in knowledge score, that making sense of all the information would take time, and any topics of confusion could be clarified by referring to other sources, including peer support groups, face-to-face group education programmes and scientific research papers. These are all described and links given to websites with further information in the very last part of the Week 8 of the programme (“Moving on: the end of the beginning”). There is also guidance about how to read and interpret scientific papers.

There are also potential negative effects of feedback that I had to be careful of avoiding. Hattie & Temperley have written that for feedback to be effective it has to clear, purposeful, meaningful, compatible with prior knowledge, and relate to clear and specific goals. Feedback is less effective if there is any threat at what they have called the ‘self’ level. Feedback at the self level is personal and expresses evaluations and affect about the student (for example, “Good effort”). It contains little task-related information, and rarely converts to greater commitment to the learning goals or enhanced self-efficacy because it deflects from the task. When feedback draws attention to the self, students try to avoid the risks of challenging learning, minimise their effort and have a high fear of failure (223). I was therefore careful to make my feedback specific to the task, and goal-oriented, in order to avoid evaluations of the user and drawing attention to the self. For example when congratulating users about improved knowledge scores, I described achievement in the task specifically, and directed the user to how to continue the learning: “Well done! We can see that your knowledge about diabetes has improved. That’s wonderful. Over the next few pages we will help you to think about how you can continue to learn about diabetes.”
3.3.5 Goal-setting

In Week 3 of the programme, users were asked to set specific, measurable, achievable, realistic, time-bound (SMART) goals (224). They could enter and save their goal onto the website (see Figure 3-11), along with a plan of exactly what they were going to do (e.g. stick to a diet goal by taking a shopping list of low calorie food to the supermarket), potential barriers, and ideas for navigating these barriers. People could also select a choice of email or text reminder and a review date, to help them monitor and achieve their goals.

Later in the course there were opportunities to review goals that had been set, and rate progress from 0 to 5. People were asked questions about how they felt about their progress, and given encouragement and feedback such as making a goal more achievable, or setting new reminders.

Figure 3-11: Screenshot of goal-setting exercise

The rationale for asking users to choose specific achievable goals is based on theories of self-efficacy (176), and goal-setting is used in other diabetes self-management programmes (225). Goal-setting and self-evaluation increase motivation, as they allow us to compare our performance against personal standards we have set for ourselves (179). Specific goals are more likely to aid learning because it is easy to monitor progress (180). There is an initial sense of self-efficacy for achieving the goal (181), and this is reinforced when
learners see they are progressing and increasing their skills (182). Providing feedback on goals also increases self-efficacy (183). Feedback is another way of notifying people about their progress, and can help people feel a sense of accomplishment and competence (184). Increased self-efficacy results in sustained motivation and skills development (181). Motivation depends on the proximity, specificity and difficulty of the goal (181). Easier, more proximal and specific goals are more likely to increase motivation, and for this reason the SMART criteria were used in the programme.

### 3.3.6 Personalised emails

I was conscious of the need to promote engagement and use of the programme, and so I also developed personalised emails to send to users to help maintain motivation. Systematic reviews of strategies to improve adherence to digital health interventions provide some evidence of effect for email reminders. Brower et al. looked at which intervention characteristics of internet-based interventions to promote healthy lifestyle increase exposure (such as completion of an initial visit, number of log-ins, and time spent on the website). They found a lack of consistency in the exposure measures that were reported, but email contact was one of the intervention characteristics that resulted in more log-ins (226). A systematic review by Alkhladi et al. of the effectiveness of prompts to increase of digital interventions found that studies reported borderline small-to-moderate positive effects of technological strategies, including emails, to improve use of interventions (227).

Email reminders were sent to HDSO programme users. Emails were sent: (i) if a user completed a session or; (ii) if a user did not log in to the programme for a week or more.

The emails were personalised by addressing users by their names. The emails sent on completing Weeks 1 and Week 8 of the programme included the personalised questionnaire feedback described above. This was another way of providing people with feedback about their progress, and helping people feel a sense of accomplishment and competence, as described in theories of self-efficacy (176). The emails also included congratulations for completing
the session, and the topic of the next part of the programme. The emails were reviewed by the PPI representatives and edited according to their comments. An example is given in Figure 3-12.

Dear.....

Congratulations on completing session one of the course! It’s now time to move on to session two. In this session we will discuss taking control of your diabetes and think about how you can become more active.

Here is the link to the log in page: https://www.help-diabetes.org.uk/learn/

We hope you enjoy this part of the course.

Best wishes,

The HeLP-Diabetes Educator Team

Figure 3-12: Email sent to users after completing Week 1

People who did not login to the programme for one week received an email reminder that the programme was open to them, and a brief outline of the content of the next part of the programme. This was repeated if the user did not login for two weeks, and again if they did not login for three weeks. An example of the reminder email is given in Figure 3-13.
It was possible to automate the emails so that they could be sent to users at the appropriate time (either after completing a session, or if they did not login for a week or more). So, despite the evidence for the effectiveness of emails being mixed, it was a resource-effective strategy.

3.4 Usability testing
The development process involved a series of usability tests. Usability testing was introduced in Chapter 2, as a method for evaluating interactive products in the iterative design cycle. The International Organization for Standardization (ISO) has proposed definitions of usability, including: ‘the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use’ (139).

Usability testing is commonly used in software engineering and human-computer interaction research. It has been described as: “representative users attempting representative tasks in representative environments, on early prototypes or working versions of computer interfaces” (228). The aim of usability testing is to find flaws in the interface that need improvement.

Dear....

We see you haven’t yet started the HeLP Diabetes programme. This is a gentle reminder that the first session is ready and waiting for you. There is lots of information in this session about what diabetes is and how to eat healthily when you have diabetes. You will be asked to complete some questionnaires to begin with, and then you will get your first personalised feedback from the HeLP Diabetes Educator Team.

Here is the link to the log in page: https://www.help-diabetes.org.uk/learn/

Best wishes
The HeLP-Diabetes Educator Team

Figure 3-13: Example reminder email
Usability can be tested at any stage of product development, and conducting usability testing during an iterative development process makes products more sensitive to users’ needs (229).

There is a wide range of techniques used in usability testing, including questionnaires, think-aloud observation and interview-based techniques (230). There is no consensus on the optimal sample size for usability testing. It has been suggested that 4 or 5 subjects can detect 80% of usability issues (231). Meta-analysis has suggested a larger number is needed, and that 9 or 10 subjects gives a better discovery rate (232).

The usability testing for HDSO was carried out using questionnaires. My academic GP colleague in the HDSO team developed a short questionnaire asking for feedback on programme design, content and specific comments about ideas for improvement. This was emailed to the two PPI representatives and three new users. An example of a questionnaire response is given below in Figure 3-14.

<table>
<thead>
<tr>
<th>User 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 7, Part 1</td>
</tr>
<tr>
<td>No indication of how many parts there are when you start the session. The first sub-heading of each part is in a smaller font than all the other sub-headings.</td>
</tr>
</tbody>
</table>

**Figure 3-14: Usability questionnaire response**

I reviewed the questionnaire responses with the rest of the HDSO team, and we agreed which changes should be made. Changes were delegated between the team and I made several changes to each session of the programme, including changes to text and titles to make the clearer and easier to understand for users.

**3.5 Rationale for evaluation of first iteration of HDSO**

Once changes to the programme had been made, I conducted an evaluation of the first iteration of the programme with patients recruited from primary care.
The Medical Research Council (MRC) guidance on developing and evaluating complex interventions (44) recommends testing interventions that have been developed using evidence and theory with a series of small pilot studies. The evaluation of the first iteration of HDSO was carried out over the next 8 months. The aim was to determine effect, feasibility and acceptability of the programme, and to optimise the programme. The MRC guidance, other frameworks for pre-trial testing of complex interventions and the methods and results of the evaluation are described in Chapter 4.
Chapter 4. Evaluation of first iteration of HeLP-Diabetes: Starting Out

4.1 Chapter summary

This chapter describes the evaluation of the first iteration of HDSO, which was a study of the acceptability and feasibility of this first version of the programme. I measured the uptake, impact and programme acceptability of the programme. I have reported my findings and the implications for the next version.

4.2 Background

4.2.1 Development and evaluation of complex interventions

As discussed in chapter 2, HDSO is a complex intervention. To summarise, complex interventions have multiple components which act independently and interdependently (117). One of the challenges of evaluating complex interventions is understanding the non-linear interactions between intervention components, and their outcomes (117). Randomised controlled trials (RCTs) are regarded as the ‘gold standard’ method for evaluating interventions. However if an intervention does not influence outcomes as expected, trials can fail to detect whether lack of intervention effect is due to implementation failure or genuine ineffectiveness (117). When evaluating complex interventions, we therefore need not only to determine whether they are effective, but also how these effects are brought about (127). This requires understanding the causal chains linking interventions and their outcomes (233). Identifying the causal chains allows a better understanding of the range of effects of the intervention, how the effects vary between people and sites, and what the causes of this variation are (104). This enables researchers to refine interventions prior to an RCT, and results in design of more effective interventions, enhanced trial processes, and application to appropriate groups and settings (104, 117). A process of iterative development of complex interventions is required, until they are stable, usable, acceptable, and appear likely to be effective.
A ‘causal modelling’ approach to framework development can be used (197), which links intervention components and health outcomes in a causal pathway. I developed a causal model for HDSO based on Corbin and Strauss’s theory on living with long-term conditions, intervention components and behavioural mediators. I have illustrated this causal model in Chapter 3 (Figure 3-10). Effectiveness of HDSO can be measured in terms of change in any of the outcomes listed in the causal model. In the evaluation of the first iteration of HDSO, I measured impact on self-reported knowledge, self-efficacy and distress using questionnaires (AdKnowl, DMSES and PAID). The questionnaires were described in Chapter 3.

In addition to these measures, I also measured uptake of the intervention. Uptake was important to measure because health education interventions seek to make improvements in population, not just individual health. Population impact depends on reach (uptake), as well as effect (234). Uptake is particularly important for digital health interventions because their impact and cost-effectiveness are dependent on the number of users (63, 235). Current guidance advice on developing digital health interventions is that an early component of evaluation of such interventions must be determination and optimization of uptake by the intended population, in addition to effect (63). Determining and optimizing uptake requires testing features related to feasibility at an early stage (63). These features include acceptability and usability (can the target audience use the intervention as part of their daily lives); demand from stakeholders; implementation (what will use be in a ‘real world’ setting); practicability (what is the burden of delivering the intervention); adaptation (can it be adapted to different contexts); and integration into health systems (63). The aim of the evaluation studies of the HDSO programme was to therefore to test feasibility and acceptability. Uptake of HDSO was determined by measuring the number (proportion) of people registering, and then starting and completing the programme.
4.2.2 Overlapping techniques in health service research and software design

As discussed in Chapter 2, I used a combination of techniques taken from health service research and software design. In health service research, the MRC guidance for the development and evaluation of complex interventions recommends a cycle of assessing user needs, developing the intervention, identifying problems, and making changes to the intervention or its delivery method (133). This bears a strong resemblance to the lifecycle models used in software development, such as the Waterfall, Spiral and Star models (135-137) (see Figure 2-5). All the life cycle models emphasise the co-dependency of development and evaluation, and the Star model in particular suggests that the essential stages of development can take place in various orders, repeated or skipped over if necessary (138). Each stage should be accompanied by evaluation, and evaluation is positioned at the centre of the star, since it guides all the other steps (138).

Hybrid models incorporating aspects of both the health research frameworks, and the lifecycle models, have started to appear (see figure 2-6). I developed my own hybrid model for the approach used in the development, evaluation and optimisation of HDSO (illustrated in Figure 2-7). To summarise, the evaluation of the first iteration of HDSO led to refinements to the programme and procedures. The second iteration of the programme was then evaluated in a second study. Recommendations for a final intervention which could be evaluated in a definitive trial were made.

The evaluation of the first iteration of HDSO was the first stage of this process. In the next section I have described the aim of the evaluation of the first iteration of HDSO, and subsequently I have described the methods used.

4.3 Aims and objectives

The aim of the evaluation of the first iteration of HDSO was to test the feasibility of the intervention, to determine the impact of the programme on outcomes (effect), and the uptake and acceptability of the programme. This facilitated optimization of the programme by allowing weaknesses to be
identified and refinements to be made. Acceptability of the programme to users was also explored, using qualitative methods.

Specific objectives were:

1. To describe uptake of the programme, including numbers (proportions) registering, starting and completing the programme;
2. To determine the demographic features of patients registering for the programme;
3. To investigate the effect of the programme on users’ levels of diabetes knowledge, diabetes-related distress, and diabetes self-management self-efficacy;
4. To explore patients’ views about the programme, including factors affecting acceptability of the programme.

4.4 Methods

4.4.1 Study design

This was a single-arm mixed method study in primary care. Mixed methods refer to the use of both quantitative and qualitative methods. Quantitative and qualitative research have different epistemological origins and are therefore used to produce knowledge about the world in different ways (236). Quantitative research is grounded in a realist perspective and values precise measurement, whereas qualitative research comes from an interpretive perspective and values the generation of novel multifaceted knowledge (236).

Mixed methods research involves more than collecting quantitative and qualitative data. It involves integrating, relating and mixing the data during the research process (237). The principle underlying this is that neither method alone is sufficient to answer the research question. When mixed and used together, quantitative and qualitative data complement each other and allow for a more complete analysis (237).

There are different ways of mixing quantitative and qualitative data. Integration can occur during at least four different phases—sampling, data collection, data analysis and interpretation (236). For example, during the data collection phase, quantitative and qualitative data can be collected in parallel or sequentially (237).
As well as being able to integrate data at different phases, there are also many options for how to integrate data. These include transforming qualitative data into quantitative data for statistical analysis (‘quantising’), transforming quantitative data into qualitative data for analysis (‘qualitising’), or presenting quantitative and qualitative data together. This can be done by cross-tabulating findings from each component of the study and considering where there is agreement or dissonance (‘triangulation’); using the initial results of one analysis to identify issues for more in-depth analysis across both data sets (‘following the thread’); and presenting quantitative and qualitative data for each ‘case’ that is involved in the research (‘mixed methods matrix’) (236, 238). The ‘following the thread’ and ‘mixed methods matrix’ approaches involve analysing the quantitative and qualitative data together, whereas ‘triangulation’ occurs at the interpretation phase of the study when both data have been analysed separately (238) (See Figure 4-1)

**Figure 4-1: Techniques for integrating data in mixed methods research (227)**

[Diagram showing techniques for integrating data in mixed methods research]

A mixed methods study design was chosen for this study because there were a number of objectives which attempted to answer different types of questions. Quantitative methods were best suited to measuring numbers of users of the programme, describing and comparing their demographic features, and measuring effect on diabetes-related distress and diabetes self-management self-efficacy. A qualitative approach was best suited to exploring patients’ and healthcare professionals’ views of the programme, including reasons why they might engage or might not engage.

The data collection was performed simultaneously, then the qualitative and quantitative data were analysed separately. Finally, the data were interpreted using the ‘triangulation’ approach, resulting in findings from each component of the study being compared and the results of the quantitative component of the study being clarified and elaborated by the results of the qualitative component.

4.4.2 Setting

The study took place at the end of the implementation study of the HeLP-Diabetes website (described in Chapter 2), and before HeLP-Diabetes was commissioned. Practices in Camden and Islington who took part in the implementation study were offered ongoing free use of HeLP-Diabetes, and additional free use of the HDSO programme as a NHS service. There were practices in Lewisham and Lambeth who were interested in commissioning the programme who were also offered free use. The programme was offered to them (as an alternative to established face-to-face courses that were already commissioned) because of the interest in commissioning an online programme, the goal of the HeLP-CiC to have the programme commissioned, and the need to determine its feasibility, uptake and acceptability in the NHS prior to optimization and commissioning agreements. The programme was offered as a NHS service rather than a research study, also due to the need to determine its feasibility as a service offered in the NHS. 17 practices were approached and 15 agreed to offer the programme to patients. The 15 participating practices gave patients information about the programme, and
asked if they were interested in registering. Details of recruitment are given below.

Primary care was the most appropriate setting for recruitment to HDSO as this is where patients in the UK are diagnosed with T2DM and referred to structured education (17).

4.4.3 Ethics

The HDSO programme collects data on registrations, completed sessions and questionnaire scores. This data is automatically pseudonymised with a numerical identifier. Patients were informed that anonymised data were collected by the programme and used anonymously for ongoing service development. I exported the pseudonymised data to Excel for analysis on a weekly basis. Secondary analysis of information collected as part of normal care is excluded from REC review by the HRA, as long as patients are not identifiable (239):

“Research limited to secondary use of information previously collected in the course of normal care (without an intention to use it for research at the time of collection) is generally excluded from REC review, provided that the patients or service users are not identifiable to the research team in carrying out the research.”

I gained ethical approval to carry out the interviews from the Health Research Authority (reference number 159488, see Appendix A).

4.4.4 Participants

As the programme was offered to patients as a NHS service, there were no formal inclusion and exclusion criteria. Practices were informed that the target population of the intervention was adults (aged 18 or over) with type 2 diabetes diagnosed in the last 9 months, and asked to offer the programme to everyone in this population.

Practices were also advised that people who could not use a computer due to severe mental or physical impairments, had insufficient mastery of English to
use the intervention, were unable to communicate without an interpreter, or
were currently participating in a trial of a self-management intervention, were
not suitable for referral to HDSO.

4.4.5 Recruitment

Practice managers, lead GPs and Practice Nurses at the 15 practices who
agreed to take part were emailed details of the HDSO programme (including
advice about who was suitable to refer, listed above). It was offered as a NHS
service and an alternative to established face-to-face course that practices
were already referring patients to. Practices were also informed about the
pseudonymised data collected by the programme, and that I would be carrying
out interviews with patients about their views of the programme. Practices
were asked to identify patients eligible to use the programme by running a
search of the electronic medical records. Practices were sent registration
packs to mail out to eligible patients. Administrative, printing and self-
addressed envelope costs were reimbursed. Practices could also promote the
programme in the practice using flyers in waiting areas. The registration pack
contained information about the HDSO programme, that it was being offered
as a NHS service, how to register, the offer to take part in research interviews
and a reply slip. Patients interested in using the programme returned a reply
slip to the HeLP administrator with their contact details, and their preference
about being contacted for research interviews. Patients were then telephoned
by the HeLP administrator who collected baseline demographic data (see
results) and created a username and password for the programme. The HeLP
administrator also confirmed whether they were happy to take part in research
interviews and securely sent me the identification numbers of all the patients
who agreed. The username and password for the HDSO programme were
then emailed to the patient, along with information about who to contact if there
were any problems.

A flowchart listing the processes that were involved in registering patients to
the programme and inviting them to take part in interviews is shown below in
Figure 4-2.
First iteration of HDSO developed

17 practices in Camden, Islington, Lewisham and Lambeth offered free use of HDSO as a NHS service

15 practices agreed

Practices offered reimbursement to identify patients with newly diagnosed T2DM and mail out recruitment packs

Patients returned reply slips and registered for the programme by telephone

Patients agreeing to interviews invited to attend

HRA ethical approval gained for qualitative interviews, and secondary analysis of anonymised data excluded
I contacted everyone who agreed to be interviewed by email and invited them to attend an interview in person or by telephone. Interviews were organised with patients who responded.

Interviewees were given an information sheet (see Appendix D) detailing the purpose of the study. They were given the opportunity to ask questions before signing a consent form (see Appendix E). Consent forms were stored securely and separately from questionnaire data.

4.4.6 Intervention

The HDSO programme was an online structured self-management education programme for type 2 diabetes called HeLP-Diabetes: Starting Out (HDSO). HDSO and its development is described in more detail in Chapter 3. The aim of the programme was to improve knowledge and skills in diabetes self-management. It consisted of 8 sessions which users were encouraged to complete at weekly intervals. Information was presented using text, images and videos, including videos of others living with diabetes. Users were asked to complete self-assessment questionnaires at the start and end of the programme, and given goal-setting tasks which they could review and set reminders for.

4.4.7 Data Collection

The data collected reflect the objectives of the study, and are summarised in Table 4-1 and then described in more detail below.

<table>
<thead>
<tr>
<th>Objective</th>
<th>Measure</th>
<th>When</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients’ use of the programme, including numbers (proportions) registering, starting and completing the programme</td>
<td>Number of patients who registered with the programme, started the programme and completed it</td>
<td>Throughout</td>
</tr>
<tr>
<td>Demographic features of patients registering for the programme</td>
<td>Age; gender; ethnicity; highest educational attainment; internet access (home or public); IT skill level (basic, intermediate or advanced); duration of diabetes; offered face-to-face education (yes or no); attended face-to-face education (yes or no).</td>
<td>At registration</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Effect of the programme on diabetes knowledge, diabetes-related distress and diabetes self-management self-efficacy</td>
<td>Change in Diabetes Knowledge (Adknowl), Problem Areas in Diabetes (PAID) and Diabetes Management Self-Efficacy (DSMSES) questionnaire scores</td>
<td>Pre- and post-education programme</td>
</tr>
<tr>
<td>Patient views about the programme, including factors affecting acceptability of the programme</td>
<td>Qualitative interview data from interviews with patients</td>
<td>End of study</td>
</tr>
</tbody>
</table>

### 4.4.8 Patients’ use of the programme

Data were collected on the number (proportions) of patients registering for the programme, and starting and completing it. The data were collected automatically on the server side of the website, and pseudonymised with a
user ID. The data collected were: user ID, date and time of login and page visited.

These data were collected to assess the feasibility and acceptability of the programme, alongside demographic data. There is evidence to suggest that adherence is a problem for DHIs, and this may be related to characteristics of the intervention, the user, and the condition addressed by the intervention (240, 241). Collecting data on uptake allowed problems to be identified, explored further, and for the programme and procedures to be refined.

Patients were asked which practice they were registered at, and which CCG their practice belonged to when they spoke to the HeLP administrator on the telephone at registration. I used this information to work out how many practices referred patients to HDSO, and which CCGs they were from. I kept a record of how many practices sent out registration packs, and how many packs each of these practices sent out. I used the number of packs sent out as a proxy for the number of newly diagnosed patients registered at the practice (practices were asked to only send out registration packs to newly diagnosed patients). I used data published by NHS England on how many patients were registered at each practice (242), and used these figures to calculate the number of newly diagnosed patients per 1,000 patients registered at the practice.

4.4.9 Demographic features of registered patients

Demographic information about patients (including age, gender, ethnicity and highest educational attainment) was collected at registration to determine the acceptability of the programme to different demographic groups. The programme was developed to be used by people from a wide range of backgrounds, and it was important to collect data to determine whether this was achieved.

Age and ethnicity of users is of particular importance for a T2DM education programme, as T2DM is usually diagnosed in middle to older age groups, and people from South Asian or Black communities are two to four times more likely to develop the disease (243).
Education level was used as a marker of socioeconomic status, as is common in epidemiological research (244, 245). Education level was also chosen because it was more acceptable than asking participants about income. Age, ethnicity and socioeconomic status were of interest due to concerns about digital health interventions and the ‘digital divide’ (the risk of those being most in need of online interventions being least likely to have access (98), as discussed in Chapter 1). Equitable access to online health interventions can be a challenge. Although home internet access in the UK is at a high of 89% (246), lack of home internet access is associated with low income and low education (98).

4.4.9.1 Effect of the programme

Diabetes knowledge, distress and self-management self-efficacy were chosen as outcome measures due to their position in the causal pathway of HDSO (see Figure 3-10). The causal pathway and the questionnaires were described in more detail in Chapter 3. Users were asked to complete the questionnaires online during Week 1 of the programme (pre-programme) and Week 8 (post-programme), and the change in questionnaire scores was automatically calculated by the programme, anonymised and stored by the website.

4.4.9.2 Diabetes Knowledge

The Audit of Diabetes Knowledge (AdKnowl) was used to assess change in knowledge. There are 23 item-sets (114 items) relating to treatment, sick days, hypoglycaemia, complication risk, physical activity, smoking, alcohol, foot care and diet. Higher scores indicate greater knowledge and the topic sub-sets allow specific knowledge deficits to be targeted (201).

4.4.9.3 Diabetes-related distress

The Problem Areas in Diabetes (PAID) questionnaire, measuring the emotional difficulties experienced by people with diabetes, was used to measure diabetes-related emotional distress. The PAID questionnaire has 20 items. A score of above 40 on the PAID scale indicates increased diabetes-related distress (213), and is significantly associated with poor lifestyle (diet and exercise) and higher HbA1c (247). The minimal clinically important difference (MCID) for PAID is 4.0 (248).
4.4.9.4 Diabetes self-management self-efficacy
The 20-item Diabetes Management Self-Efficacy Scale (DMSES) was used to measure self-efficacy. The questionnaire measures the individual’s expectations for being able to engage in diabetes self-management activities like daily exercise, and keeping to a healthy eating plan when away from home (206). DMSES scores range from 0 to 150. Low scores indicate low self-efficacy and high scores indicate high self-efficacy.

4.4.9.5 Patient views about the programme
Semi-structured interviews were carried out with patients. Interviews were carried out face-to-face or over the phone and lasted between thirty and sixty minutes. Interviews were audio-recorded and transcribed. I developed the topic guide based on the objective of the interviews, to gain views on the acceptability of the programme. The topic guide included some background information such as experiences of being diagnosed with T2DM, accessing health information in general, accessing diabetes structured education and reasons for registering for HDSO. I also asked about likes and dislikes about the programme, and factors contributing to engagement with the programme such as problems logging in or completing the questionnaires, and when and where people used the programme and how long it took them to complete a session. The topic guide can be found in Appendix H.

4.5 Data analysis

4.5.1 Patients’ use of the programme
I calculated the proportion of people registered for the programme who started and completed it as a percentage.

4.5.2 Demographic features of registered patients
The mean age (and standard deviation) of patients who registered for the programme was calculated, as well as the number (and percentage) of patients in each demographic group.
4.5.2.1 Effect of the programme

Questionnaire scores at Week 1 (pre-programme) and Week 8 (post-programme) were analysed as follows. The mean and standard deviation of the questionnaire scores were calculated and the change in score described. As there were only 3 completers, there were not enough data to carry out a statistical test to determine if there was a significant change in scores at the end of the programme.

4.5.2.2 Patient views about the programme

Audio recordings were transcribed by professional transcribers, and I checked the transcripts against the original recordings for accuracy and anonymity.

3 patients who registered for the HDSO programme were interviewed. I read the transcripts, and based on the content I decided formal analysis was not yet indicated. I therefore did not complete the analysis until I collected more interview data in the evaluation of the second iteration of the programme. I wanted to gain more perspectives on the programme from patients before finalizing the codes and themes and discussing their implications. The analysis and results of the qualitative research are therefore presented in Chapter 6.

4.6 Results

4.6.1 Uptake and use of the programme

15 practices sent out HDSO registration packs to everyone registered as newly diagnosed with T2DM. Patients from 10 of the 15 practices registered for the programme. These 10 practices were in four different CCGs. The data on how many packs each of these practices sent out are given in Table 4.2 below.

24 people registered for the programme, 3 (12.5%) completed it, 13 (54.2%) started the programme but didn’t complete it, and 8 (33.3%) did not start the programme.
The number of newly diagnosed patients with T2DM per 1,000 patients registered with the practice varied from 0.91 to 9.34. The practice with the highest number of newly diagnosed patients with T2DM per 1,000 registered patients (Practice 2) only had 1 patient who was registered for HDSO. The practice with the highest number of patients registered for HDSO (Practice 9) did not have the highest number of newly diagnosed patients with T2DM per 1,000 registered patients. These figures are listed in Table 4-2.
Table 4-2: Practice and CCG details of patients who registered for the HDSO programme

<table>
<thead>
<tr>
<th>Practice</th>
<th>CCG</th>
<th>No. patients registered with the practice (2011/2012)</th>
<th>No. newly diagnosed patients</th>
<th>Packs sent to newly diagnosed patients</th>
<th>No. newly diagnosed patients per 1,000 registered with the practice*</th>
<th>No. patients registered for HDSO programme</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Camden</td>
<td>10,971</td>
<td>10</td>
<td>0.91</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Lambeth</td>
<td>10,704</td>
<td>100</td>
<td>9.34</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Camden</td>
<td>10,310</td>
<td>69</td>
<td>6.69</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Islington</td>
<td>3,818</td>
<td>16</td>
<td>4.19</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Lambeth</td>
<td>10,759</td>
<td>16</td>
<td>1.49</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Camden</td>
<td>18,334</td>
<td>73</td>
<td>3.98</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Lewisham</td>
<td>8,848</td>
<td>5</td>
<td>0.57</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Camden</td>
<td>6,519</td>
<td>6</td>
<td>0.92</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Camden</td>
<td>7,254</td>
<td>19</td>
<td>2.62</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Camden</td>
<td>1,946</td>
<td>8</td>
<td>4.11</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Totals</td>
<td></td>
<td>89,463</td>
<td>322</td>
<td>34.82</td>
<td>24</td>
<td></td>
</tr>
</tbody>
</table>

*Source of number of patients registered at each practice: NHS Digital. Patients registered at a GP practice 2016 [cited 2017 01 Nov]. Available from: https://app.powerbi.com/view?r=eyJrIjoiNjQxMTI5NTEtYzlkNi00MzjiLWE0OGItNGUyOGY4YzRjZGQ0IiwidCI6IjUwZjYwNzFmLWJiZmUtNDAxYS04ODAzLTY3Mzc0OGU2MjllMiIsImMiOjdh9.
4.6.2 Demographic features of registered patients

The mean age of patients who registered for the programme was 60.1 years (SD 3.1). The age of registered patients ranged from 27 to 81. Exactly 50% were male and 50% were female. 33% of registered patients were White British, 17% were White Other, 17% were Asian Other, 17% were Black African, 8% were Asian Chinese and 8% were Asian Indian. 39% of registered patients had a degree, 39% were school-leavers, 9% had post-graduate qualifications and 9% had A Level qualifications. Demographics are listed in Table 4-3.

Table 4-3: Demographic characteristics of patients who registered for HDSO

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean (SD) or Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>60.1 (3.1)</td>
</tr>
<tr>
<td>Gender</td>
<td>50% Male</td>
</tr>
<tr>
<td></td>
<td>50% Female</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
</tr>
<tr>
<td>White British</td>
<td>8 (33)</td>
</tr>
<tr>
<td>White Other</td>
<td>4 (17)</td>
</tr>
<tr>
<td>Asian Chinese</td>
<td>2 (8)</td>
</tr>
<tr>
<td>Asian Indian</td>
<td>2 (8)</td>
</tr>
<tr>
<td>Asian Other</td>
<td>4 (17)</td>
</tr>
<tr>
<td>Black African</td>
<td>4 (17)</td>
</tr>
<tr>
<td>Highest level qualification</td>
<td></td>
</tr>
<tr>
<td>School leaver</td>
<td>9 (39)</td>
</tr>
</tbody>
</table>
4.6.3 Effect of the programme

The mean diabetes-related distress score increased from 8 to 11, the mean self-management self-efficacy score increased from 82.3 to 89.3, and the mean diabetes knowledge score increased from 53.3 to 92.7 (see Table 4-4). There were not enough data to perform a statistical analysis to look for a significant change in scores.

Table 4-4: Completer questionnaire scores

<table>
<thead>
<tr>
<th></th>
<th>Completer 1</th>
<th>Completer 2</th>
<th>Completer 3</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-programme PAID</td>
<td>13</td>
<td>3</td>
<td>8</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td>score</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post-programme PAID</td>
<td>17</td>
<td>4</td>
<td>12</td>
<td>11</td>
<td>6.6</td>
</tr>
<tr>
<td>score</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-programme DSMES</td>
<td>57</td>
<td>119</td>
<td>71</td>
<td>82.3</td>
<td>32.5</td>
</tr>
<tr>
<td>score</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post-programme DSMES</td>
<td>55</td>
<td>142</td>
<td>71</td>
<td>89.3</td>
<td>46.3</td>
</tr>
<tr>
<td>score</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-programme AdKnowl</td>
<td>58</td>
<td>61</td>
<td>41</td>
<td>53.3</td>
<td>10.8</td>
</tr>
<tr>
<td>score</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post-programme AdKnowl</td>
<td>94</td>
<td>94</td>
<td>90</td>
<td>92.7</td>
<td>2.3</td>
</tr>
</tbody>
</table>
4.7 Discussion

4.7.1 Principal findings

This was a mixed methods study of HeLP-Diabetes: Starting Out which aimed to determine the feasibility of the programme by exploring the uptake, effect and acceptability of the programme.

The findings were that uptake and completion were low. 24 people registered for the programme, 3 (12.5%) completed it, 13 (54.2%) started the programme but didn’t complete it, and 8 (33.3%) did not start the programme. The demographic features of the people who registered for the programme were diverse, suggesting the programme was acceptable to a wide range of demographic groups. The questionnaire scores from the three completers showed an increase in the mean knowledge, emotional distress and self-efficacy scores, but there were not enough data to conclude if this was statistically significant.

The low uptake may be due to intervention, patient or practice factors. All 15 practices involved in the study sent out registration packs to eligible patients. Patients registered for the programme from only 10 practices (the number of packs sent by each of these practices is given in Table 4-2). This might suggest that the registration packs were not sufficient to encourage patients to register. The practice with the highest number of patients with newly diagnosed T2DM did not have the highest number of patients registered with the programme. This may suggest that there are practice factors involved in how many patients register for the programme, as practices with more eligible patients did not recruit more patients to the programme.

The mean age of people who registered to use the programme was 60, which is consistent with T2DM being more commonly diagnosed in middle age. There were patients ranging in age from 27 to 81. There were the same number of men and women registered for the programme, and a range of ethnic groups. 39% of registered patients had a degree, and 39% were school leavers. These findings suggest that the programme met its aims of being acceptable to a diverse range of people.
The aim of the programme was to decrease distress, so the increase in mean distress scores was an unexpected finding. As described in Chapter 3, diabetes-related distress can increase with learning about diabetes self-management due to a greater awareness of the illness, its implications and the work of self-management. There were not enough data to carry out statistical tests to determine if the change in scores was significantly significant, and so it is not possible to draw inferences from these data.

4.7.2 Comparison with existing literature

The finding of a programme completion rate of 12.5% is low but compares favourably with National Diabetes Audit data showing that only 7.1% of patients referred to face-to-face education attend (250). The findings are explored further in Chapter 5.

The high attrition we saw between registration and completion is consistent with findings from other studies of online health interventions, including web-based self-help programmes for panic disorder (86), depression (87) and HIV prevention (251). A review of fourteen internet-delivered diabetes self-management education programmes (73) found that participant interest and time spent logged on decreased as studies continued. All of these programmes were from outside the UK.

The finding of a socially and ethnically diverse group of patients registering for the programme suggests that a wide demographic can use the programme. This conflicts with existing literature that suggests that online health interventions may increase digital exclusion and widen the digital divide (98).

4.7.3 Strengths and limitations

One of the limitations was that patients registered for the programme from only 10 of the 15 practices that sent out registration packs. The registration packs may not have been effective enough at encouraging patients to register, and other strategies needed to be considered.

The low number of people who completed the programme meant that statistical analyses could not be performed to look for significant changes in
questionnaire scores. This meant that the effect of the programme could not be adequately assessed.

Only 3 patients registered for the programme were interviewed, and this meant that there were inadequate findings to complete the qualitative analysis. Therefore the qualitative findings cannot be used to help explain the quantitative finding of poor uptake, at this stage.

4.7.4 Implications for research and practice

More research was needed to improve the number of patients registering and the number of patients completing the programme. This would allow more quantitative and qualitative data to be collected and statistical and thematic analyses to be performed, which would allow further conclusions to be drawn (see Chapter 6).

4.8 Conclusion

The evaluation of the first iteration of the programme resulted in the finding of poor uptake and completion. I had more control over completion than uptake, as completion was more dependent on controllable factors (i.e. programme and delivery package factors). There was an opportunity for changes to be made to the programme and delivery package to improve completion, prior to further evaluation, as recommended by the frameworks for pre-trial testing of complex interventions (44). There was also an opportunity to explore the factors I had less control over, including patient and health system factors. Chapter 5 describes how I explored these factors with a user experience study, and the changes I made to the programme.
Chapter 5. Changes to the first iteration of HeLP-Diabetes: Starting Out

5.1 Chapter summary

This chapter describes the changes made to the HDSO programme. The changes were informed by the findings of the evaluation of the first iteration of HDSO, and an additional user experience study exploring the barriers to completing the programme that was conducted. I have discussed the methods used in the user experience study, and the changes that arose as a result, in this chapter.

5.2 Background

The aim of the evaluation of the first iteration of the programme was to determine its feasibility by testing the components of the programme and its delivery, determine impact on outcomes (effect), and identify weaknesses which would lead to refinement of the programme. This is in line with the MRC guidance on the development and evaluation of complex interventions, and current guidance on development and evaluation of digital health interventions (63). One of the findings was poor uptake and completion of the programme.

In order to find out how to improve completion rate, I conducted a user experience study to explore the barriers to completing the programme. This user experience study is described below.

5.3 User experience study exploring barriers to completing the HDSO programme

My decision to conduct this study was made during the data collection period of the evaluation of the first iteration of the programme. This was a result of the poor completion rate of the programme. The user experience study was part of the iterative process of establishing and optimizing the uptake and feasibility of the programme. It became clear from the quantitative data I was collecting on the number of people completing and registering for the programme, that there were programme, patient and health system factors that acted as barriers to registering for and using the programme. I could hypothesise as to what these barriers may have been (lack of information from
health professionals about the programme, lack of time to use the programme, or lack of computer skills). However, I had no evidence for these suggestions without speaking to the people who registered for the programme themselves, in order to understand their experiences of registering for and using the programme. As discussed in Chapter 2, understanding user experience is integral for designing products which fit into people’s everyday lives. The ISO definition of user experience is a person’s perceptions and responses that result from the use or anticipated use of a product, system or service (252). There is growing consensus in the eHealth research community that addressing the needs and perspectives of intended users is a vital part of intervention development, and critical for making interventions usable and engaging and overcoming challenges with uptake and adherence (253).

It seemed highly necessary at this stage, therefore, to conduct a user experience study with programme users. I needed to collect data rapidly, and to use the data to inform the optimization of the programme and improve its uptake, and to recognise if there were barriers which were harder to overcome by optimizing the programme alone.

5.3.1 Methods used in user experience research

Established methods of collecting data in user experience (or usability) studies are traditionally qualitative (109, 134). However, there are key differences in the qualitative methods used in user experience research, and in health and social science research. One difference is where the locus of expertise is assumed to lie. In user experience research, the user is assumed to be the expert in what they do and what they need. In health and social science research, typically researchers start with their own expertise, and design interventions which (it is hoped that) users will engage with (109). In order to address the challenge of low uptake and adherence of digital health interventions, more “user-centred” approaches to digital health research have been developed, including the person-based approach to intervention development proposed by Yardley et al (253). This involves qualitative research with a wide range of people from the target populations, at every stage of intervention development. The focus of this kind of research is on
understanding and accommodating the perspectives of the people who will use the intervention (253).

Another difference between user experience research and health and social science research, is that the qualitative research conducted as part of user experience studies is more formative than in health and social science. Methods more common to industry are used, driven by time and resource, rather than the principles of ethics and quality used in health and social science research. User experience studies are conducted at a number of stages during product development. Importance is given (as described in Chapter 2) to the continuous assessment and refinement of the design of the intervention, in order to optimize usability (230). In the case of HDSO, I described in Chapter 3 the usability testing that occurred during the development stage of the HDSO programme. The aim of evaluation at this stage was to make the intervention more specific to user needs (254). User experience was evaluated again in the current study, to explore user perceptions during routine use. In this study there was more of a focus on intervention effectiveness (completeness with which user goals can be achieved), efficiency (level of effectiveness achieved to expenditure of resources) and user satisfaction (230). The data from this study was used to underpin work on optimisation and further iterations of the intervention. In health and social science, a less formative and more summative approach is taken. There is more focus on impact of the final intervention.

The iterative nature of user experience research, and the time and resource limitations, have implications on how the research is carried out in practice. Sample sizes in user experience research are much smaller. As discussed in Chapter 3, there is no consensus on the optimal sample size, but it has been suggested that nine to ten participants can detect over 80% of usability issues (231, 232). In health and social care research, more emphasis is placed on achieving data saturation by conducting of interviews of sufficient depth and duration. Large qualitative studies include up to fifty to sixty people (255).

As discussed in Chapter 2, theoretical frameworks are used in research to hypothesize relationships, events or behaviours, to help design interventions
and to guide analysis (156, 157). For many social science researchers, choice of research methods is linked to theoretical perspective, and frameworks for how we see the social world (255). Social theory can help researchers identify concepts and processes that they might not have identified through inductive processes (256). In user experience research, theoretical frameworks exist from HCI and cognitive behavioural science, but reviews have shown that the majority of publications of usability studies lack explicit theoretical frameworks, and there are no clear guidelines for the utilisation of theoretical frameworks in health IT usability studies (230).

The methods used in the user experience study of HDSO were guided by HCI and computer science, and therefore differed from methods more common to health and social science. I have described the methods used in this study below, and I have reflected on their differences with health and social science research in the Discussion. The evaluation of the next iteration of the intervention, did not include usability studies and the methods used are described in Chapter 6.

5.4 Aim

The aim of this user experience study was to explore views of patients registered for the HDSO programme on barriers to starting, progressing through and completing the programme. The need to collect the data quickly enough to inform the optimization process had implications for the methods I used, which are described below.

5.5 Methods

5.5.1 Study design

I collected data using a combination of methods. There were short online surveys built into the HDSO programme, which were used as end of session feedback forms. The surveys collected data on user satisfaction with the programme. This provided me with information from people who completed sessions about what they thought of the programme, and whether they were experiencing any problems which may have been affecting their progress.
The surveys (shown below) asked specific questions about the content of the session. This gave me information about whether users found the programme useful or not. However, I wanted to find out if there were factors other than the content of the sessions that affected user engagement and progress. The most suitable way of addressing this was to speak to users themselves via telephone calls, to ask them what was stopping them from completing the programme.

During the calls I asked participants open-ended questions about problems with starting the programme, or using it regularly, and if they needed any help using the programme. A topic guide is given in Table 5-1.

5.5.2 Participants

The quantitative findings from the evaluation of the first iteration of HDSO were that 24 people registered for the programme. Of these 24 people, 3 completed the programme, 13 started the programme but didn’t complete it, and 8 did not start the programme.

As my study aim was to explore barriers to starting and completing the programme, I called the 21 people who either did not start or complete the programme by telephone to record their views.

Online feedback was automatically collected from the 16 people who used the programme.

5.5.3 Ethics

Ethical approval for interviewing people who used the programme was gained from the Health Research Authority (reference number 159488, see Appendix A). Everyone who registered for the programme was informed that interviews were being conducted as part of the research, and were able to opt in or out of being contacted about being interviewed. Only people who agreed to be contacted about interviews were called.

When contacting people for interview, I conformed to ethical principles by explaining the purpose of the interviews at the start and gaining verbal consent.
if people were happy to proceed. I explained that I was taking notes and that these would be anonymised for the analysis and written report in order to maintain confidentiality.

5.5.4 Data collection

5.5.4.1 Online feedback

Online feedback forms were included at the end of every session of the HDSO programme. Everyone who completed a session of the programme completed the form before moving on to the next session. Programme users were asked to submit a response to the following four questions (see below and Figure 5-1):

1. How relevant was the information? (very relevant, relevant, moderately relevant, slightly relevant, or not relevant)
2. What did you like?
3. What would you change?
4. What is the most useful thing you have learnt?

Figure 5-1: Screenshot of HDSO programme feedback page

5.5.4.2 Telephone calls

I contacted 21 people who were registered for the programme but did not start or complete it to explore their views
The calls were semi-structured, and lasted approximately ten minutes. A topic guide is given in Table 5-1 below.

**Table 5-1: Topic guide for telephone interviews**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Have you had any problems getting started with the programme? Is there anything stopping you?</td>
</tr>
<tr>
<td>2.</td>
<td>How important is it to you to learn about your diabetes?</td>
</tr>
<tr>
<td>3.</td>
<td>How confident are you to use HeLP-Diabetes: Starting Out?</td>
</tr>
<tr>
<td>4.</td>
<td>Do you need any help using the programme?</td>
</tr>
<tr>
<td>5.</td>
<td>What would help you to use the programme regularly?</td>
</tr>
</tbody>
</table>

Information was needed on problems with the programme and personal reasons for not completing the programme. I took detailed notes during the interviews and recorded these on an anonymised Excel spreadsheet, which had a row for each participant and columns for the interview notes with dates documented for each one. An example is given in Table 5-2 below.

**Table 5-2: Notes from telephone interview**

<table>
<thead>
<tr>
<th>User ID</th>
<th>Demographics</th>
<th>Notes</th>
</tr>
</thead>
</table>
| 942     | 63 year old Female Asian, Camden. | - Finds programme “very helpful and motivating”, discussed with Practice nurse and puts improvement in blood results partly down to programme  
- Didn’t have any expectations of programme, “all very new”  
- Nothing missing in terms of content  
- One difficulty- goal setting- expected to be reminded /be able to go back to it  
- Suggestions for making it easier to fit into busy schedule- shorter more frequent sessions |

I chose to carry out the interviews by telephone and make written notes rather than audio-record and transcribe because I needed to collect and analyse the data quickly to inform the programme optimization. Note-taking is a recognised form of recording (255), and although it has the disadvantage of not capturing every word verbatim, I mitigated against this by noting down
verbatim quotes where I thought the participants’ were particularly pertinent. The methods used were fit for purpose for collecting data to meet the aim of the study in the given context. A detailed list of barriers to completion of the programme was developed from the interviews.

5.5.4.1 Data analysis
I analysed the interview notes and questionnaire responses using thematic analysis, as this allowed an exploratory approach which was appropriate for the aim of the study. I read and re-read the data to identify initial codes. I then grouped codes into thematic headings. These categories were further refined and grouped together if there was substantial overlap. I did this manually by highlighting sections of my notes and coding them by colour and using data labels. Finally I checked the notes from all the participants to make sure I hadn’t missed anything out with my theme headings.

I increased the rigour of my analysis by sharing the data with the clinical members of the HeLP team to get their insights and interpretations from the data. I then went back to the data and checked my thematic framework against their comments. I presented the themes to my colleagues and we agreed on the final themes from the analysis which are given below. Once these themes were agreed, we were able to discuss the changes that needed to be made to the programme and its delivery. These changes are described below (Implications for the HDSO programme).

5.6 Results
Data were collected from five people via the online feedback forms (the remaining 11 people who started the programme either did not complete a session or did not leave free text comments).

13 telephone calls were conducted with people who had not completed the programme. I could not speak to the other eight people who were registered but did not complete the programme, either because they did not answer or their telephone line was busy. I tried contacting everyone three times. Table 5-3 gives the participant characteristics. 61.5% of participants were male; the mean age was 62.6 years old; 58.3% were white and 41.7% were from ethnic
minority backgrounds, and 61.5% had an undergraduate degree level education or above.

Table 5-3: Participant characteristic

<table>
<thead>
<tr>
<th>Participant number</th>
<th>Gender</th>
<th>Age</th>
<th>Ethnicity</th>
<th>Education level</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Male</td>
<td>63</td>
<td>Black</td>
<td>Undergraduate degree</td>
</tr>
<tr>
<td>2</td>
<td>Male</td>
<td>66</td>
<td>White</td>
<td>A Level</td>
</tr>
<tr>
<td>3</td>
<td>Male</td>
<td>32</td>
<td>Asian</td>
<td>Undergraduate degree</td>
</tr>
<tr>
<td>4</td>
<td>Female</td>
<td>80</td>
<td>Black</td>
<td>A Level</td>
</tr>
<tr>
<td>5</td>
<td>Male</td>
<td>49</td>
<td>Black</td>
<td>School leaver</td>
</tr>
<tr>
<td>6</td>
<td>Female</td>
<td>62</td>
<td>White</td>
<td>Undergraduate degree</td>
</tr>
<tr>
<td>7</td>
<td>Female</td>
<td>70</td>
<td>Black</td>
<td>School leaver</td>
</tr>
<tr>
<td>8</td>
<td>Male</td>
<td>59</td>
<td>White</td>
<td>Undergraduate degree</td>
</tr>
<tr>
<td>9</td>
<td>Male</td>
<td>71</td>
<td>White</td>
<td>Postgraduate degree</td>
</tr>
<tr>
<td>10</td>
<td>Male</td>
<td>53</td>
<td>Asian</td>
<td>Undergraduate degree</td>
</tr>
<tr>
<td>11</td>
<td>Male</td>
<td>73</td>
<td>White</td>
<td>Postgraduate degree</td>
</tr>
<tr>
<td>12</td>
<td>Female</td>
<td>63</td>
<td>White</td>
<td>School leaver</td>
</tr>
</tbody>
</table>
I analysed the data from the questionnaires and the telephone calls together. The themes that emerged are listed below. I grouped themes into barriers to starting the programme, and barriers to completing it (See Figure 5-2):

**Figure 5-2: Themes from analysis of telephone calls and feedback forms**

Some people reported that they lacked time to start or complete the programme, illustrated by this quote:

“Finding time is the main issue, I use it when I have time after work or on Sunday. I remember that I must go on it.” Participant 6, 62 year old White female with undergraduate level education
Others were ambivalent about starting the programme due to lack of understanding about what they needed to know, illustrated by this quote:

“It’s in the background, I keep it in mind, but I don’t know what information I need.” Participant 11, 73 year old White male with postgraduate level education

Some patients did not feel the content was relevant to them (e.g. if they did not take medication), illustrated by this quote:

“My bloods are OK and I’ve come off my medication, I don’t need it.” Participant 5, 49 year old male Black school leaver

Others had the expectation that the programme would take too long to complete, illustrated by this quote:

“I’d like shorter sessions, so I can do it at work when I’ve got a spare 10 minutes. At the moment it’s going to take a while” Participant 10, 53 male Asian with undergraduate level education

5.7  Discussion

5.7.1  Principal findings

Data from five online questionnaires and thirteen telephone calls were analysed to determine the barriers to completion of the HDSO programme. I found that there were barriers to starting the programme (lack of time to start, ambivalence about starting and an expectation that it would take too long), and barriers to completing the programme (feeling of content not being relevant, and lack of time or an expectation that it would take too long). These emerging ideas were followed up in subsequent interviews conducted as part of Study 2 (discussed in Chapter 6).

5.7.2  Comparison with existing literature

The findings are consistent with those of a systematic review of qualitative studies looking at engagement and recruitment to digital health interventions.
by O’Connor et al (257). The authors identified four main themes: 1) personal agency and motivation; 2) personal life and values; 3) engagement and recruitment approach; and 4) quality of the DHI. A barrier to engaging for some was seeing no value in the DHI, or lacking the awareness or motivation to improve their health using the DHI. The authors also found that people who had multiple priorities and demands on their time such as work, families and caring responsibilities, had little time or enthusiasm to engage with DHIs (257).

5.7.3 Strengths and limitations

This was a rapidly conducted study using methods common to computer science, and driven by time and resource. For this reason there were differences in the way that the qualitative methods I used were operationalised, to the way I would have used qualitative methods in a (non-digital) health or social science study. I have described the differences in the way I operationalised qualitative methods in this study below, and the impact I think this may have had on the results.

My target population was people who had not started or completed the programme (n=21). I contacted all 21 of these people, but was only able to get through to 13 of them, giving me a sample size of 13. In a social science study, instead of being driven by who I could contact in the time available, I would have continued to recruit participants and collect data until I achieved data saturation. The strength of my sampling method was that I was able to collect data quickly, which enabled me to optimise the first iteration of the intervention rapidly and proceed to the next round of evaluation. The weakness of my sampling method was that I could have gained more views on the intervention if I had continued to try and contact the other users, and this may have added depth to my understanding of how the intervention needed to be optimised.

The calls lasted only ten minutes which did not allow for views to be explored in depth. This contrasts highly with semi-structured interviews conducted in social science research, where the aim of the interviews are to achieve depth of understanding and exploration of the topic. The interviews were not audio-recorded or transcribed, and the analysis was conducted using notes I made.
during the telephone calls. This meant that not all of the participants’ words were recorded and included in the analysis, as is commonly done in social science research to allow for a more detailed and explorative analysis. I conducted a thematic analysis, and was not guided by a theoretical framework. In social science research it is more common to be guided by theory, and to map where there are consistencies and inconsistencies between the data and what is already known.

5.7.4 Implications for the HDSO programme

I acknowledged that some of the barriers were difficult to overcome with programme changes alone, like ambivalence about starting. However I tried to change the programme to address barriers that could be overcome, like people feeling that the programme would take too long. The following changes to the programme and procedures were agreed upon with the HeLP team, to address concerns identified by the data presented above:

1. Reducing the number of sessions in the programme
2. Reducing the number of questionnaires
3. Online self-registration

It was also decided to offer the programme to everyone with type 2 diabetes, and not just people who were newly diagnosed. This was not an idea that emerged from the user experience study, but I hypothesised that offering the programme to more people might help to improve the uptake of the programme, and subsequently the number of people completing the programme.

5.7.4.1 Reducing the number of sessions in the programme

Reducing the number of sessions in the programme was considered as one way of giving people with less time the opportunity to complete the programme, and to remove the expectation that the programme would take too long to complete. The decision was also based on evidence from digital health research and research on adult online learning. A systematic review conceptualising engagement with digital behaviour change interventions (241) found several studies suggesting that participants disengage if the
intervention is perceived as too long or overly complicated, including trials of internet interventions for anxiety and depression (258).

Research on adult online learning suggests that shorter course length is associated with greater course completion. An analysis of factors associated with completion rate of 221 Massive Online Open Courses (MOOCs) was carried out by researchers at the Open University (OU) (259). MOOCs are open education courses that give learners access to study material and expert facilitators via social networking (260). MOOCs are designed for large numbers of learners to follow over the internet and have been embraced by higher learning institutions, who offer courses for free with no academic accreditation (261). The OU research found that course completion negatively correlated with course length, and that there was high attrition in the initial weeks of courses. They suggest that shorter, more modular courses should be used (259).

The decision about what content to retain and what to remove was made after discussions with the Diabetes Specialist Nurses in the HeLP team, who were trained educators and experienced in delivering face-to-face structured education courses. The NICE guidance on structured education does not include guidance on content, but states that education should be evidence-based, theory-driven, and have specific aims and objectives (15). Therefore in order to decide what content to retain and what to remove, we discussed comments from the qualitative data described above, and examined the curriculum closely. The qualitative data showed that some users did not feel that some of the content was relevant to them, for example newly diagnosed patients who were managed with lifestyle changes only did not feel that information about medication was relevant to them. However it was decided that all aspects of management should be included, to give people a good overview and an understanding of the types of treatment they might receive in the future.

Table 5-4 compares the 8 session programme with the new 4 session programme to show the differences in content. The changes to each session are described below.
<table>
<thead>
<tr>
<th>8-session programme session titles</th>
<th>4-session programme session titles</th>
<th>8-session programme session parts</th>
<th>4-session programme session parts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 1 – Getting Started</td>
<td>Week 1 – Getting Started</td>
<td>Part 1 – Self-assessment</td>
<td>Part 1 – An introduction to diabetes</td>
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<tr>
<td></td>
<td></td>
<td>Part 2 – An introduction to diabetes</td>
<td>Part 2 – Self-assessment</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Part 3 – Eating well for diabetes</td>
<td>Part 3 – Eating well for diabetes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Part 4 – Becoming more active</td>
<td>Part 4 – Becoming more active</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Part 2 – Becoming more active</td>
<td>Part 2 – Protecting my body and mind</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Part 3 – Handling feelings</td>
<td>Part 3 – Handling feelings</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Part 4 – Making changes</td>
<td>Part 4 – Making changes</td>
</tr>
<tr>
<td>Week 3 – Improving my health and wellbeing</td>
<td>Week 3 – Improving my health and wellbeing</td>
<td>Part 1 – Protecting my body and mind</td>
<td>Part 1 – Making the most of the NHS</td>
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<tr>
<td></td>
<td></td>
<td>Part 2 – Making changes</td>
<td>Part 2 – Medication</td>
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<tr>
<td></td>
<td></td>
<td>Part 3 – Understanding my moods</td>
<td>Part 3 – Reducing the risks of heart attack and strokes</td>
</tr>
<tr>
<td></td>
<td>Part 4 – Working with diabetes</td>
<td>Part 4 – Update my goals and plans</td>
<td>Part 5 – Understanding my moods</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 4 – Taking control of my diabetes</td>
<td>Week 4 – Taking control of my diabetes</td>
<td>Part 1 – Making the most of the NHS</td>
<td>Part 1 – My diabetes review</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Part 2 – Update my goals and plans</td>
<td>Part 2 – Looking after my feet</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Part 3 – Managing my moods</td>
<td>Part 3 – Review my goals and plans</td>
</tr>
<tr>
<td>Week 5 – medication and lifestyle</td>
<td>Part 4 – My social life</td>
<td>Part 5 – Moving on: the end of the beginning</td>
<td></td>
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<tr>
<td>----------------------------------</td>
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<td>---------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Part 1 – Medication</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Part 2 – Review my goals and plans</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Part 3 – How to fix almost everything</td>
<td></td>
<td></td>
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<tr>
<td>Part 4 – Driving</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 6 – Reducing my risks</td>
<td>Part 1 – Reducing the risks of heart attack and strokes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Part 2 – Looking after my feet</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Part 3 – Review my goals and plans</td>
<td></td>
<td></td>
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<tr>
<td>Part 4 – Living with diabetes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Part 1 – Managing illness</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Week 7 – working with my healthcare team

<table>
<thead>
<tr>
<th>Week 7 – working with my healthcare team</th>
<th>Part 2 – My diabetes review</th>
<th>Part 3 – review my goals and plans</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 8 – celebrating success and planning for the future</td>
<td>Part 1 – Self-assessment</td>
<td>Part 2 – Looking after my diabetes</td>
</tr>
<tr>
<td></td>
<td>Part 3 – Moving on: the end of the beginning</td>
<td></td>
</tr>
</tbody>
</table>

The session titles of the four sessions in the 4-session programme were kept the same as the first four sessions in the 8-session programme, but the content was adjusted, and this is described below. The criteria for decisions about removing, adding or moving content were made with the DSNs and GP in the HeLP team, based on what we agreed were relative priorities to users.

**Week 1**

In Week 1 the ‘Introduction to diabetes’ was moved to Part 1 and the ‘Self-assessment’ was moved to Part 2 in order to give people basic information about what diabetes is first, before asking them to complete the questionnaires. This decision was made due to the finding from the user experience study that people were concerned that they did not have enough time to complete the programme. Moving the ‘Introduction to diabetes’ to Part 1 meant that users accessed the educational material immediately on starting the programme, rather than spending time completing the questionnaires first.
Part 3 of Week 1 was kept the same (‘Eating well for diabetes’) as diet information is crucial for learning about diabetes self-management. Physical activity is also important in self-management and so ‘Becoming more active’ was added to Week 1 (in the 8-session programme it features in Week 2).

**Week 2**

‘Taking control’ and ‘Handling Feelings’ were retained in Week 2 of the programme, and ‘Becoming more active’ was moved to Week 1 (as described above). ‘Protecting my body and mind’ and ‘Making changes’ were added from Week 3.

**Week 3**

‘Understanding my moods’ was retained in Week 3 of the programme, and ‘Protecting my body and mind’ and ‘Making changes’ were moved from Week 3 to Week 2 as described above. ‘Working with diabetes’ was removed from the 4 session programme, and added to bonus content in Week 5 which is described below. This decision was made as information on working with diabetes was not seen as core information that was relevant to everyone, and could be something that could be looked up if necessary.

‘Making the most of the NHS’, ‘Medication’ and ‘Reducing the risks of heart attacks and strokes’ were moved from Weeks 4, 5 and 6 of the programme as they were important sections to retain. It was decided that everyone needed information about navigating the NHS, and an understanding of medication and complications as some of the aims of diabetes self-management that are relevant to everyone are delaying the need for medication, and the onset of complications.

**Week 4**

‘My diabetes review’, ‘Looking after my feet’, and ‘Review my goals and plans’ were added from Weeks 5, 6 and 7 of the 8-session programme. This decision was made as everyone with diabetes has an annual review and a foot check with their GP or nurse and patients need an understanding of preparing and
making the most of it. Reviewing goals was also important, as it gave people an opportunity to reflect on progress with goals they had set and add new ones if they wanted to.

‘Managing my moods’ and ‘My social life’ were removed from Week 4 and added to the bonus content in Week 5 described below.

The content in Week 6, 7 and 8 that were not retained in the 4 session programme were ‘How to fix almost everything’, ‘Driving’, ‘Living with diabetes’ and ‘Managing illness’. ‘How to fix almost everything’ and ‘Living with diabetes’ were removed from the programme altogether, and ‘Driving’ and ‘Managing illness’ were moved to the bonus content in Week 5.

**Week 5- Bonus content**

The content of Week 5 was as follows:

- Part 1 - Working with Health Professionals
- Part 2 - Managing my diabetes when I'm ill
- Part 3 - Diabetes and my social life
- Part 4 - Working with diabetes
- Part 5 - Driving with diabetes
- Part 6 - Review my goals and plans
- Part 7 - Managing my moods - part 1

‘Working with health professionals’ was new content that was added to give people information about the roles of the various health professionals they may come across, including the GP and hospital doctors, and advice about how to feel more supported by health professionals. This was aimed to supplement the information in Week 2 about making the most of the NHS (see Figure 5-3).
The remaining content of Week 5 was moved from latter parts of the 8-session programme as described above. This content, including information on driving, working and having a social life with diabetes, was considered to be supplementary information that may not be prioritised by everyone and could be looked up as and when needed, rather than being part of the core programme.

5.7.4.2 Reducing the number of questionnaires

Programme users were asked to complete three questionnaires at Weeks 1 and 8: (i) the Audit of Diabetes Knowledge (AdKnowl); (ii) Problem Areas in Diabetes (PAID) and (iii) Diabetes Management Self-Efficacy (DMSES). 33.3% of all those who registered for the programme did not start it. One of my finding from the user experience study was that some people thought the programme would take too long. This suggested to me that it was possible that people were logging on to the programme, started Week 1, seeing that there were three questionnaires to complete and were put off continuing the programme because of this. Respondent burden has been described by
researchers as “the degree to which a survey respondent perceives participation in a survey research project as difficult, time consuming, or emotionally stressful” (262). Using shorter questionnaires has been suggested as one way of reducing this burden. There is some existing evidence for the impact of length of questionnaires on response rates (263-265). Deutskens et al (265) studied response rates to internet-based surveys for market research purposes and found a response rate of 24.5% for a questionnaire taking 15 to 30 minutes to complete, compared a response rate of 17.1% for a questionnaire taking 30 to 45 minutes to complete. Marcus et al (264) studied responses to web-based surveys sent to owners of personal websites. They found a response rate of 30.8% for a questionnaire with 91 items taking approximately 10 to 20 minutes to complete, compared with a response rate of 18.6% for a questionnaire with 359 items and described as taking 30 to 60 minutes. McCambridge et al (263) compared adding an additional 23 or 34 questions rather than an additional 10 questions in a study of attrition in online trials, and found there was no significant difference. However, the authors concluded that it was very likely that the difference in questionnaire lengths was too small to impact upon attrition.

I decided, with the agreement of the HeLP team and the evidence from my user experience study and literature review, to reduce the number of questionnaires from three to two, by removing the AdKnowl questionnaire. The AdKnowl (knowledge) questionnaire (201) was removed because it was significantly longer and more time-consuming than the other two questionnaires; and because the evidence I found from systematic reviews of diabetes self-management education programmes suggests that there is a lack of a consistent positive relationship between knowledge and glycaemic control, and that factors other than knowledge are needed to achieve long-term behaviour change (40). I therefore prioritised change in distress and self-efficacy.

5.7.4.3 Including all patients with type 2 diabetes
The HDSO programme was developed for people newly diagnosed with T2DM (diagnosed within the last 9 months), and newly diagnosed patients were
invited to register for the programme during the evaluation of the first iteration of the programme. This was because the HDSO programme was developed in line with national clinical guidance for GPs advising them to offer patients with T2DM structured education at and around the time of diagnosis (15). However, we know from the National Diabetes Audit (NDA) that not all patients are offered structured education at the time of diagnosis, and of those who are offered it, in 2016-7 only 7.1% attended (250). There are therefore many patients with T2DM who are not newly diagnosed but have not received structured self-management education, and are in need of it.

I found from the data collected in the evaluation of the first iteration of the programme, that the number of newly diagnosed patients with T2DM per 1,000 patients registered with the practice varied from 0.91 to 9.34. The total number of patients with T2DM (newly diagnosed or otherwise) on the other hand is much higher, due to its increasing prevalence. Data on the incidence and prevalence of T2DM in the UK shows that TDM prevalence rates have more than doubled between 2000 and 2013, but incidence rates have increased more slowly (266, 267). This suggests that there are more people being diagnosed younger and living longer, rather than new diagnoses, which consequently suggests it would be easier to recruit people who are not newly diagnosed to the HDSO programme than people who are newly diagnosed.

The advantage of limiting the programme to newly diagnosed patients was that this would be consistent with NICE guidance on offering structured education. The data we collected would tell us about the uptake, impact and acceptability of the programme for newly diagnosed patients, which would provide relevant evidence to CCGs and policy-makers interested in online structured education for newly diagnosed patients. The disadvantages of limiting the programme to newly diagnosed patients were the restriction this placed on the number of people that could register for the programme, and the withholding of the programme from patients who needed it but didn’t meet the criteria of being newly diagnosed.

On balance I decided that it was more important to offer the programme to more people and be able to collect more data, even if this data were not from
newly diagnosed patients alone. I proposed instead to collect data on duration since diagnosis at registration, so that the newly diagnosed and non-newly diagnosed groups could be compared.

5.7.4.4 Online registration

During the evaluation of the first iteration of the HDSO programme, patients were registered by telephone after returning a reply slip expressing their interest in the programme. This was initially used as an opportunity to talk to patients about the programme, make sure they were newly diagnosed with T2DM and able to use the programme, and to collect baseline demographic data. However this was time-consuming and created a back-log of people waiting to be contacted and registered. This may have meant patients became less interested in using the programme by the time they were registered and did not start the programme, contributing to the high attrition.

It was decided to change to online registration to save time and to make it easier for patients to access the programme quickly. Giving users the opportunity to self-register provided them with greater autonomy. Autonomy refers to “being the perceived origin or source of one’s behaviour” (268). Self-determination theory proposes that learners have a basic psychological need for autonomy, as well as competence (feeling effective in one’s social environment) and relatedness (feeling connected to others) (269). When these needs are supported in the learning environment, learners are more likely to internalise their motivation to learn and be engaged in their studies (270).

An online self-registration system was developed and implemented during the evaluation of the second iteration of the programme, to replace the telephone registration system.

The self-registration page included a demographic questionnaire shown in Figure 5-4, which allowed for baseline data to be collected. Telephone support from the HeLP team was still available for those who had difficulty registering online or using the programme.
The advantage of the self-registration page was that people could access the programme more quickly, and this could potentially improve motivation and engagement and reduce attrition from the programme. The disadvantage was that people who had basic computer skills may have had difficulty using the self-registration page, and login details that were sent to them subsequently by email. Although a questionnaire was built into the self-registration to collect demographic and clinical information, a self-administered questionnaire was

![Figure 5-4: Online registration webpage](image-url)
less likely to be fully completed than questions asked by the HeLP administrator over the telephone. Overall I decided that it was more important to give people quicker access to the programme to try and reduce attrition, and so online registration was introduced. For people who had difficulty self-registering there was a telephone number for the HeLP administrator on the self-registration page that they could call to get assistance or be registered over the phone.

5.8 Conclusion

The changes to the programme and procedures described in this chapter resulted in a second iteration of the HDSO programme. The second iteration of the programme needed to be evaluated to determine its effect, feasibility and acceptability. The evaluation of the second iteration of the HDSO programme is described in Chapter 6.
Chapter 6. Evaluation of second iteration of HeLP-Diabetes: Starting Out

6.1 Chapter summary

In this chapter I have described how the second iteration of HeLP-Diabetes was evaluated after being commissioned in the NHS, and the results and implications of the evaluation for further research.

6.2 Background

The evaluation of the first iteration of HDSO was described in Chapter 4. One of the findings was poor uptake and completion of the programme. This led to the following changes to the programme and procedures described in Chapter 5:

1. All patients with T2DM were invited to register for the programme, not just newly diagnosed patients;
2. The number of sessions in the programme was reduced from eight to four;
3. The number of questionnaires users were asked to complete was reduced from three to two;
4. Online registration was introduced.

The improved second iteration of the programme needed to be evaluated, again to determine its uptake, effect and acceptability. This was based on the guidance from the MRC and digital health on developing and evaluating interventions, which states that an iterative process should be carried out which involves assessing user needs, developing the intervention, identifying problems and making changes to the intervention and its delivery (63, 133).

6.3 Aim and objectives

The aim of this study was to determine the feasibility of the second iteration of the programme, and to determine its uptake, effect and acceptability to patients. I used mixed methods and interviewed patients because I was interested in their views on acceptability of the programme. I was also interested in health professionals' views on acceptability of the programme to
patients. Health professionals had experience of talking to patients about the programme, and were therefore able to talk about patients’ responses to being offered online structured education.

Specific objectives were:

1. To describe patients’ use of the programme, including numbers (proportions) registering, starting and completing the programme;
2. To determine the demographic and clinical factors associated with completion of the programme;
3. To investigate the effect of the programme on users’ levels of diabetes-related distress and diabetes self-management self-efficacy;
4. To explore patient and health professional views about the programme, including factors affecting acceptability of the programme.

6.4 Methods

6.4.1 Study design

The evaluation of the second iteration of the HDSO programme was a mixed methods study undertaken over 16 months.

A mixed methods approach was chosen for the evaluation of the second iteration of the programme, as the objectives were trying to answer different types of questions. Quantitative methods were needed to measure uptake, effect and factors associated with completion. Qualitative methods were needed to explore patient and health professional views about the programme.

Similarly to the evaluation of the first iteration, data collection was performed simultaneously, quantitative and qualitative data analyses were performed separately, and the findings of the qualitative study were used to elaborate on the findings from the quantitative study.

6.4.2 Setting

By the time the second iteration of the programme was developed, the programme had been commissioned by four CCGs for use as an NHS service: in Islington, Lewisham, Lambeth and Haringey. Camden was still using the
programme for free following the evaluation of the first iteration. This meant that the programme was available to all patients registered at a practice in these five CCGs. The populations served by these CCGs were diverse, with over 30% of the population from black and minority ethnic (BAME) groups (271). All five CCGs were in the top quartile for deprivation in England (272). Patients were offered the programme and registered using the methods described below. The commissioning of the programme had implications for the methods I used, which are also explained below.

6.4.3 Ethics

I had ethical approval from the Health Research Authority (reference number 159488, see Appendices A-C).

The programme was being offered to patients as part of service delivery, so the use of the data on registrations, activity and questionnaire scores generated through the online programme was permissible under the HRA clause that secondary use of information collected in the course of normal care is generally excluded from REC review (239).

Again, data collected by the programme was pseudonymised with a unique identifier and exported to an Excel file for analysis.

Patients were aware that pseudonymised data were used for service improvement. They were asked at registration if they would be happy to be contacted about taking part in interviews. I collected the identification numbers of those who were willing to be contacted, stored them securely and subsequently contacted patients by email inviting them to attend an interview.

Patients who attended interviews were given an information sheet detailing the purpose of the study (see Appendix D). They were given the opportunity to ask questions before signing a consent form. Consent forms were stored securely and separately from questionnaire data. Consent forms were stored securely and separately from questionnaire data (See Appendix E).
6.4.4 Participants

As the programme was again being offered as a service, there were no formal inclusion and exclusion criteria. Practices were informed that the target population of the intervention was adults (aged 18 or over), with type 2 diabetes diagnosed at any time (not just newly diagnosed patients).

Practices were also advised that people who could not use a computer due to severe mental or physical impairments, had insufficient mastery of English to use the intervention, were unable to communicate without an interpreter, or were currently participating in a trial of a self-management intervention, were not suitable for referral to HDSO.

6.4.5 Recruitment

Practice engagement during the evaluation of the second iteration was driven by the commissioning of the programme. The programme was available to all practices within the five commissioning CCGs listed above, and the Programme Manager and DSNs working in the HeLP team contacted Practice Managers, GP commissioning leads and Practice Nurses by email, telephone and face-to-face meetings to try and ensure all practices were aware of the programme and referral procedures. Practices were again asked to send out recruitment packs, and nine practices agreed to do this. Other practices notified patients about the programme using a variety of methods, including text messages to eligible patients, flyers and posters in the practice, and in consultations with patients. In Lewisham there was a dedicated Change Manager whose role it was to visit practices to talk to staff and patients about the programme.

Patients were initially registered for the programme by telephone. For the final five months of the study, patients were able to register themselves online and their username and password were generated and sent to them by email (as described in Chapter 5).

Patients were asked if they were happy to be contacted about interviews at registration. I then emailed everyone who agreed to be contacted, and
arranged face-to-face or telephone interviews with those who responded. Healthcare professionals (HCPs) working at practices with a high or low number of patients registered for HDSO were also invited to take part in interviews. I also contacted staff who had a role in the CCGs commissioning to support practices in implementing the programme. Interviews were organised with HCPs who responded.

**6.4.6 Intervention**

The second iteration of the HDSO programme was a 4-session online structured self-management education programme for type 2 diabetes. Each session consisted of four or five parts and took about an hour to complete. Session titles are listed in Chapter 5. Sessions could be completed at one sitting, or progress could be saved and users could dip in and out. Users were encouraged to complete one session a week. They also had access to the information on the HeLP-Diabetes website. Self-assessment quizzes were included in Weeks 1 and 4, and users received personalised feedback by email. There were also goal-setting tasks, and users received personalised emails after completing a session or if they had not logged in for a week or more.

**6.4.7 Data Collection**

The data collected reflected the objectives of the study and are summarised in Table 6-1. The AdKnowl questionnaire (Audit of Diabetes Knowledge) was removed from the programme after the evaluation of the first iteration (explained in Chapter 5).

I collected demographic information about registered patients with the aim of determining the demographic, clinical or demographic factors associated with completion of the programme.
<table>
<thead>
<tr>
<th>Objective</th>
<th>Measure</th>
<th>Stage of study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients’ use of the programme, including numbers (proportions)</td>
<td>Number of patients who registered with the programme, started the programme and completed all 4 sessions</td>
<td>Throughout the study</td>
</tr>
<tr>
<td>registering, starting and completing the programme</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Demographic and clinical factors associated with completion of the</td>
<td>Age; gender; ethnicity; highest educational attainment; internet access (home or public); IT skill level (basic, intermediate or advanced); duration of diabetes; offered face-to-face education (yes or no); attended face-to-face education (yes or no)</td>
<td>Baseline</td>
</tr>
<tr>
<td>programme</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Effect of the programme on diabetes-related distress and diabetes</td>
<td>Change in Problem Areas in Diabetes (PAID) and Diabetes Management Self-Efficacy (DSMSES) questionnaire scores</td>
<td>Weeks 1 and 4 of the HDSO</td>
</tr>
<tr>
<td>self-management self-efficacy</td>
<td></td>
<td>programme</td>
</tr>
<tr>
<td>Patient and health professional views about the programme, including</td>
<td>Qualitative interview data from interviews with patients and health professionals</td>
<td>End of study</td>
</tr>
<tr>
<td>factors</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
6.4.7.1 Patients’ use of the programme
In order to determine the feasibility and acceptability of the programme, data were collected on its uptake (reach), including the number of patients who registered for the programme, how many started it (completed at least one part of one session), and how many completed all 4 sessions. The data were collected automatically by the programme as server side data, and pseudonymised with a user ID. The data collected were: user ID, date and time of login and page visited.

6.4.7.2 Demographic and clinical factors associated with programme completion
Demographic and clinical psychological data were collected from patients to help determine acceptability of the programme. Data collected included age, gender, ethnicity, highest educational attainment, internet access, IT skills, duration of diabetes and whether patients were offered or attended face-to-face education (yes or no). The aim was to compare data on completers and non-completers in order to determine if there were groups that were significantly more likely to complete the programme. It was important to collect data on demographic factors to see if the programme was being used by different groups of people. It was important to collect data on duration of diabetes and offer of and attendance at face-to-face education to determine whether these factors made patients significantly more likely to complete the programme.

6.4.7.3 Effect of the programme
Effect of the programme was determined by measuring change in diabetes-related distress and diabetes management self-efficacy. These outcome measures were chosen due to their role in the causal pathway proposed in Chapter 3.
The Problem Areas in Diabetes (PAID) questionnaire is a 20-item questionnaire which measures the emotional difficulties experienced by people with T2DM (213). A high score (above 40) indicates high emotional distress and is associated with poor lifestyle and increased HbA1c (213). The minimal clinically important difference (MCID) for PAID is 4.0 (248).

The 20-item PAID questionnaire was replaced with the 5-item questionnaire (PAID-5) during the evaluation of the second iteration of the programme, to reduce respondent burden. PAID-5 is a reliable and valid short form of the PAID questionnaire comprising of five questions identified as having the highest psychometric properties (273).

The Diabetes Management Self-Efficacy Scale (DMSES) is a 20-item questionnaire which measures an individual’s expectations to be able to engage in diabetes self-management tasks (274). Self-efficacy scores of 0 indicate no self-efficacy and scores of 150 indicate very high self-efficacy (274).

6.4.7.4 Patient and health professional views about the programme
Semi-structured interviews were carried out with patients and health professionals. I conducted 13 of the 17 the interviews, and a user experience design expert employed by the HeLP team to explore usability of the programme conducted four interviews.

The participants were informed of my profession as a GP and researcher and the profession and role of the user experience design expert. Our differing roles may have affected the dynamics with the participants.

Interviews were carried out face-to-face or over the telephone and lasted between thirty and sixty minutes. The telephone interviews, and the interviews carried out by my user experience design expert colleague, did not allow for me to explore the non-verbal communication.

Interviews were audio-recorded and transcribed. I developed the topic guides based on the objective of the interviews, to explore views on the acceptability of the programme. The patient topic guide included experiences of being
diagnosed with T2DM, accessing health information in general, accessing diabetes structured education and reasons for registering for HDSO. I also asked about likes and dislikes about the programme, and factors contributing to engagement with the programme such as problems logging in or completing the questionnaires, when and where people used the programme, and how long it took them to complete a session. The topic guide for health professionals was tailored for the different roles of the staff referring patients to the programme, or supporting practices to refer patients to the programme. Questions included their role in the practice or CCG, their experience of talking to patients about the programme, responses from patients about the programme, and patients’ perceived barriers to use. The topic guide evolved over time in response to themes that were emerging from the interviews. The topic guides can be found in Appendices H and I.

6.4.8 Data analysis

6.4.8.1 Patients’ use of the programme
I analysed the automatically captured usage data and calculated the proportion of people who completed the programme as a % of those who started it.

6.4.8.2 Demographic and clinical factors associated with programme completion
I compared the gender and ethnicity of people registered for the programme with the type 2 diabetes population of the boroughs involved in the study. I obtained data on gender and ethnicity of the type 2 diabetes population in each borough from the Public Health England (PHE) Diabetes profiles (275). I compared the education level of people registered for the programme with the general population in each borough. I obtained data on education level in each borough from the Greater London Authority (GLA) London borough profiles (276). I could not obtain data on education level of the diabetes populations of these boroughs because the data are not collected for QoF.

The mean age (and standard deviation) of completers and non-completers of the programme was calculated, as well as the proportion (and percentage) of
completers and non-completers in each demographic group. A t-test was used to compare completion status for age as the comparison was being made between two means, and chi-squared tests were used to look for an association between completion status and all the other characteristics. Statistical analyses were carried out using SPSS version 22.

6.4.8.3 Effect of the programme
Week 1 and Week 4 (pre- and post-programme) questionnaire scores were analysed to look at their distribution. I determined that they did not have a normal distribution and therefore median and lower and upper quartiles were calculated, and then nonparametric Wilcoxon sign rank tests were used to determine any significant change between Week 1 and Week 4.

6.4.8.4 Patient and health professional views about the programme
Audio recordings were transcribed by professional transcribers, and I checked the transcripts against the original recordings for accuracy and anonymity. The interviewer is identified in the transcripts with the abbreviation IV and the respondent is identified with the abbreviation RE. I started analysing the transcripts as soon as I received transcripts, and interviews and analysis continued concurrently.

I analysed interview findings manually using a thematic analysis. Thematic analysis was employed to explore the perspectives of patients and health professionals with a particular focus on exploring similarities and differences between the perspectives expressed by professionals and patients (255, 277). The thematic analysis involved examining the transcripts line by line to generate initial codes, searching for themes among codes, then reviewing and defining the themes. This form of analysis was conducted as the objective of the qualitative component of the study was to explore patient and health professional views of the programme, and thematic analysis allows for themes that are anticipated as well as those that emerge from the data (255).

All transcripts were read by Elizabeth Murray and Fiona Stevenson and themes were examined and discussed with them. In order to gain further perspectives on the emerging themes, transcripts and themes were discussed
at two data clinics which qualitative researchers from different disciplines at the Department of Primary Care and Population Health at UCL. A description of the study, one of the transcripts and a list of the initial themes was sent out prior to the data clinics in order for the researchers to familiarise themselves with the study. The transcript that was selected for distribution was an interview with a GP at a practice with a low number of patients registered with the programme. Attendees of the data clinic were asked individually for their reflections on the transcript, and then a group discussion was held to discuss possible themes.

Following these discussions I completed the data analysis and produced the final themes. It became clear that the themes from the interviews were closely related to the constructs from Normalisation Process Theory (NPT), a theory of implementation that was introduced in Chapter 2. I therefore mapped the themes from my interviews to the NPT constructs, to add ‘thickness’ and conceptual density to the analysis. This two-stage process of analysis has been used in qualitative studies of GP uptake of interpreting services in the Republic of Ireland (256), and home telecare (278). In the MacFarlane study, an iterative process was used following the principles of the constant comparative method (279), moving backward and forward between themes and NPT literature. Although NPT offers pre-defined constructs of the work of implementation, the study-specific meaning of the constructs was determined by details of the study setting, including the health professionals, the nature of their work, the technology introduced, and the clinical and wider organizational contexts. Knowledge of emergent themes and NPT constructs were used to determine the ways in which they did and didn’t relate to each other. The authors reported that using NPT in the analysis made the interpretation of the themes more insightful and advanced, by allowing them to think about the layers of meaning in individual themes, the relationship between these, and the complex processes of implementation and conditions for normalization (256). I used a similar process to map the themes from my interviews to NPT constructs, and I have described this mapping in Section 6.6 below.
6.5 Results

6.5.1 Patients’ use of the programme

During the evaluation of the second iteration of the programme, 791 people registered to use the programme. 74 people (9.4%) completed the programme, 114 (14.4%) started but did not complete it (completed at least one part of one session), and 603 (76.2%) did not start the programme. The proportions of people registering for the programme, starting and completing it are illustrated in Figure 6-1.

Figure 6-1: Flowchart showing numbers of patients who registered, started and completed the programme

<table>
<thead>
<tr>
<th>Registered with programme (n=791)</th>
<th>Registered but did not start programme (n=603, 76.2%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Started programme (n=188, 23.8%)</td>
<td>Started but did not finish programme (n=114, 14.4%)</td>
</tr>
<tr>
<td>Finished programme (n=74, 9.4%)</td>
<td></td>
</tr>
</tbody>
</table>

In order to understand the uptake data better, I determined at which stage of the course users dropped out and discontinued using it. I answered this question by analysing the data on the last sessions visited by users, illustrated in Table 6-2. 80.6% of people who visited at least one page of the programme, did not go further than Week 1.
Table 6-2: Last page visited by HDSO users

<table>
<thead>
<tr>
<th>Last session visited</th>
<th>Number of users (% of all users who started the programme)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Homepage</td>
<td>348 (57.7)</td>
</tr>
<tr>
<td>Week 1 - Getting started</td>
<td>138 (22.9)</td>
</tr>
<tr>
<td>Week 2 - Self-management</td>
<td>12 (2.0)</td>
</tr>
<tr>
<td>Week 3 - Improving my health and well-being</td>
<td>20 (3.3)</td>
</tr>
<tr>
<td>Week 4 - Taking control of my diabetes</td>
<td>82 (13.6)</td>
</tr>
<tr>
<td>Bonus session 5 - Celebrating success and planning for the future</td>
<td>3 (0.5)</td>
</tr>
</tbody>
</table>

6.5.2 Demographic and clinical factors associated with programme completion

I compared the gender and ethnicity of study participants with that of the type 2 diabetes population of the corresponding CCGs to explore how representative the study population was. The CCG data were obtained from the Public Health England (PHE) CCG profiles (275). Table 6-3 shows the results (276). The percentage of males and females and the percentage of BAME people registered to use HDSO compared well with the diabetes population in each CCG.
Table 6-3: Comparison of gender and ethnicity characteristics of people in the study with the general population in each borough

<table>
<thead>
<tr>
<th>Demographic characteristic</th>
<th>Camden</th>
<th>Haringey</th>
<th>Islington</th>
<th>Lambeth</th>
<th>Lewisham</th>
<th>Population registered</th>
</tr>
</thead>
<tbody>
<tr>
<td>QoF diabetes prevalence in age 17+ (%)</td>
<td>4.0</td>
<td>6.2</td>
<td>5.0</td>
<td>5.5</td>
<td>6.5</td>
<td>N/A</td>
</tr>
<tr>
<td>Percentage of people with type 2 diabetes who are male</td>
<td>54.7</td>
<td>51.9</td>
<td>52.5</td>
<td>52.5</td>
<td>51.7</td>
<td>53.9</td>
</tr>
<tr>
<td>Percentage of people with type 2 diabetes who are female</td>
<td>45.3</td>
<td>44.2</td>
<td>47.5</td>
<td>47.5</td>
<td>48.3</td>
<td>46.1</td>
</tr>
<tr>
<td>Percentage of people with type 2 diabetes who are white</td>
<td>45.5</td>
<td>33.8</td>
<td>49.2</td>
<td>31.3</td>
<td>41.4</td>
<td>47.4</td>
</tr>
<tr>
<td>Percentage of people with type 2 diabetes who are of BAME origin</td>
<td>50.4</td>
<td>60.5</td>
<td>48.3</td>
<td>62.6</td>
<td>55.8</td>
<td>51.2</td>
</tr>
</tbody>
</table>


I compared the education level of the people registered to use HDSO with that of the general population in the participating CCGs, using GLA data (276). The data are illustrated in Table 6-4. The percentage of people with no qualifications was higher in the population registered to use HDSO than in the general population of two of the five CCGs. The percentage of people with a
degree or above was lower in the population registered to use HDSO than in the general population of every CCG apart from Haringey.

Table 6-4: Education level of HDSO users compared with general population of participating CCGs

<table>
<thead>
<tr>
<th>CCG</th>
<th>Study % no qualifications</th>
<th>General Population % no qualifications</th>
<th>Study % degree or above</th>
<th>General Population % degree or above</th>
</tr>
</thead>
<tbody>
<tr>
<td>Camden</td>
<td>5.1</td>
<td>6.2</td>
<td>40.4</td>
<td>60.5</td>
</tr>
<tr>
<td>Haringey</td>
<td>6.9</td>
<td>11.9</td>
<td>53.5</td>
<td>46.0</td>
</tr>
<tr>
<td>Islington</td>
<td>15.4</td>
<td>8.8</td>
<td>50.8</td>
<td>58.8</td>
</tr>
<tr>
<td>Lambeth</td>
<td>5.1</td>
<td>7.3</td>
<td>40.4</td>
<td>62.3</td>
</tr>
<tr>
<td>Lewisham</td>
<td>8.6</td>
<td>5.8</td>
<td>47.5</td>
<td>53.3</td>
</tr>
</tbody>
</table>


Table 6-5 shows the characteristics of registered patients, completers and non-completers. Completing the programme was associated with duration of diabetes of less than a year (p=0.040), and having been offered (p=0.001) and attended (p=0.002) face-to-face education. There was no association between the age, gender, ethnicity, level of education or IT skills and completion or non-completion, nor between treatment modality and completion.

The mean age of completers was 56.7 and the mean age of non-completers was 56.8. 50.7% of completers were male and 54.4% of non-completers were male, (p=0.497). Patients represented a wide range of ethnic groups, education and IT skills levels.

There was a statistically significant relationship between diabetes duration and completing the programme (45.1% of completers had diabetes for less than a
year, compared to 28.5% of non-completers, p=0.04). There were also
statistically significant relationships between being offered and attending face-
to-face education and completing the programme. 68.9% of completers were
offered face-to-face education compared to 45.3% of non-completers,
p=0.001. 17.7% of completers attended face-to-face education compared to
7.8% of non-completers, p=0.002. 69.4% of completers took tablets and/or
insulin, and 72.3% of non-completers took tablets and/or insulin (p=0.216).

Table 6-5: Characteristics of registered patients, completers and non-
completers

<table>
<thead>
<tr>
<th>Variable</th>
<th>Registered patients</th>
<th>Completers</th>
<th>Non-completers</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean or n/N</td>
<td>SD or %</td>
<td>Mean or n/N</td>
<td>SD or %</td>
</tr>
<tr>
<td>Age</td>
<td>57.6</td>
<td>12.9</td>
<td>56.7</td>
<td>13.4</td>
</tr>
<tr>
<td>(years)</td>
<td>n=749</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>316/586</td>
<td>53.9</td>
<td>36/71</td>
<td>50.7</td>
</tr>
<tr>
<td>White</td>
<td>287/605</td>
<td>47.4</td>
<td>37/72</td>
<td>51.4</td>
</tr>
<tr>
<td>Black</td>
<td>206/605</td>
<td>34.0</td>
<td>24/72</td>
<td>33.3</td>
</tr>
<tr>
<td>Asian</td>
<td>67/605</td>
<td>11.1</td>
<td>8/72</td>
<td>11.1</td>
</tr>
<tr>
<td>Category</td>
<td>N</td>
<td>Percentages</td>
<td>Other</td>
<td>Decline</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>---------</td>
<td>-------------</td>
<td>-------</td>
<td>----------</td>
</tr>
<tr>
<td>Mixed</td>
<td>20/605</td>
<td>3.3</td>
<td>2/72</td>
<td>2.8</td>
</tr>
<tr>
<td>Other</td>
<td>17/605</td>
<td>2.8</td>
<td>0/72</td>
<td>0</td>
</tr>
<tr>
<td>Prefer not to say</td>
<td>8/605</td>
<td>1.3</td>
<td>1/72</td>
<td>1.4</td>
</tr>
<tr>
<td>School leaver</td>
<td>181/602</td>
<td>30.1</td>
<td>19/67</td>
<td>28.4</td>
</tr>
<tr>
<td>Basic or intermediate IT skills</td>
<td>406/568</td>
<td>71.5</td>
<td>46/65</td>
<td>70.8</td>
</tr>
<tr>
<td>Diabetes duration &lt;1 year</td>
<td>170/589</td>
<td>28.9</td>
<td>32/71</td>
<td>45.1</td>
</tr>
<tr>
<td>Offered face-to-face education</td>
<td>193/394</td>
<td>49.0</td>
<td>42/61</td>
<td>68.9</td>
</tr>
<tr>
<td>Attended face-to-face diabetes education</td>
<td>37/394</td>
<td>9.4</td>
<td>11/62</td>
<td>17.7</td>
</tr>
</tbody>
</table>
Lifestyle alone (i.e. diet and physical activity) | 111/394 | 28.2 | 19/62 | 30.6 | 92/332 | 27.7 | 0.216
Tablets and/or insulin | 283/394 | 71.8 | 43/62 | 69.4 | 240/332 | 72.3 |

### 6.5.3 Effect of the programme

Tables 6-6 and 6-7 shows the median and lower and upper quartiles of the PAID and DSMES scores of completers of the programme at Weeks 1 and 4. Median distress (PAID) scores were lower at week 4 of the programme, and median self-efficacy (DSMES) scores were higher at week 4. Both changes were found to be statistically significant.

**Table 6-6: Week 1 and Week 4 PAID (distress) scores**

<table>
<thead>
<tr>
<th></th>
<th>Week 1 (n=74)</th>
<th>Week 4 (n=74)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (SE)</td>
<td>7.73 (0.58)</td>
<td>6.15 (0.56)</td>
<td>.001</td>
</tr>
<tr>
<td>95% Confidence Interval for Mean</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lower bound</td>
<td>6.58</td>
<td>5.04</td>
<td></td>
</tr>
<tr>
<td>Upper bound</td>
<td>8.88</td>
<td>7.26</td>
<td></td>
</tr>
<tr>
<td>Quartiles</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25th</td>
<td>4.00</td>
<td>2.00</td>
<td></td>
</tr>
<tr>
<td>50th (Median)</td>
<td>7.50</td>
<td>5.00</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Week 1 (n=74)</td>
<td>Week 4 (n=74)</td>
<td>p-value*</td>
</tr>
<tr>
<td>-----------</td>
<td>---------------</td>
<td>---------------</td>
<td>----------</td>
</tr>
<tr>
<td>Mean (SE)</td>
<td>98.68 (3.06)</td>
<td>109.30 (2.61)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Lower bound</td>
<td>92.58</td>
<td>104.09</td>
<td></td>
</tr>
<tr>
<td>Upper bound</td>
<td>104.77</td>
<td>114.50</td>
<td></td>
</tr>
<tr>
<td>Quartiles</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25th</td>
<td>78.00</td>
<td>95.50</td>
<td></td>
</tr>
<tr>
<td>50(^{th}) (Median)</td>
<td>101.50</td>
<td>107.50</td>
<td></td>
</tr>
<tr>
<td>75(^{th})</td>
<td>119.25</td>
<td>130.50</td>
<td></td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>26.32</td>
<td>22.46</td>
<td></td>
</tr>
</tbody>
</table>

*Wilcoxon Signed Rank Tests

### Table 6-7: Week 1 and Week 4 DSMES (self-efficacy) scores

#### 6.5.4 Patient and health professional views of the programme

Interviews were conducted with seventeen participants (ten patients and seven healthcare professionals). Of the ten patients, seven had completed the programme and three had registered for the programme but not completed it. Of the healthcare professionals, three were Diabetes Specialist Nurses (DSNs), two were General Practitioners (GPs), one was a HeLP-Diabetes Change Manager and one was a CCG Project Officer. The Change Manager was employed by the local NHS Trust to liaise with the GP Practices and promote the HDSO programme. She visited practices to talk to GPs and patients about the programme, and to help register people to the programme.
The CCG Project Officer worked for a CCG to help manage integrated care services, including HDSO. She helped launch the service in her CCG by visiting practices, talking to Practice Managers and GPs and showing them the programme. The characteristics of the ten patients who were interviewed are listed in Table 6-8. 60% were female, 60% were White British, 50% had a degree level education or above, 70% had intermediate level IT skills or above, 60% had diabetes for 1-5 years (40% less than a year), 80% had not attended face-to-face education, and 70% were managed with lifestyle changes and tablets (30% with lifestyle alone).
Table 6-8: Characteristics of patients who participated in the interviews

<table>
<thead>
<tr>
<th></th>
<th>Age (years)</th>
<th>Gender</th>
<th>Ethnicity</th>
<th>Education level</th>
<th>IT skill level</th>
<th>Diabetes duration</th>
<th>Offered face-to-face education</th>
<th>Attended face-to-face education</th>
<th>Treatment type</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>61</td>
<td>Female</td>
<td>White British</td>
<td>Degree or vocational equivalent</td>
<td>Intermediate</td>
<td>1-5 years</td>
<td>Yes</td>
<td>Yes</td>
<td>Lifestyle and tablets</td>
</tr>
<tr>
<td>2</td>
<td>62</td>
<td>Female</td>
<td>Black Caribbean</td>
<td>School leaver (GCSE or vocational equivalent)</td>
<td>Not stated</td>
<td>1-5 years</td>
<td>Yes</td>
<td>No</td>
<td>Lifestyle alone (i.e. diet and physical activity)</td>
</tr>
<tr>
<td>ID</td>
<td>Age</td>
<td>Gender</td>
<td>Ethnicity</td>
<td>Education</td>
<td>Skill Level</td>
<td>Experience</td>
<td>Lifestyle</td>
<td>Supplements</td>
<td>Notes</td>
</tr>
<tr>
<td>----</td>
<td>-----</td>
<td>--------</td>
<td>-----------</td>
<td>-----------</td>
<td>-------------</td>
<td>------------</td>
<td>-----------</td>
<td>-------------</td>
<td>-------</td>
</tr>
<tr>
<td>3</td>
<td>59</td>
<td>Male</td>
<td>Black African</td>
<td>School leaver (GCSE or vocational equivalent)</td>
<td>Basic</td>
<td>1-5 years</td>
<td>No</td>
<td>No</td>
<td>Lifestyle and tablets</td>
</tr>
<tr>
<td>4</td>
<td>63</td>
<td>Female</td>
<td>White British</td>
<td>Degree or vocational equivalent</td>
<td>Advanced</td>
<td>1-5 years</td>
<td>Yes</td>
<td>No</td>
<td>Lifestyle and tablets</td>
</tr>
<tr>
<td>5</td>
<td>64</td>
<td>Female</td>
<td>White British</td>
<td>Postgraduate or vocational equivalent</td>
<td>Intermediate</td>
<td>1-5 years</td>
<td>Yes</td>
<td>Yes</td>
<td>Lifestyle and tablets</td>
</tr>
<tr>
<td>6</td>
<td>55</td>
<td>Male</td>
<td>White Other</td>
<td>A-Level or vocational equivalent</td>
<td>Basic</td>
<td>1-5 years</td>
<td>No</td>
<td>No</td>
<td>Lifestyle and tablets</td>
</tr>
<tr>
<td>7</td>
<td>47</td>
<td>Male</td>
<td>White British</td>
<td>A-Level or vocational equivalent</td>
<td>Intermediate</td>
<td>Less than one year</td>
<td>Yes</td>
<td>No</td>
<td>Lifestyle alone (i.e. diet and physical activity)</td>
</tr>
<tr>
<td>8</td>
<td>60</td>
<td>Female</td>
<td>White British</td>
<td>Degree or vocational equivalent</td>
<td>Intermediate</td>
<td>Less than one year</td>
<td>Yes</td>
<td>No</td>
<td>Lifestyle and tablets</td>
</tr>
<tr>
<td>No</td>
<td>Age</td>
<td>Gender</td>
<td>Ethnicity</td>
<td>Education</td>
<td>Level</td>
<td>Experience</td>
<td>Lifestyle</td>
<td>Sex</td>
<td>Tablets</td>
</tr>
<tr>
<td>----</td>
<td>-----</td>
<td>--------</td>
<td>-----------</td>
<td>-----------</td>
<td>-------</td>
<td>------------</td>
<td>----------</td>
<td>-----</td>
<td>---------</td>
</tr>
<tr>
<td>9</td>
<td>51</td>
<td>Male</td>
<td>Asian Chinese</td>
<td>Postgraduate or vocational equivalent</td>
<td>Advanced</td>
<td>Less than one year</td>
<td>Yes</td>
<td>No</td>
<td>Lifestyle alone (i.e. diet and physical activity)</td>
</tr>
<tr>
<td>10</td>
<td>67</td>
<td>Female</td>
<td>Asian Other</td>
<td>School leaver (GCSE or vocational equivalent)</td>
<td>Intermediate</td>
<td>Less than one year</td>
<td>Yes</td>
<td>No</td>
<td>Lifestyle and tablets</td>
</tr>
</tbody>
</table>
Four major themes emerged from the analysis of the interview data, each with a number of subthemes (Table 6-8). The data from patients and health professionals are combined in the results, as many of the subthemes are shared. Where a subtheme is unique to a particular group this is stated in its description and illustrated with a quote.

Table 6-9: Themes from qualitative data

<table>
<thead>
<tr>
<th>Major theme</th>
<th>Subthemes</th>
</tr>
</thead>
<tbody>
<tr>
<td>The role of health professionals in engaging</td>
<td>Importance of discussing benefits of structured education</td>
</tr>
<tr>
<td>patients with DSME</td>
<td>Poor understanding of structured education by professionals</td>
</tr>
<tr>
<td></td>
<td>Lack of time to discuss structured education</td>
</tr>
<tr>
<td>Patient non-prioritisation of DSME</td>
<td>Competing priorities</td>
</tr>
<tr>
<td></td>
<td>Not being ready for information</td>
</tr>
<tr>
<td></td>
<td>Perceived relevance</td>
</tr>
<tr>
<td></td>
<td>Perceived need</td>
</tr>
<tr>
<td>Factors affecting the acceptability of the HDSO programme</td>
<td>The way the information is presented</td>
</tr>
<tr>
<td>--------------------------------------------------------</td>
<td>-------------------------------------</td>
</tr>
<tr>
<td></td>
<td>Being able to take your time</td>
</tr>
<tr>
<td></td>
<td>Information about managing emotions</td>
</tr>
<tr>
<td></td>
<td>Telephone support from the HDSO team</td>
</tr>
<tr>
<td></td>
<td>The quizzes</td>
</tr>
<tr>
<td>Suggestions for improving uptake of the HDSO programme</td>
<td>Familiarising professionals with the programme</td>
</tr>
<tr>
<td></td>
<td>Health assistant or administrative assistant-led referral</td>
</tr>
<tr>
<td></td>
<td>Involving patient champions and health coaching</td>
</tr>
<tr>
<td></td>
<td>Personalised information</td>
</tr>
<tr>
<td></td>
<td>Smartphone access</td>
</tr>
</tbody>
</table>

1. **The role of healthcare professionals**

**Importance of discussing the benefits of structured education**

Some patients said they were given limited information from healthcare professionals about how to manage their diabetes or about education courses.
This patient described getting information about being diagnosed with diabetes and being referred to a face-to-face education programme in a letter, rather than face-to-face.

*Interviewer:* “How much information did you get from your GP and your practice nurse about the diabetes when you first got it?”

*Interviewee:* “I don’t remember getting that much, just referrals. I got it in a letter. She didn’t call me and say, you have diabetes, so you have tipped over and we are now referring you.” Participant 4, 63yo female non-completer, duration of illness 1-5y

Health professionals who were interviewed felt that it was important to spend time explaining the benefits of diabetes education to patients.

“I do think it’s important that healthcare professionals, particularly GPs and practice nurses, sell the benefits of education to patients.” Participant 16, Diabetes Specialist Nurse

**Poor understanding of structured education by professionals**

However, participants said that professionals lack understanding of what structured education is, and this affects patient uptake.

“The mode of referral played a part in how effectively people took up structured education programmes. And a lot of this is due to, I think there are two main facts. One, lack of knowledge about what structured education is amongst health care professionals, and also the time and type of engagement that people have when engaging with patients who have been newly diagnosed with diabetes, and the use of motivational techniques to get people to be able to understand what the purpose and process of structured education is.

So I think that there are big issues there, and I think a poor experience is just being told, well, I’m referring you to a Desmond Programme and you’ll be contacted, and not explaining to people what it means.” Participant 14, GP
Lack of time to discuss structured education

In addition, all the professionals said there is not enough time in the consultation to discuss or demonstrate the programme.

“I think you’re asking the impossible. GPs have a few minutes, the practice nurses probably have 20 minutes, at best…” Participant 17, Diabetes Specialist Nurse

Some of the patients expressed the view that they were not given much information from healthcare professionals about how to manage their diabetes or how to learn more about it, but they wanted more information so they sought information in other ways instead.

“IV Okay, and when you were first diagnosed, how much information were you given about how to manage your diabetes?

IE From my GP, I received no information. Maybe, I mean, verbal, saying you have to change your diet. Don’t eat packaged food and that was it, and I was referred to the diabetes programme and that’s a whole day session, which I learned about the spleen, which is why I’m saying that [?] because I’d done [unclear] physiology and biology course, that we were taught in the class, talking about different kinds of sweeteners from all the fruit and veg and as well as other soft drinks, how much sugar they contain, and that gave me an insight to do more research.

IV So you did your own research as well?

IE Yes.

IV And where did you go to look for information?

IE The information was through the internet.”

Participant 6, 55yo male completer, duration of illness 5-10y
2. Patient non-prioritisation

Competing priorities

Interviewees described patient barriers to engaging. These included competing priorities.

“I think it was again just due to work. It may have fallen over periods where I’m so busy at work that I just didn’t have time to do it.” Participant 5, 64yo female completer, duration of illness 1-5y

Perceived relevance

Newly diagnosed patients didn’t feel that information such as treatment with medications was relevant to them at their stage of the illness.

“a lot of the online also I think targeted people who are on medication so how much as a, sort of a newly diagnosed I don’t know how helpful it was to be honest with you. Because some of it I just felt didn’t apply to me.” Participant 5, 64yo female completer, duration of illness 1-5y

Perceived need

Some patients expressed that they didn’t feel they needed more information about their diabetes, because they already knew what they needed to know.

“They probably could give me further hints but at the same time, I just feel I really do know what to do – don’t eat any carbs or sugars or anything and you’ll keep it under control.” Participant 4, 63yo female non-completer, duration of illness 1-5y

Not being ready for information

Another barrier to engagement with the programme that was described was not being ready for information about T2DM at an early stage of the illness.

“If we’re talking about complications it’s too far away for them to think about, if we’re talking about behaviour change they think... It’s a disease with no symptoms, largely, and I think that that’s the massive issue, I think that people
take it seriously when things start to go wrong.” Participant 17, Diabetes Specialist Nurse

3. Programme acceptability

Being able to take your time

Patients talked about it being useful to learn about self-management over a longer period than a one day face-to-face course, which is crucial in understanding the importance of giving patients an online option for DSME.

“I think that was the other thing which was really good about this site, is that with the Desmond, it’s all there in one day, like packed into a day. And... I mean, yes, they... you go away with nice little booklets and that, but I don't... I swear to God; I haven't really even looked at it. Whereas this, it’s, sort of, like, telling you that you can make tiny little changes. You don't have to go to like, some kind of commando into this, you know. You can be a stealthy ninja. But they're, sort of, putting you in control, so, whereas Desmond is just chucking a load of stuff at you.” Participant 1, 61yo female completer

The way information is presented

Patients described a range of things they liked about HDSO, and which contributed positively towards engaging with the programme. These included the way information was presented as text, video and diagrams.

“The videos explain things... some things really, really well. I think everybody is different, aren’t they? Some people work well with visual stuff, and other people work well with written stuff. I’d always think if you read and look, you know, it gets into the brain. You know, I think those things were really, really good.” Participant 8, 60yo female completer, duration of illness less than 1y

Information about managing emotions

Some participants found the information about managing the emotional side of the illness useful, particularly watching the videos of others talking about living with the illness.
“I thought it concentrated a lot about your emotional side. And listening to some of the other people, and I thought, oh, it’s not just me who was annoyed. I know a lot of people got upset, and, I mean, I didn’t get upset, I was just annoyed. And so I felt that there were similar experiences, you know, other people probably, it’s not just me who was feeling that way. The other people reacted probably similar when they found out that they were.”

Participant 1, 61yo female completer

**Telephone support from the HeLP team**

Participants talked about the importance of having an element of interaction with a professional, such as telephone support, in case of any problems with using the online programme.

*IE*  “It’s always good to have somebody talking to you. I mean, it’s good online, but I think that there was good access phone-wise; there was _always_ a number to phone.

*IV*  Yes, you could always call.

*IE*  Which is always helpful because not everyone is happy online.”

Participant 4, 63yo female non-completer

4. Suggestions for improving uptake

**Familiarising professionals with the programme**

A number of suggestions were made for supporting professionals with referrals and engaging patients with the programme. These included familiarising professionals with the programme.

*RE*  “I think really it’s about trying to get professionals to trial it for themselves, that’s the most important thing.

*IV*  Okay, do you mean with a small group of patients?

*RE*  Just go into the system and trial it for themselves.
IV Oh, okay, yes; so have a look at the website themselves.

RE Yes, I think so, and then when they see what’s in there, the value of it, how they could use it with their patient and get their patient to buy into it?”

Participant 15, Change Manager

Healthcare assistant or administrative assistant-led referral

Another suggestion was support from healthcare assistants and administrators with referrals.

“Ideally, if there were a healthcare assistant or an admin person who could catch the patient separately either before or after the appointment to show them the website and sign them up, I think that would work really well.”

Participant 16, Diabetes Specialist Nurse

Involving patient champions

One participant suggested asking patients who have completed the programme to act as “patient champions” to discuss the programme with their peers.

“We need people who’ve done the whole programme to be saying to people you need to do the whole programme, it’s really great and you will get a lot out of it.”

Participant 16, Diabetes Specialist Nurse

Personalised information

Some patients expressed the need for more detailed or personalised information, particularly about diet.

“The one thing that I did not find there is a suggestion of, I mean – there was mainly suggestion but no ingredients of what’s needed for the person to follow. There was more talk on the video but it does not, kind of like, break it down and how one needs to take and what needs not to be taken.” Participant 6, 55yo male completer, duration of illness 5-10y
Smartphone access

Participants mentioned that they would like to be able to use the programme on their mobile phones, for convenience, and that they were unable to do so with the current format.

“I, sort of, get on it and go through it, because I’m in that mood [inaudible]. Then go through two of the modules, let’s say, from part four. I’ve done part four and part five today. But when I wanted to [unclear] on my mobile phone, when I was [unclear], I thought: right, no I’ll sit down on the phone, you know. I jumped on my phone and do the modules. I found it, kind of, difficult. I find I had to restart the modules on my mobile phone. It wasn’t... it wasn’t, sort of... it didn’t jump out at me and I found it quite frustrating.”

Participant 7, 47yo male completer

6.6 Applying concepts of Normalization Process Theory to the data

NPT was introduced in Chapter 2. It provides a framework for understanding how and whether complex interventions, like HDSO, can become embedded in health care practice (256). NPT focuses on the work of implementation by identify four constructs (130) which are listed, along with the HDSO-specific meaning of each construct, in Table 6-10.
Table 6-10: NPT constructs and HDSO-specific meaning of constructs

<table>
<thead>
<tr>
<th>Constructs</th>
<th>HDSO-specific meaning of the constructs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Coherence (sense-making of the intervention; anchoring in experience)</td>
<td>How well HCPs understood the HDSO programme and how it was different to face-to-face courses. Whether HCPs valued the projected benefits of the HDSO programme to patients and the primary care team, and whether they developed a shared sense of benefit of the programme with patients.</td>
</tr>
<tr>
<td>2. Cognitive participation (engagement and commitment of the participant)</td>
<td>The engagement of HCPs in the HDSO programme, whether they thought it was a good idea, and whether they were willing to invest time, energy and work into it.</td>
</tr>
<tr>
<td>3. Collective action (the work participants do to make the intervention function)</td>
<td>The additional work for practices of promoting the programme to patients (including sending recruitment packs or text messages to patients, and printing and displaying flyers in waiting areas). The work for HCPs of fitting discussions about DSME and referrals to the HDSO programme into time-limited consultations. Any additional training needed to be able to explain and demonstrate the programme to patients, and send referrals.</td>
</tr>
<tr>
<td>4. Reflexive monitoring (how participants reflect on or appraise the intervention)</td>
<td>Whether HCPs perceived the worth of the HDSO programme, and its impact on their other tasks.</td>
</tr>
</tbody>
</table>

The analysis of the data using NPT constructs is given here, and the mapping of themes to constructs is summarised in Table 6-11. I was able to map the
NPT constructs to the two themes which related to the health system and healthcare professionals (The role of health professionals in engaging patients with DSME; and Suggestions for improving uptake of the HDSO programme). Patient and programme factors related less to NPT, and more to behaviour and human-computer interaction.

1. The role of health professionals in engaging patients with DSME

Coherence was a factor influencing successful implementation of the HDSO programme. In particular, interviewees said that limited knowledge and understanding about structured self-management education and the HDSO programme was a reason for lack of uptake by patients.

“The mode of referral played a part in how effectively people took up structured education programmes. And a lot of this is due to, I think there are two main facts. One, lack of knowledge about what structured education is amongst health care professionals, and also the time and type of engagement that people have when engaging with patients who have been newly diagnosed with diabetes, and the use of motivational techniques to get people to be able to understand what the purpose and process of structured education is.

So I think that there are big issues there, and I think a poor experience is just being told, well, I’m referring you to a Desmond Programme and you’ll be contacted, and not explaining to people what it means.” Participant 14, GP

It also seemed that HCP did not discuss the projected benefits of the HDSO programme with patients, or develop a shared sense of benefit with patients (cognitive participation).

Interviewer: “How much information did you get from your GP and your practice nurse about the diabetes when you first got it?”

Interviewee: “I don’t remember getting that much, just referrals. I got it in a letter. She didn’t call me and say, you have diabetes, so you have tipped over and we are now referring you.” Participant 4, 63yo female non-completer, duration of illness 1.5y
In addition, interviewees commented that HCPs did not have time to discuss the benefits of structured education and the HDSO programme to patients. HCPs may not have been willing to invest their consultation time in this discussion (cognitive participation), or they may not have been able to fit the discussion into their consultations (collective action).

“I think you’re asking the impossible. GPs have a few minutes, the practice nurses probably have 20 minutes, at best…” Participant 17, Diabetes Specialist Nurse

2. Suggestions for improving uptake of the HDSO programme

Improving professionals’ knowledge of the HDSO programme was suggested, in order to increase familiarity and encourage patient engagement. This is an example of how additional training (collective action) could be used to improve uptake of the programme, and also a way to allow HCPs to appraise the intervention and reflect on its worth to patients (reflexive monitoring).

RE “I think really it’s about trying to get professionals to trial it for themselves, that’s the most important thing.

IV Okay, do you mean with a small group of patients?

RE Just go into the system and trial it for themselves.

IV Oh, okay, yes; so have a look at the website themselves.

RE Yes, I think so, and then when they see what’s in there, the value of it, how they could use it with their patient and get their patient to buy into it?”

Participant 15, Change Manager

It was also suggested that different members of staff could be allocated the work of referring patients to the programme, due to the limited amount of time HCPs had. This is an example of collective action, where the work needs to be re-allocated to make the intervention function.

“Ideally, if there were a healthcare assistant or an admin person who could catch the patient separately either before or after the appointment to show
them the website and sign them up, I think that would work really well.”
Participant 16, Diabetes Specialist Nurse

The suggestion of asking patients who completed the programme to discuss the HDSO programme with peers, and encourage engagement, was another example of re-allocation of work and collective action.

“We need people who’ve done the whole programme to be saying to people you need to do the whole programme, it’s really great and you will get a lot out of it.”

Participant 16, Diabetes Specialist Nurse

Table 6-11: Mapping of themes onto NPT constructs

<table>
<thead>
<tr>
<th>Theme</th>
<th>NPT construct</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Subtheme</strong></td>
<td></td>
</tr>
<tr>
<td>The role of healthcare professionals in engaging patients with DSME</td>
<td></td>
</tr>
<tr>
<td>Importance of discussing benefits of structured education</td>
<td>Cognitive participation</td>
</tr>
<tr>
<td>Poor understanding of structured education by professionals</td>
<td>Coherence</td>
</tr>
<tr>
<td>Lack of time to discuss structured education</td>
<td>Collective action</td>
</tr>
</tbody>
</table>

| Suggestions for improving uptake of the HDSO programme | |
| Familiarising professionals with the programme | Collective action; Reflexive monitoring |
| Health assistant or administrative assistant-led referral | Collective action |
| Involving patient champions and health coaching | Collective action |
6.7 Discussion

6.7.1 Principal findings

This mixed methods study of HeLP-Diabetes: Starting Out aimed to determine the effect, feasibility and acceptability of the programme. The quantitative component showed that 791 people registered to use the programme. 74 people (9.4%) completed the programme, 114 (14.4%) started but did not complete it, and 603 (76.2%) did not start the programme.

The qualitative component of the study helped me to explore the poor uptake more fully. Findings from interviews with patients and health professionals suggested that professional factors, patient factors and programme factors affected programme acceptability and patient attrition. Professional factors included lack of understanding of structured education and its benefits, and lack of time to discuss structured education with patients. Patient factors included competing priorities, not being ready for the information, perceived lack of relevance of structured education and perceived lack of need.

Programme factors which enhanced programme acceptability were information being presented clearly, being able to take your time, being given information about managing emotions, and having telephone support from the HeLP team. Suggestions for improving uptake included familiarising professionals with the programme, healthcare assistant or administrative assistant-led referral, involving patient champions, personalised information and smartphone access.

Quantitative data were also collected on impact on patients’ diabetes-related distress and diabetes self-management self-efficacy. A decrease in distress was seen at the end of the programme with a decrease in the median PAID score of 2.5 points. This was statistically significant (p=.001), but did not meet the MCID of 4 points. There was an increase in patients’ self-efficacy at the end of the programme with an increase in the median DSMES score of 15.5. This was again statistically significant (p<.0005). I could not find a published MCID for the DSMES, with which to compare the findings to. The median baseline PAID score for completers was low, suggesting they had low baseline
distress. The median baseline DSMES score for completers was high, suggesting baseline self-efficacy was high, and high self-efficacy may be a confounding factor that contributed to why this group completed the programme.

The demographic and clinical characteristics of patients who registered for the programme were analysed, and characteristics of completers and non-completers were compared. There was no relationship between age, ethnicity, education level and IT skills level and completion. There was a relationship between diabetes duration and completing the programme (45.1% of completers had diabetes for less than a year, \( p=0.04 \)); being offered face-to-face education and completing the programme (68.9% of completers had been offered face-to-face education, \( p=0.001 \)); and attending face-to-face education and completing the programme (17.7% of completers had attended face-to-face education, \( p=0.002 \)).

Ethnicity and education level of patients who registered for the programme was compared with ONS data (271) on the general population in their respective CCGs. I found that there was a higher proportion of BAME people registered for the programme than two out of the five CCG diabetes populations. The proportion of people with no qualifications and degree level education also compared well. The percentage of people with no qualifications in the study was higher than in the general population in Islington and Lewisham. The percentage of people with a degree or above was lower in the study than in the general population in every borough apart from Haringey.

I determined at which stage of the course users dropped out and discontinued using it. I answered this question by analysing the data on the last sessions visited by users, illustrated in Table 6-2. The data showed that 80.6% of people who visited at least one page of the programme, did not go further than week 1. 57.7% of people did not go further than the homepage. The programme was developed with a spiral curriculum, so that people could build on knowledge they had acquired in previous sessions. This meant that people could only access the next session of the programme once they had completed the last one. This may have acted as a barrier to engagement for
some people. There may have been a lack of motivation to complete a session and move on to the next one. This is discussed further in Chapter 11.

28.9% of people who registered for the programme had T2DM for less than a year, and only 9.4% had attended face-to-face education. This finding supported the change in the programme procedure to offer access to people with T2DM of any duration, as it showed that people with T2DM for longer than a year want and need structured education. However, the finding that completion was associated with diabetes duration of less than a year, suggests that newly diagnosed patients were more likely to complete the programme. So although patients with a longer duration of diabetes may need structured education, they may not have the motivation to complete it.

6.7.2 Comparison with existing literature

Our finding of a programme completion rate of 9.4% is low but compares favourably with National Diabetes Audit data showing that only 7.1% of patients referred to face-to-face education are recorded as having attended (250).

Reasons for poor uptake and completion were explored in the interviews, and the findings are consistent with a 2016 systematic review of reasons why patients referred to diabetes education programmes do not attend (56). The review included 12 quantitative and qualitative studies published in Europe, USA, Pakistan, Canada and India and, in keeping with our findings, found that patients did not prioritise education, were influenced by healthcare professionals who lacked enthusiasm for education, and did not feel they would benefit from it or felt they knew enough already (56). A 2017 Norwegian qualitative study of reasons for dropout from an eHealth intervention for people with T2DM, based on the Guided Self-Determination (GSD) counselling method (280), also found that patients perceived content as irrelevant to them, and reported having more important priorities in their lives (280). Some patients also reported frustrations with the webpage and online activities, and a preference for face-to-face encounters (280). Stangeland explain their findings using research examining health interventions based on self-
determination theory (281, 282). These studies suggest that motivation is influenced by the value patients place on activities and their anticipated results (281, 282). This can also be useful in explaining why patients’ perception of intervention content being irrelevant affects engagement. There were some barriers that online education could overcome, such as difficulty travelling to face-to-face courses and taking time off work to attend face-to-face courses. Other problems like patients not perceiving self-management education as relevant or a priority, were not overcome by offering online education.

The high attrition we saw in programme users between registration and completion is consistent with findings from other studies of online health interventions (240), including web-based self-help programmes for panic disorder (1% programme completion) (86), and depression (0.5% programme completion) (87). A review of fourteen internet-delivered diabetes self-management education programmes (73) found that participant interest and time spent logged in decreased as studies continued. All of these programmes were from outside the UK.

The findings are consistent with research suggesting that engagement with online self-management interventions may be improved by personalising interventions (283); and providing facilitation from healthcare providers, educators and peers in combination with the online intervention (73).

Our findings of an increase in self-efficacy and decrease in emotional distress are consistent with a 2010 randomised trial of an internet-based diabetes self-management programme, which found a significant increase in self-efficacy at 6 months in programme users when compared with usual care control subjects (284).

The finding of a socially and ethnically diverse group of patients registering for the programme suggests that it appeals to a wide demographic. This conflicts with existing literature that suggests that online health interventions may increase digital exclusion and widen the digital divide, and this is explored further in Chapter 7 (98).
There was no relationship between gender and highest level of education and completion of the programme. This conflicts with a study by Roelofsen et al (285) which showed that more patients with T2DM expressed an interest in using an online platform which offered access to clinical data, laboratory results, education modules and self-management support programme, if they were male and had a higher level of education (285). The lack of relationship between education level and completion also conflicts with an analysis of data from seven RCTs evaluating web-based health behaviour interventions, which found that dropout was higher among low and middle education level participants (286). This may have been because HDSO was specifically designed for people with low literacy.

The Roelofsen study also found that patients were more interested in the online platform for T2DM if they had a shorter TDM duration, which is in keeping with the findings from this study. The overall participation rate was low (110 used the intervention out of 974 who were registered, 11.3%), which again is in keeping with the findings in this study (285).

Younger age has also been found to be a predictor of attrition (285, 287-289), which is consistent with the findings in this study.

6.7.3 Strengths and limitations

This evaluation of an online structured education programme for T2DM during its implementation in primary care had a number of strengths and limitations. One strength of the study was that the setting was routine clinical practice rather than a controlled research environment. The procedures were dictated by the requirements of the service delivery. The study would therefore be expected to have greater external validity. The study also followed user-centred design principles (discussed in Chapter 2) of understanding the lived experience of users i.e. how they use the product in their daily lives, and the context in which they live, work and learn. These principles allowed for a greater understanding of acceptability of the programme to users.

Another strength of the study was the use of mixed methodology. The findings from the qualitative interviews helped to explain the quantitative findings and
add meaning to the results of the study. The quantitative findings told me that there was patient attrition between registering and completing the programme. The qualitative findings helped me to explore this more fully. I found that programme acceptability contributed to engagement with HDSO, but that lack of encouragement from healthcare professionals and patient non-prioritisation may have led to disengagement. I also found suggestions for improving uptake. Using NPT in the qualitative analysis, and mapping themes to NPT constructs, allowed me to improve my understanding and interpretation of the themes. For example I was able to more richly understand how lack of time was a factor in influencing engagement. Lack of time to discuss the benefits of self-management education and the HDSO programme, meant that HCPs could not integrate this interaction into their routine practice, and it could not be ‘normalized’.

Implementing the programme in clinical practice led to several methodological weaknesses. It was necessary to engage practices and health professionals with the programme in order to improve registration numbers. The work put into engaging practice staff with the programme was challenging due to the limited amount of time and resources that practices were able to dedicate to learning about the programme and to talking to patients about registering for the programme. This was a sub-theme that emerged from the qualitative data (see ‘Professional factors’). Suggestions for improving uptake were made in the interviews, and included healthcare assistant or administrator-led referral to the programme, and this is one potential way that the methods could be improved if the study were to be repeated. One of the CCGs in which the programme was implemented (Lewisham) employed a Change Manager to visit GP Practices and encourage patients to register for the HDSO programme. This took the emphasis away from health professional time being used to promote the programme and helped improve the number of registrations in that CCG. This is a model that could be replicated in other CCGs to improve the number of registrations, if the study were to be repeated.

Another methodological weakness was the lack of clinical outcome measures like HbA1c, weight, lipids and blood pressure. It was not possible to collect
clinical data as the study was not carried out as part of a clinical trial and therefore practice staff could not be asked to collect clinical data for the research. If the study were to be repeated, I could visit practices to extract clinical data from the electronic medical records. It would be useful to collect clinical data, particularly HbA1c, in order to provide more evidence to determine the effectiveness of the programme.

A further limitation of the study was that data were only collected on the number of registrations and use of the programme. Data were not collected on the number of patients who were offered the programme and declined. These data would have helped to add to the evidence for feasibility and acceptability of the programme. It was not possible to collect these data due to the context of the study in routine clinical practice and the lack of standardised procedures for offering the programme to patients. Some practices chose to mail out recruitment packs to patients who met the eligibility criteria for the programme, some practices chose to text eligible patients and others did not send eligible patients information about the programme at all, but discussed the programme with eligible patients opportunistically. If I were to repeat the study I would use a more standardised method of offering the programme to patients and recording the number of patients declining to register.

A final limitation of the quantitative part of the study was that the gender and ethnicity of people registered to use HDSO were compared with that of the diabetes population of each CCG. However, the education level of people registered to use HDSO was compared with the general population of each CCG. This was because there are no data on the education level of the diabetes population by CCG available. This may not be an accurate comparison, but, this was the best comparison I could make with the available data.

Having qualitative interviews was a strength as themes could help explain the findings of the quantitative study. However, interviews were only conducted with patients who registered for the programme. Ethics and the recruitment process did not permit interviews with patients who were offered the
programme but did not register. Their views could have improved our understanding of the feasibility and acceptability of online structured education. Likewise, seven out of the ten patients who were interviewed had completed the programme. It would have been useful to interview more non-completers, but unfortunately they did not respond when emailed to take part.

I did not conduct all the interviews; some were conducted by a user experience expert over the telephone. We had different professional roles and interviewing techniques so this may have led to different responses from the patients we interviewed (I have reflected on the influence of the roles of the interviewers further in Section 6.7.3.1, “Reflexive statement” below). Additionally, when I analysed the transcriptions, I was not able to reflect on things like tone of voice, or non-verbal communication, to interpret the data from the interviews I did not conduct.

Convenience sampling was used to recruit HCPs for interviews (HCPs at high and low referring practices who were willing to participate). Convenience sampling is often used when the group of interest is difficult to access (290). An alternative method would have been purposive (or theoretical) sampling which would have identified “outliers”, and given more attention to deviant cases (290). The limitation of my approach was that I was less likely to have a spread of respondents representing the diversity of the population (HCPs with the opportunity to offer HDSO to patients).

The interviews were conducted until I had enough data to inform the quantitative findings on uptake and completion, but not until I reached saturation. This meant that I gained an understanding of user experience and acceptability, but I may have missed other views from patients and HCPs I did not interview, and there may have been more emergent themes which I did not identify.

6.7.3.1 Reflexive statement

When using qualitative research methods, it is important to acknowledge the ways in which the researchers may have shaped the data collected, in order to provide transparency (255, 291). The assumptions and experiences of researchers can influence the interaction with interviewees, for example (255).
This is particularly relevant in primary care research, where researchers can have diverse professional backgrounds such as general practice, nursing and sociology (291). As an academic GP, I approached the research with my own set of assumptions and experiences. I have reflected on how these assumptions and experiences may have influenced my data, in terms of the dynamics between me and the interview participants. I have considered power dynamics, role conflict and role boundaries, as suggested in the literature on ethical dilemmas and reflexivity in qualitative research (292).

Doctors have a clearly defined role and are considered to have a higher social status than non-clinical researchers by some people (291). This could have had an effect on the power dynamics in my interviews. For example, my role as a GP may have led some participants to feel that they had to have a more formal, consultation-style conversation with me, and been more reserved about their views and experiences. They may also have felt the need to give ‘desirable’ responses to questions, to give an impression that they were following doctors’ advice and taking care of their health. They may also have avoided saying anything negative about GPs and the care they were receiving, for fear of offending me.

My background as a GP also led to role conflict and issues with role boundaries. I felt that some participants saw the interviews more as a consultation, and an opportunity to ask me clinical questions about their diabetes and general health. For example during one interview, the following participant asked me a question about what she could eat whilst taking steroid medication below (participant=IE, interviewer=IV):

**RE** But what confuses me I have [unclear 0:13:43] small, [unclear 0:13:46] when I was on the steroids, you’re only allowed two a day, aren’t we?

**IV** Yes, you have to limit, well, carbohydrates in general.

**RE** Do you know what? This confuses me. I don’t now how much carbs you should have a day or sugar.
IV Yes. We try and look at it in portion sizes. I don’t know if you remember there’s a healthy eating plate.

RE Yes.

IV And then we split it into three, and your biggest portion should be the salad, and then you have a bit of carbohydrate, a bit of protein with it, so.

Participant 2, 62yo female completer, duration of illness 1-5 years

The participant’s confusion and request for advice made me feel (as a GP) compelled to give the information, but this steered me away from my role as a researcher and for that short time the interview was less of an exploration of her views about DSME and the HDSO programme, and more of a clinical encounter with a health professional. I could sense this happening during the interview and made the conscious effort to return to being the ‘researcher’ and used my topic guide to explore issues relevant to the research further.

There are other ways that my role may have influenced the dynamics in the interviews. As a GP I am trained in diagnosing and treating diabetes, and therefore had the advantage of being able to understand issues participants brought up around their diagnosis (including blood tests and HbA1c levels) and treatment (including medications, monitoring and complications). This allowed the interviews to flow naturally without my needing to interrupt to clarify terms or procedures. This may also have made participants to feel more comfortable to talk freely about their diabetes, as they might do with their own GP.

As described above, four of the interviews were conducted by a user experience expert. The user experience had a different professional background to me, and difference skills, experience and assumptions that he brought to the interviews. As described in Chapter 5, qualitative research in user experience studies is more “industrial” in nature, in that it is driven by time and resource rather than theory, rigor and data saturation. Interviews can be shorter and less in-depth. The user experience expert did not have my clinical background and training to be able to discuss the participants’ illness in depth,
but had more training in user experience research and asking questions about
the online programme. For example, when the user experience expert
discussed the participants’ illness experience with them, he related it to his
own experience of friends and family with illness. This can be seen in the
extract below (participant=IE, interviewer=IV):

IE  (And) obviously explains a lot of other things that have been happening
to me over the last nine months or a year I guess.

IV  Right, I would say that’s been, that’s been quite a result, in some ways
that’s a sense of relief. I’ve got a friend who’s got MS, when she got the MS
diagnosis she was hugely relieved. Because it’s not a good diagnosis to have,
but it’s better than a lot of things that could have been causing the symptoms.
So yes, I understand that.

Participant 9, 51yo male completer, duration of illness less than one year

The dynamic between the user experience expert and participants, and the
dynamic between me and the participants, was therefore very different and
this would have been seen in the data collected. Even though an inductive
approach to the analysis was taken, it was impossible to avoid any influence
from our professional roles, and this needs to be acknowledged.

6.7.4 Implications for research and practice

Further research is needed to improve uptake and completion. The findings
from this study suggested that it may be possible to improve uptake and
completion by making changes and optimising the programme and its delivery
package. This is discussed further in Chapters 9 and 10. There are also factors
which are less easy to control and these are discussed in Chapter 11.

Once the programme has been optimised, research will be needed to compare
online structured education with established face-to-face courses, to
determine relative effectiveness and cost-effectiveness. If found to be effective
and cost-effective, online structured education could give patients with T2DM
more options for learning about self-management and help improve structured
education uptake and health outcomes for those living with the condition.
6.8 Conclusion

The study showed that it was feasible to deliver structured education online, and that a wide demographic could use the programme. There were problems with uptake, and patient attrition between registration and completion of the programme, which need to be addressed. For those patients who did use HDSO, it appeared to be acceptable and may have improved their self-efficacy and emotional distress.
Chapter 7. Analysis of usage data and exploring the digital divide

7.1 Chapter summary

Chapter 6 described the evaluation of the second iteration of the HDSO programme. The results of this study showed that the demographic characteristics of the people who registered to use HDSO were diverse. The average age of people who registered was 57.6 years, about half were male (53.9%), about half were from black and minority ethnic (BAME) backgrounds (51.2%), and nearly one third had no qualifications beyond school-leaving age (30.1%). Age, gender, ethnicity and education showed no relationship with completing the programme. This provided initial evidence to suggest that HDSO is acceptable to people of different demographic groups. In this chapter I explored in more detail the demographic characteristics of people who registered for and used the HDSO programme. I did this by looking at whether the demographic characteristics of people who registered for the programme differed from the target population; whether certain demographic groups were more likely to use the programme; and whether certain demographic groups had different patterns of use (visited different webpages). This allowed me to determine if there was evidence of a “digital divide” when the programme was implemented, and, by comparing visits to the structured HDSO programme with visits to the HeLP-Diabetes website, I explored whether some groups prefer unstructured learning to a more structured pathway.

7.2 Background

7.2.1 What is the digital divide and why is it important

7.2.1.1 The policy context

The role of digital health interventions in the modern NHS has been discussed in Chapter 1. To summarise, there are fundamental challenges facing the NHS which are forcing policy-makers to consider new ways of providing treatment and support to patients. Challenges include a rise in long-term conditions (which now consume 60% of the health care budget), patient preference to be more involved in their care, improved survival rates and an aging population.
There is increasing recognition from the government for the need "to exploit the information revolution" to meet the population’s growing health needs and expectations, and to promote self-care by patients (28, 69).

The 2014 NHS Five Year Forward View proposed using digitisation as one of the means to close gaps identified in NHS care and quality, funding and efficiency, and health and wellbeing (28, 65). The expansion of online resources to help patients manage and organise their own health was described as an opportunity for narrowing the inequalities that exist in accessing information, particularly for the elderly. A pledge was made to support those who are less able to use technology (28).

Since the publication of the Five Year Forward View, further plans and investments have been made for digitisation. A framework for delivering the proposals was set out in the National Information Board report “Personalised Health and Care 2020”, and ‘Local digital roadmaps’ led by Clinical Commissioning Groups (CCGs) have been developed to drive implementation locally (69). In 2016 £4.2 billion was allocated by the government to deliver digital projects in the NHS (65). In the same year the Wachter Report made a series of recommendations including additional funding for digitisation, interoperability and a national engagement strategy for educating and involving stakeholders in the creation of digital strategies and systems (68).

There are many potential benefits of improving the use of digital health, including the economic benefits and the potential to reduce health inequalities by reaching isolated and vulnerable populations. The scalability and low marginal cost per additional user should make digital health interventions more cost-effective than face-to-face health care delivery. Improving patient self-care should also reduce health care costs, and there is emerging data to support this (59, 66, 67). There is also anxiety about the potential for digitisation to widen health inequalities. This has been termed the “digital divide”, defined as the gap between those who do and do not make regular use of digital technologies and the internet (293, 294). There are arguments both for and against the digital divide and widening health inequalities, which I have presented below.
7.2.1.2 Arguments against the digital divide: digital health decreases inequalities by improving access to hard to reach groups

7.2.1.2.1 Rural communities

The principle challenge in delivering health care in rural areas is the geographic isolation of the population relative to the distribution of trained health professionals and health care facilities (295). There is a lack of trained health professionals in rural areas in almost all countries, whether they have a high or low income (296). About half of the world’s population live in rural areas, but only 38% of the nursing workforce and less than a quarter of physicians are located there (296). This results in people needing to travel long distances to access health care, which is costly and time-consuming (297). There is a concentration of poverty, low educational attainment and lower health status in rural populations (298-300), yet despite the greater need these populations have worse access to health care than urban populations. This is a concept captured by the ‘inverse care law’, which states that “good medical care tends to vary inversely with the need for it in the population served” (301).

Improved communication and dissemination of health information is fundamental to addressing inequalities, and could be enhanced using digital technologies (302). There are numerous potential applications for eHealth in rural communities, which could help to improve health care quality and safety. These include electronic health records, electronic decision support tools, remote patient monitoring, and online education for health professionals (303). Many of these have been implemented, predominantly in primary care, as multistate or national projects in Australia (303). But factors like poor infrastructure and lack of readiness for eHealth have been recognised as impeding uptake and successful implementation (303). Mobile phone-based interventions offer a novel way of providing high quality care to rural communities. A systematic review of eHealth literacy in underserved populations in the US (304) found some evidence of the acceptability of computerised cognitive behavioural therapy (CCBT) for anxiety and depression in rural areas when compared to urban areas (305), and of mobile phone-based interventions for the management of chronic health conditions.
in migrant farm workers (306). The CCBT review found that rural participants were less likely to want more face-to-face contact (305).

7.2.1.2.2 The homeless
Several studies show increased mortality amongst homeless people, the causes of which include infectious diseases (e.g. HIV and tuberculosis), ischaemic heart disease, substance misuse, unintentional injury and suicide (307, 308). However homeless people can face multiple challenges to receiving face-to-face health care due to surgery locations and opening times, lack of address for registration procedures and correspondence, multiple competing needs and discrimination (due to perceptions they are migrants, violent, antisocial or ‘undeserving’) (309-311). These challenges suggest there may be a potential role for information technology, particularly the use of mobile phones for communication with health professionals and accessing the internet (311). A 2013 systematic review found surprisingly high levels of internet access among homeless populations in the US (311). The results suggested that 44-57% of homeless people in the US have access to the internet, and use it for health-related reasons amongst other reasons. However only 16 studies were identified, each with small sample sizes, suggesting a need for more research in this area (311).

7.2.1.2.3 Non-English speakers
Language barriers present a challenge to health care services all over the world. Research suggests that London is one of the most linguistically diverse cities in the world, with more than 300 languages (excluding dialects) spoken by children at home (312, 313). People who speak poor English have particular difficulty accessing healthcare, due to lack of knowledge of services, limited ability to make contact by telephone and limited ability to communicate with doctors and nurses (314, 315). Many patients depend on interpreters to assist with communication. It has been estimated that 2,520,885 general practice consultations may require interpreting services per year in England (312). However accessing face-to-face interpreting services can be problematic, and appropriately translated health information can be limited (316-318). eHealth provides the opportunity to present health information in
simpler English, other languages, and in visual or auditory form, which conforms to the information presentation preferences of non-English speakers (319, 320). Digital health interventions could also be used to improve access to health behaviour change and disease management information, by providing culturally relevant materials (321).

7.2.1.3 Arguments for the digital divide: digital health worsens inequalities for groups who have problems with IT access, literacy and motivation

7.2.1.3.1 Access
There have been dramatic changes in use of technology in the last five years. The percentage of people accessing the internet via a mobile phone or smartphone has more than doubled from 2011 to 2017 (from 36% to 73%) (322). However, 10% of the UK population have never even used the internet, and just over half of these people were aged over 75 (322).

Figure 7-1 shows which devices were used to access the internet in Great Britain in January-April of 2018 (323). It shows that internet use is lowest in the over 65 age group, and also mobile phones or smartphones were the most popular device to access the internet across most age groups apart from those aged over 65 years who reported a tablet computer as the most popular device to access the internet.
Economic barriers to IT use exist too, due to the cost of buying or accessing computer equipment. Therefore, concerns exist that there is decreased access to information technologies for older adults, and people with low socioeconomic status (SES) (96). This could lead to groups who suffer the highest health burden being the least likely to access the internet and benefit from web-based interventions, and widening of the digital divide (97, 98).

7.2.1.3.2 Literacy
The digital divide is about more than just access. For those who do have access to the internet, there are challenges to being able to use it effectively, including general literacy, health literacy and computer literacy. Health literacy has been defined by the World Health Organization (WHO) as follows: “Health
literacy represents the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health” (324). Low health literacy has been linked to poorer health, greater use of emergency care and increased hospitalisation (325). Computer literacy involves the ability to use new technologies productively and efficiently to solve problems or answer questions (326, 327). Health literacy and computer literacy may be linked as people with low health literacy can find it difficult to navigate webpages and understand online health information. A construct called ‘eHealth literacy’ has been developed which encompasses general literacy, health literacy and computer literacy (as well as information, science and media literacy), and describes the ability to seek, find, understand and appraise online health information and use the information to solve a health problem (326, 327), see Figure 7-2.

**Figure 7-2: eHealth literacy model (306)**
Both health and computer literacy have been found to be lower amongst older people, people from BAME backgrounds, people with lower incomes and people with lower educational attainment (99-102). This can lead to these groups being marginalised, and limit their empowerment to take care of their own health (328).

7.2.1.3.3 Motivation

Another factor that affects use of digital health interventions by some demographic groups is motivation. Motivation is influenced by habits, emotional responses and decision-making, and requires acknowledgement that health is affected by actions (329). The 2014 Government Digital Inclusion Strategy (330) identified three challenges to going online, in addition to not having internet access: (1) not having the skills to be able to use the internet (computer literacy); (2) not having the motivation to go online (not understanding the benefits); and (3) lack of trust in internet security (330). Government initiatives to provide free internet access and digital skills have been instigated to help digitally excluded people; £85 million has been spent on digital skills training, and free Wifi is offered in all libraries in England (330). This goes some way to address issues of access and computer literacy, but does not address patient motivation.

There are concerns that people with higher levels of motivation and self-efficacy with better access to social, economic and practical resources, may be better able to engage with programmes which aim to promote self-care by patients, such as the Expert Patient Programme, and that this may in turn widen health inequalities (331, 332).
7.2.1.4 Actions to address barriers to digital health

There is real uncertainty about whether the arguments for eHealth widening the digital divide are stronger than the arguments for narrowing it. There are barriers which may be possible to address by digital health intervention developers and health professionals, such as access, computer literacy, and motivation.

**Access**

The rise in use of smartphones improves levels of access to the internet, and could be used to target vulnerable or marginalised groups. As described above, mobile and smartphone use has more than doubled since 2011, while desktop use has decreased. More than 7 in 10 adults use mobile or smartphones to access the internet (322). There are socioeconomic differences in device use. Low SES adults are less likely to use a desktop computer to go online than other devices (333). Eight per cent of all adults only use a smartphone to go online, and adults in low SES households are more likely to only use a smartphone to go online than adults in high SES households (333).

The rapid increase in adoption of smartphones, and the preference for smartphone use by low SES adults, means that it may be possible to improve access to health care and health information for this group with smartphone applications. Smartphone use is highest in 16-64 year olds, but use in the over 65 year olds is increasing (333). Use amongst younger adults offers opportunities for early disease management and disease prevention (334).

**Computer literacy**

The problems of low health and computer literacy could also be addressed. Digital health interventions can be developed to be accessible to people with low health and computer literacy, and it is the responsibility of the developer to make this a priority. Research suggests that it is possible to design eHealth interventions for people with a range of health literacy levels. A qualitative study of the views of people with high and low health literacy about a digital intervention to promote physical activity for diabetes found that most
participants expressed positive views about the features of the intervention (335). A 2014 US review of eHealth interventions to improve health literacy included studies targeting a number of health risks including cardiovascular risk reduction, diabetes, colon cancer, eating practices and physical activity (336). The eHealth interventions resulted in significant improvements in health literacy and/or at least one lifestyle behaviour (336). A variety of modalities were used for delivering information, such as video segments, animations, photos, text and narration (337, 338).

As part of their corporate social responsibilities, developers need to design digital health interventions with diverse groups vulnerable to exclusion in mind. Otherwise market-driven forces may further exclude low income groups. Understanding the perspectives of the people who use digital health interventions has been established as part of good intervention development (339), and vital for improving problems with uptake and adherence (340). Well-designed interventions that take a “user-centred” approach and offer features like choice, tailoring and human support can increase motivation and engagement to use eHealth (341) as discussed in Chapter 6. HeLP-Diabetes was developed with significant user input, and the needs of people with lower health and computer literacy in mind.

**Motivation and lack of trust**

Motivation and lack of trust may be related to input from health professionals. Professionals have a role to play in recommending and directing patients to digital health interventions that are available to their patients and of benefit. The qualitative findings in Chapter 6 suggested that discussing the benefits of structured education are important in improving patient engagement, and these findings are supported by a systematic review of reasons why patients referred to diabetes education programmes do not attend (56). However, health professionals also need to be convinced of intervention effectiveness by being provided with rigorous evidence from RCTs and other high quality studies. Health professionals also need assurances of data security. Medical app accreditation has started to be introduced to provide assurance to patients and professionals about quality and safety. The NHS Health Apps Library was
launched in 2013 and is still under development, and it aims to curate a list of apps suitable for professionals to recommend to patients and for patients to use themselves. Registered apps go through an approval process to ensure clinical safety and data protection requirements. Huckvale et al (342) carried out a review of the NHS Health Apps Library to assess whether included apps complied with data protection laws. They found that there was considerable variation in compliance, and over half transferred personal information to online services. The review highlighted the limitations to self-declared compliance with data protection laws and suggests that regulators should explicitly define criteria and assess whether apps are meeting these with a formal evaluation, not just a self-assessment.

HDSO was developed to be used by people with diverse backgrounds and differing levels of health and computer literacy. This study aims to determine if this was achieved, and if the digital divide was overcome by analysing data on use of the programme. I collected data on age, gender, ethnicity and educational attainment, but not on income or disability. Age, gender, ethnicity and educational attainment were the best markers for the groups that are vulnerable to digital exclusion, which could be collected from our participants sensitively. Educational attainment was used as a marker of SES, as is common in epidemiological research (244, 245), and also digital and health literacy. I also used educational attainment as a marker of SES as it is less sensitive than income. Low health literacy has been found to be more common amongst older people, people from minority black and minority ethnic (BAME) backgrounds, people with lower incomes and people with lower educational attainment (99-101). Lower digital literacy has also been found to be associated with lower educational attainment (102). Data on ethnicity was collected due to the prevalence of low health literacy, and the concern about health inequalities, amongst BAME groups. Inequalities in health have been documented across ethnic groups in the United States and the United Kingdom, with Bangladeshi and Pakistani people reporting the poorest health, followed by Caribbean, Chinese, and Indian people. White people have the best health (343, 344). Factors underlying these differences include socioeconomic status (SES), genetic and cultural factors (345).
Use of the programme is an objectively measurable behaviour and less prone to bias than other factors involved in engagement such as motivation. I have discussed other measures of use and engagement, and my choice of measure, below.

7.2.2 Usage data as a measure of engagement

Use of the programme was measured in this study by number of website logins, and this was compared for different demographic groups, as well as which pages were visited. The number of visits someone makes to a website is one of a number of ways of measuring use and engagement.

Tracking of use patterns, including number of logins, amount of time spent logged into the intervention, and amount and type of information used, have been identified as the most commonly used measures of engagement in the literature on online behaviour change interventions (346, 347). The degree of completion of modules within a program has also been used (347).

Reviews which have studied the association between engagement and outcomes have not shown clear patterns due to the variation in types of measurements in the literature (347). It has also been suggested that it is difficult to interpret the “dose” of the intervention the participant receives even if logins and module completion are measured (347). Others suggest usage data should be viewed as one of a set of measures of engagement which should also include objective measures such as comprehension and practice of content, self-reported satisfaction and measures of self-efficacy. Although exposure to an intervention through use is key to determining impact, it may not be enough on its own to understand program effectiveness (348). Usage data does not tell us about what the person does when they are offline, and if they are engaging with the content of the intervention outside of the webpages. If a person stops using the intervention we don’t know if they have stopped engaging or they have sufficiently mastered the content that they don’t need to use it anymore (349). ‘Effective’ engagement may therefore be a more helpful approach, focusing on mediating positive outcomes (349). Methods for measuring effective engagement have been suggested which
include qualitative interviews, questionnaires, smartphone, mobile and environmental sensors for automatically collecting data on user behaviour, and physiological measures of arousal and attention (349). However qualitative methods may be subject to reporting bias, and sensors and physiological monitoring require costly and intrusive resources. Further work is needed to understand the most efficient combination of methods (349).

7.2.3 Comparing use of HeLP-Diabetes with HeLP-Diabetes: Starting Out

Everyone who registered for the HDSO programme had access to both the HeLP-Diabetes website and the structured HDSO modules. People could therefore choose how to use the website according to their preferences. There is evidence from a study of use of a website teaching people about hepatitis, that perceived user control is higher if users are given freedom of choice to skip pages instead of viewing webpages in a pre-determined order (a tunnelled version of the website) (350). However the users who progress through the website in the pre-determined order may process the information more efficiently (350). By looking at visits to the HeLP-Diabetes website in addition to the HDSO structured programme, I was able to determine if there was preferential use of one over the other, and if there were any patterns of preferential use by specific demographic groups.

7.3 Aim

The overall aim of the study was to determine whether there was evidence of a digital divide when HeLP-Diabetes (including HDSO) were integrated into NHS care as a routine service.

Specific objectives were to determine:

1. Whether the demographic characteristics of people who registered to use the programme differed from the target population, and if so how;
2. Whether, once registered, specific demographic groups differed in terms of overall use of the programme;
3. Whether there were different patterns of use (different pages viewed) by specified demographic characteristics;
4. Whether specific demographic groups differed in their use of the HeLP-Diabetes website, compared with the HDSO structured programme.

7.4 Methods

7.4.1 Study design

A retrospective analysis of data on the use of the HDSO programme and HeLP-Diabetes website was conducted. Data were collected from 334 people who registered for the programme over 12 months.

7.4.2 Study setting

The programme was offered to patients with T2DM in four inner London CCGs (Haringey, Islington, Lambeth and Lewisham) who commissioned the programme as an NHS service. Camden was not included as it did not commission the programme and the agreement to offer it to patients for free ended during the study period.

The patients were not involved in any other research study, which allowed me to explore the “real world” use of the programme rather than use of the programme under research conditions (127). The findings would therefore be expected to be more realistic and generalisable to use by the general population.
7.4.2.1 General population of study setting

Haringey, Islington, Lambeth and Lewisham are inner London boroughs with young, ethnically diverse, relatively deprived populations (272), see Figure 7-3 and Table 7-4.

**Figure 7-3: London borough atlas**
Table 7-1: London borough profiles

<table>
<thead>
<tr>
<th></th>
<th>Haringey</th>
<th>Islington</th>
<th>Lambeth</th>
<th>Lewisham</th>
<th>England</th>
</tr>
</thead>
<tbody>
<tr>
<td>Greater London Authority (GLA)</td>
<td>278,000</td>
<td>231,200</td>
<td>328,900</td>
<td>303,400</td>
<td>55,609,600</td>
</tr>
<tr>
<td>population estimate, 2017</td>
<td>35.1</td>
<td>34.8</td>
<td>34.5</td>
<td>35.0</td>
<td>40.1</td>
</tr>
<tr>
<td>Average age (years), 2017</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percentage from BAME groups (%)</td>
<td>38.2</td>
<td>32.0</td>
<td>41.5</td>
<td>47.4</td>
<td>14.0</td>
</tr>
<tr>
<td>2013</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proportion of working age people with no qualifications (%)</td>
<td>8.8</td>
<td>6.2</td>
<td>6.2</td>
<td>5.8</td>
<td>8.8</td>
</tr>
<tr>
<td>2015</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>National ranking for indices of deprivation, 2015 (1/326=most deprived)</td>
<td>30/326</td>
<td>26/326</td>
<td>29/326</td>
<td>39/326</td>
<td>N/A</td>
</tr>
</tbody>
</table>


The average age of people in the four CCGs is 34.5-35.1 years, which is younger than the national comparator (40.1 years) (271). The percentage of people from BAME groups in the four CCGs is 32.0-47.4%, which is much higher than in the whole of England, where the percentage of people from BAME groups is only 14.0% (271, 351). The proportion of people of working age with no qualifications is 8.8% in England and in Haringey, but lower in Islington (6.2%), Lambeth (6.2%) and Lewisham (6.2%) (271).

The indices of deprivation are the government’s primary measure of deprivation in small areas of England. Seven domains of deprivation are included in the calculation: income; employment; health and disability; education, skills and training; barriers to housing and services; living environment; and crime (272). All four CCGs fall within the most deprived 20% of England (272).

7.4.2.2 Diabetes population of study setting
The target population of the intervention was adults with T2DM. The diabetes populations of England, and the four CCGs, are described here and in Table 7-2. There is a higher percentage of people in the 40-64 age group, than any other age group. More than 48% of people with T2DM in the four participating CCGs are of BAME origin, reflecting the ethnic diversity of these areas (275).
<table>
<thead>
<tr>
<th>Demographic characteristic</th>
<th>Haringey</th>
<th>Islington</th>
<th>Lambeth</th>
<th>Lewisham</th>
<th>England</th>
</tr>
</thead>
<tbody>
<tr>
<td>QoF diabetes prevalence in age 17+ (%)</td>
<td>6.2</td>
<td>5.0</td>
<td>5.5</td>
<td>6.5</td>
<td>6.7</td>
</tr>
<tr>
<td>1. Percentage of people with type 2 diabetes aged under 40</td>
<td>4.6</td>
<td>4.8</td>
<td>4.9</td>
<td>4.8</td>
<td>3.9</td>
</tr>
<tr>
<td>2. Percentage of people with type 2 diabetes aged 40 to 64</td>
<td>50.4</td>
<td>49.3</td>
<td>54.4</td>
<td>51.4</td>
<td>42.8</td>
</tr>
<tr>
<td>3. Percentage of people with type 2 diabetes aged 65 to 79</td>
<td>32.8</td>
<td>32.2</td>
<td>29.2</td>
<td>31.0</td>
<td>38.0</td>
</tr>
<tr>
<td>4. Percentage of people with type 2 diabetes aged 80 and over</td>
<td>10.0</td>
<td>10.6</td>
<td>9.6</td>
<td>11.0</td>
<td>13.8</td>
</tr>
<tr>
<td>5. Percentage of people with type 2 diabetes who are male</td>
<td>51.9</td>
<td>52.5</td>
<td>52.5</td>
<td>51.7</td>
<td>55.8</td>
</tr>
<tr>
<td>6. Percentage of people with type 2 diabetes who are female</td>
<td>48.1</td>
<td>47.5</td>
<td>47.5</td>
<td>48.3</td>
<td>44.2</td>
</tr>
<tr>
<td>7. Percentage of people with type 2 diabetes who are white*</td>
<td>33.8</td>
<td>49.2</td>
<td>31.3</td>
<td>41.4</td>
<td>64.4</td>
</tr>
<tr>
<td>8. Percentage of people with type 2 diabetes who are of black or minority ethnic (BAME) origin*</td>
<td>60.5</td>
<td>48.3</td>
<td>62.6</td>
<td>55.8</td>
<td>19.3</td>
</tr>
</tbody>
</table>


*Total percentage ≠100% as remaining ethnicities unknown.
7.4.3 Intervention

7.4.3.1 Registration process and collection of demographic data
HDSO was described in detail in chapters 3 and 5. At the time of data collection it was commissioned by 4 CCGs in inner London (Lambeth, Lewisham, Haringey and Islington). Patients with T2DM were referred to the programme by healthcare professionals, or learned about the programme from flyers in waiting areas and text messages from practices. The data presented here are from the period when patients were registered by the HeLP-Diabetes administrative team over the telephone. The team collected the demographic data and provided people with a secure username and password. A link to the homepage was then emailed. The data from the period when online registration was introduced are not presented here because of the large decrease in the amount of data collected on gender, ethnicity and education. When people were registered by telephone, age data were provided by 98.1% of people; gender data by 93.9% of people; ethnicity data by 98.1% of people and education data by 97.7% of people. However, when people were required to enter their own demographic data during online self-registration, age data were provided by 97% of people; and gender, ethnicity and education data were provided by only 59.1% of people. As the demographic data were so crucial in answering the research questions for this study, the data from people who self-registered were not combined with data from people who were registered by the HeLP-Diabetes team over the telephone in this study.

7.4.3.2 Access to the HeLP-Diabetes website
As mentioned earlier, everyone who registered for the HDSO programme also had access to the HeLP-Diabetes programme. The HDSO programme follows a structured pathway of four modules, each with four to five parts. Each page was accessed in a pre-determined order, and once one module was completed the next became available to access, see Figure 7-4. In contrast, the HeLP-Diabetes website contained information categorised into topics. Each topic was available by clicking on a tab. Users were free to click on pages in any order, and could skip pages they were not interested in.
Figure 7-4: Screenshot showing restricted access to pages until previous page is completed

7.4.4 Ethics

Everyone who registered for the HDSO programme consented to pseudonymised data on webpage visits being collected and analysed for service improvement purposes. Formal ethics approval was not needed for service evaluation (239). Users were automatically pseudonymised with a unique identifier. Pseudo anonymised data were collected by the website (on demographic characteristics and webpage visits) and subsequently exported to Excel and then Tableau reader for analysis.

7.4.5 Data collection

Demographic data for each user were collected by the HeLP administrator at the point of registration, and entered on the user’s profile on the website. The demographic data used in this study were: gender, age, ethnicity and education level.
All logins to the HDSO programme and HeLP-Diabetes website were automatically logged and recorded by the server side of the website. The server collected all data on user activity, including user identification number, date and time of login to the website, and pages visited. Usage data on number of website logins were used in this study because I was able to collect data on the date and time of login. This was a non-obtrusive objective measure automatically collected by the website, so did not require additional resources, did not require any input from users, and was not subject to reporting bias. I was not able to collect date and time of logout, so I was unable to calculate the duration of time that users were logged in. But it been recognised that there may be interruptions or distractions during a login to an online intervention and so there are limitations to using time logged in as a measure of exposure to the intervention anyway (352).

These data were exported to Excel by an Academic Clinical Fellow working with the HeLP team to provide support with data management. He also cleaned the data and checked for missing data. He then transferred the data to Tableau for visualisation.

### 7.4.6 Data analysis

For the analysis, webpages were categorised into the eight sections of the website (Understanding diabetes; Staying healthy; Treating diabetes; Living and working with diabetes; Managing my feelings; My health record; News and research; and Forum and help), and three additional sections: (1) the homepage; (2) miscellaneous articles; and (3) the HDSO programme. The profile, admin, logout and registration pages were excluded from the analysis. Statistical analysis was carried out using Stata (version 14.1) (353).

The four modules of the HDSO structured programme were not included as distinct categories in the analysis because the modules of the structured programme were visited in a pre-determined order, and were not accessible to users unless they had completed the previous module. I already had data on users’ progression and completion of the programme from study 2, and the objectives of this study were to look at page activity rather than completion of
the structured programme. Therefore it was more useful to collect data on number of visits to the HDSO programme as a whole, and compare this with visits to the sections of the HeLP-Diabetes website.

The analysis addresses each of the three research questions listed under the aims above.

**Q1. Was there evidence of the digital divide in overall registration numbers?**

To address the question of whether there was evidence of a digital divide in overall registration numbers, the mean age and proportion (percentage) of people who registered for HDSO from each gender, ethnic, education and age group was calculated. The percentage of Black and minority ethnic (BAME) people registered for HDSO was compared with the percentage of BAME people with T2DM in the CCGs they were recruited from, as these data were available from the Public Health England national general practice profile for diabetes (275). Data on education level of people with T2DM in each CCG were not available, and so education level of people who registered for HDSO was compared with the education level of the general population of each CCG. These data were available from the London Datastore London borough profiles (271).

A statistical analysis to compare characteristics of the user population and the target population could not be carried out as the data were categorised differently. For example, Public Health England age categories were age less than 40, 40-64, 65-79, and over 80, whereas the user population age categories were 18-30, 31-40, 41-50, 51-60, 61-70, 71-80, 81-90 and 90 or over. I used these age groups to illustrate the age distribution of the user population more clearly. Instead of carrying out a statistical analysis, I compared the proportions of male and female registered users with the proportions of males and females with T2DM in the four CCGs, and compared the proportion of BAME registered users with the proportion of BAME people with T2DM in the four CCGs narratively.
Q2. Was there evidence of the digital divide in overall use?

The percentage of registered users who were “active” was calculated for each demographic group. Being “active” was defined in this study as having made at least two separate logins to the HeLP-Diabetes website or HDSO programme. This differs from study 2, where “active” was defined as having completed at last one section of one module. This was in order to determine who returned to the website, rather than just visiting once. The percentage of people who visited at least twice was calculated for each demographic group. Logistic regression analyses were performed to look for evidence of association between the binary dependant variable (use/non-use) and each of the covariates (gender, ethnicity, education level and age group).

Q3. Was there evidence of differential use by demographic characteristic?

The number of visits to each of these twelve sections was presented by demographic group. Wilcoxon-sum rank tests were used to determine if there was an association between age and number of visits to each section of the website. Kruskal-Wallis equality-of-populations rank tests were used to determine if there was an association between ethnicity, education and number of webpage visits per user to each section of the website.

Q4. Is there evidence of an overall difference in use between the HDSO programme and the HeLP-Diabetes website?

The overall number of visits to the HDSO programme and to each section of the HeLP-Diabetes website was summarised. Results were presented numerically and graphically.

7.5 Results

7.5.1 Q1. Was there evidence of the digital divide in overall registration numbers?

Demographic characteristics of people registered for the programme are summarised in Table 7-3.
The mean age was 58 years (SD=30). The age group with the highest proportion of people registered to use HeLP-Diabetes or HDSO was the 51-60 year olds (30.2%), followed by the 61-70 year olds (24.0%), and 71-80 year olds (16.8%). Of the people with T2DM in the general population of the four CCGs (see Table 7-2), the highest proportion of people was in the 40-64 year old age group. This suggests that the age of the registered users reflected the target population. The most common education level was undergraduate level (34.1%), followed by GCSE (29.8%).

55.5% of registered users were male. Public Health data on the four CCGs the programme was offered in, showed 51-53% of people with T2DM in these areas were male. 53.6% of registered users were BAME, and 48-60% of people with T2DM in the four CCGs were BAME. This suggested that the gender and ethnicity of people who registered to use the programme reflected the target population in the four CCGs.

Table 7-3: Demographic characteristics of people who registered to use HeLP-Diabetes

<table>
<thead>
<tr>
<th>Demographic characteristic</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CCG 1</td>
<td>97</td>
</tr>
<tr>
<td>CCG 2</td>
<td>51</td>
</tr>
<tr>
<td>CCG 3</td>
<td>154</td>
</tr>
<tr>
<td>CCG 4</td>
<td>41</td>
</tr>
<tr>
<td>Gender (n=317)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>176 (55.5)</td>
</tr>
<tr>
<td>Female</td>
<td>141 (44.5)</td>
</tr>
<tr>
<td>Ethnicity (n=330)</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>150 (44.7)</td>
</tr>
<tr>
<td>Black</td>
<td>117 (34.9)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>Count (Percentage)</td>
</tr>
<tr>
<td>----------------</td>
<td>--------------------</td>
</tr>
<tr>
<td>Asian</td>
<td>46 (13.7)</td>
</tr>
<tr>
<td>Mixed</td>
<td>17 (5.0)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Education level (n=299)</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GCSE</td>
<td>89 (29.8)</td>
</tr>
<tr>
<td>A-level</td>
<td>64 (21.4)</td>
</tr>
<tr>
<td>Undergraduate level</td>
<td>102 (34.1)</td>
</tr>
<tr>
<td>Postgraduate level</td>
<td>44 (14.7)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age group (n=334)</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-30</td>
<td>6 (1.7)</td>
</tr>
<tr>
<td>31-40</td>
<td>20 (6.0)</td>
</tr>
<tr>
<td>41-50</td>
<td>55 (16.5)</td>
</tr>
<tr>
<td>51-60</td>
<td>101 (30.2)</td>
</tr>
<tr>
<td>61-70</td>
<td>80 (24.0)</td>
</tr>
<tr>
<td>71-80</td>
<td>56 (16.8)</td>
</tr>
<tr>
<td>81-90</td>
<td>13 (3.9)</td>
</tr>
</tbody>
</table>
7.5.2 Q2. Once registered, were specific demographic characteristics associated more likely to use the programme?

As shown in table 7-4, around two thirds of white, black and Asian people who registered to use HeLP-Diabetes, logged in at least twice. This was lower in the mixed group (29.4\%, OR=0.26, 95\% CI=0.09-0.78), but overall the p-value for ethnicity was not significant. The median age of people who logged in at least twice was 59 years old (LQ, UQ=59, 69), and age groups were categorised into quartiles for this analysis. Use of the programme (at least two logins) by the different age groups ranged from 45.8\% in those aged 60-69 years to 57.3\% in those aged 22-50 years. There was no significant difference in use of the programme for gender, education level or age.
**Table 7-4: Proportion of people registered to use HeLP-Diabetes who logged in at least twice**

<table>
<thead>
<tr>
<th>Demographic characteristic</th>
<th>Proportion of registered users who logged in at least twice, n/N (%)</th>
<th>OR (95% CI)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (n=317)</td>
<td></td>
<td></td>
<td>0.19</td>
</tr>
<tr>
<td>Female</td>
<td>77/141 (54.6)</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>109/176 (61.9)</td>
<td>1.35 (0.86-2.12)</td>
<td></td>
</tr>
<tr>
<td>Ethnicity (n=335)</td>
<td></td>
<td></td>
<td>0.12</td>
</tr>
<tr>
<td>White</td>
<td>92/150 (61.3)</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>70/117 (59.8)</td>
<td>0.94 (0.57-1.54)</td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>28/46 (60.9)</td>
<td>0.98 (0.50-1.93)</td>
<td></td>
</tr>
<tr>
<td>Mixed</td>
<td>5/17 (29.4)</td>
<td>0.26 (0.09-0.78)</td>
<td></td>
</tr>
<tr>
<td>Education Level (n=299)</td>
<td></td>
<td></td>
<td>0.95</td>
</tr>
<tr>
<td>School leaver</td>
<td>53/89 (59.6)</td>
<td>1.00</td>
<td></td>
</tr>
</tbody>
</table>
7.5.3 Q3. Were there different patterns of use by demographic characteristics?

Overall, the two sections of the website that had the highest number of visits were: (1) My health records; and (2) Staying healthy. There was no evidence of differential use of the programme by any demographic group, apart from education level, where there was weak evidence of an association between education level and visits to “Living and working with diabetes” section (p=0.03) (Figure 7-5), and the “Treating diabetes” section (p=0.04) (Figure 7-6). The difference between people educated to secondary school level and people with an undergraduate degree was small (34.3% of users who visited the “Living and working with diabetes” had an undergraduate degree, and

<table>
<thead>
<tr>
<th>Education Level</th>
<th>Visits</th>
<th>Odds Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A-level or equivalent</td>
<td>36/64 (56.3)</td>
<td>0.87 (0.46-1.67)</td>
</tr>
<tr>
<td>Undergraduate degree or equivalent</td>
<td>61/102 (59.8)</td>
<td>1.06 (0.59-1.90)</td>
</tr>
<tr>
<td>Postgraduate degree or equivalent</td>
<td>26/44 (59.1)</td>
<td>0.98 (0.47-2.05)</td>
</tr>
<tr>
<td>Age Group (n=334)</td>
<td></td>
<td>0.54</td>
</tr>
<tr>
<td>22-50</td>
<td>49/96 (51.0)</td>
<td>1.00</td>
</tr>
<tr>
<td>51-59</td>
<td>62/111 (55.9)</td>
<td>1.21 (0.70-2.10)</td>
</tr>
<tr>
<td>60-69</td>
<td>50/107 (46.7)</td>
<td>0.84 (0.49-1.46)</td>
</tr>
<tr>
<td>70-93</td>
<td>44/80 (55.0)</td>
<td>1.17 (0.65-2.13)</td>
</tr>
</tbody>
</table>
32.9% were educated to secondary school level; 34.9% of users who visited the “Treating Diabetes” section had an undergraduate degree, and 33.3% were educated to secondary school level. The proportion of users who visited both sections with A Levels or postgraduate degrees was much lower. Detailed results are given in the appendices.

**Figure 7-5: Proportion of visits to the “Living and working with diabetes” section of the HeLP-Diabetes by education level**
7.5.4 Q4. Is there evidence of an overall difference in use between the HDSO programme and the HeLP-Diabetes website?

The overall number of visits to the HDSO programme and the various sections of the HeLP-Diabetes website are summarised in Table 7-5 and Figure 7-7. The most frequently visited section was “My health records”, followed by “Staying Healthy”, “Profile, Admin, Log in, Log out, Register”, “Home Page” and then HDSO. Excluding “Profile, Admin, Log in, Log out, Register” and “Home Page” as these are mandatory to view when users login to the site, HDSO was the third most frequently visited section. Detailed data on webpage visits is given in Appendices J-M.
Table 7-5: Overall number of page visits to each section of the website

<table>
<thead>
<tr>
<th>Website Section</th>
<th>Overall number of page visits</th>
</tr>
</thead>
<tbody>
<tr>
<td>My health records</td>
<td>1377</td>
</tr>
<tr>
<td>Staying Healthy</td>
<td>1223</td>
</tr>
<tr>
<td>Profile, Admin, Log in, Log out, Register</td>
<td>1069</td>
</tr>
<tr>
<td>Home Page</td>
<td>1029</td>
</tr>
<tr>
<td>HeLP-Diabetes: Starting out</td>
<td>1004</td>
</tr>
<tr>
<td>Understanding Diabetes</td>
<td>856</td>
</tr>
<tr>
<td>Forum and Help (includes blog)</td>
<td>540</td>
</tr>
<tr>
<td>Living and Working With Diabetes</td>
<td>455</td>
</tr>
<tr>
<td>Treating Diabetes</td>
<td>374</td>
</tr>
<tr>
<td>Managing My Feelings</td>
<td>261</td>
</tr>
<tr>
<td>Miscellaneous Articles</td>
<td>221</td>
</tr>
<tr>
<td>News and Research</td>
<td>137</td>
</tr>
</tbody>
</table>
7.6 Discussion

7.6.1 Summary of main results

This study aimed to determine whether there was evidence of a digital divide when HDSO and HeLP-Diabetes were integrated into routine care. There was a lack of strong evidence of differential patterns of registration, or patterns of use by age, gender, educational attainment or ethnicity. There was weak evidence that people from the mixed ethnicity group were less likely to use the programme than the white group, due to the confidence intervals not including 1 despite the p-value (OR=0.26, 95% CI=0.09-0.78, p=0.12). There was also weak evidence of differences in visits to the “Living and working with diabetes” and “Treating diabetes” sections of the website by education level (p=0.03 and p=0.04). The highest proportion of users who visited these sections of the website, were those with an undergraduate degree, but this was closely followed by people with secondary school level education.

HDSO was the fourth most popular section of the eleven website sections, and the third most popular of the ten non-mandatory sections of the website.
7.6.2 Strengths and limitations

Individuals were offered use of HDSO as a NHS service, and not as a research study. There are advantages and disadvantages to this approach. Firstly, an advantage is the insight this offers into ‘real world’ use of the programme in standard practice, rather than generating data from a highly controlled research setting, such as a randomised controlled trial (RCT). The evaluation of an intervention in practice is more likely to include a broad representation of the population at risk (354), and therefore have greater external validity than RCTs. The limited generalisability of trials of T2DM self-management training has been highlighted in reviews (40, 355), and attributed to the volunteer nature of RCT participants, and the lack of reporting of the representativeness of study populations.

Real world data allows for the heterogeneity of included patients, and contextual factors including the doctor-patient relationship. The outcome of activities such as patient education, physiotherapy or community nursing, in contrast to drug treatments, are highly dependent on the characteristics of the provider, setting and patients (125). The health care professionals, setting and patients in this study would have reflected the target population, whereas in a RCT these factors would have been more uniform due to the research protocol, interests of participating health care professionals, and patient inclusion and exclusion criteria for the trial (125, 354). A strict research protocol must be adhered to in RCTs, but in routine practice treatment is tailored to patients’ individual problems and needs (354). The exclusion criteria of trials often exclude patients with comorbidities and varying levels of disease severity, leaving a group of eligible patients who represent a small proportion of patients treated in normal practice (125). A literature review on the representativeness of RCT samples and implications for the external validity of trial results (356) has found that RCT samples are highly selected and exclude elderly patients and patients with co-morbidities. A high proportion of the general disease population are excluded from trials. RCT samples are not representative of real-world patients and this limits external validity (356).
There are also disadvantages of studying interventions in routine practice. When determining treatment effects, lack of randomisation can introduce bias. Important sources of bias are selection bias, confounding, recall bias, performance bias, attrition bias and detection bias (357, 358). These can give biased estimates of treatment effects (358). Studies in routine practice can be helpful in detecting potential effects but random allocation to intervention and control groups in RCTs, is necessary to minimise bias and provide reliable estimates of effect (357). Determining treatment effect was not one of the aims of this study, and therefore random allocation and bias were not as relevant. Non-experimental approaches to complex intervention evaluation have been suggested by the MRC (44) when implementation in the health service is already underway, and in this case quasi-experimental or observational study designs can be considered (44). Quasi-experimental studies have been identified in systematic reviews of studies looking at engagement with digital behaviour change interventions (241), and provide a contribution to the evidence. The limitations of both experimental and non-experimental studies need to be recognised and employed appropriately to meet the study objectives.

Actual website visits were measured, in addition to number of people who registered to use the programme, and the proportion who actively used the programme (logged in at least twice). There are other subjective and objective measures that could have been used. Subjective measures include self-report questionnaires, qualitative approaches such as interviews and think-aloud methods (241). Such measures can provide insight into the user’s experience of the digital intervention, and answer questions such as “why” the intervention was or was not used. However, these methods rely on memory and may result in bias from social desirability. Physiological measures can also be used to measure engagement with a digital intervention, such as cardiac activity, respiratory depth and electro-dermal activity (241). Physiological measures were not appropriate for this study, as my aim was to look at patterns of webpage visits rather than physiological stimulation. Other objective measures that I could have used include time spent online. However, time
spent online is not necessarily a reliable measure given that people can leave their computers whilst still logged on to the programme.

A limitation of the research is the total number of participants (n=334). This may limit the power of the study to detect significant differences between demographic groups. It would have been possible to increase the number of participants by including the data collected after self-registration was introduced in January 2017. However, I found that the number of people who provided data on gender, ethnicity and education decreased to 59.1% after self-registration was introduced, and so these data were not included.

The profile, admin, logout and registration pages were not included in the analysis of webpage visits. It was a strength of the research that these pages were excluded as they don’t tell us much about use of the educational content. The login and home pages could also have been excluded for the following reasons. They have to be visited before accessing any of the educational materials on the website, therefore data on visits to these pages (like the profile, admin, logout and registration pages) do not tell me as much about use of the programme as an educational tool. My data may include people who logged in and only viewed the home page, and comparing people who did not visit the programme at all with people who only visited the login and home pages may not be a valuable comparison, as both groups are not using the programme as intended (for educational purposes). It could be argued that people who only visited the login and home pages should be grouped with the ‘active’ users of the programme as they engaged with the programme more than people who did not login in to the programme at all. Alternatively, ‘active’ users could have been defined as people visiting the login page, the home page and one page in at least one other section.

7.6.3 Comparison with existing literature

The finding of a lack of association between demographic factors and use of the online programme, is inconsistent with a systematic review of patterns of user engagement with mobile- and web-delivered self-care interventions for adults with T2DM (359), which found lower rates of engagement in older adults
and people with lower health literacy and lower education (359). The review included a study of use of a mHealth medication adherence promotion intervention for low-income adults with T2DM (360). Participants received daily text messages assessing medication adherence. The authors found that responding to texts tended to increase from about age 25 until roughly age 50 years, and then appeared to decrease as age increased (360).

The finding is also inconsistent with a systematic review of electronic portal usage among patients with diabetes (361) which suggests that demographic factors such as higher education, younger age, higher income, and non-Hispanic, non-black race were associated with higher portal utilisation. An electronic patient portal is an online personal health record which provides patients with information from their provider’s electronic health record system, as well as information they add themselves (361).

The finding of a lack association between demographic factors and use of the online programme (except the weak evidence of association with ethnicity) is consistent with a qualitative study in five countries of people with high and low levels of health literacy about a digital intervention to promote physical activity for diabetes (335). Participants were recruited from areas and clinics with high levels of deprivation. The mean age of the participants was 65. Most participants found that the design of the intervention was acceptable and engaging. The findings suggest that it is possible to design digital health interventions that appeal to a diverse population, including people with low literacy and health literacy levels.

I found that the most frequently visited section was “My health record”, followed by “Staying healthy” on the HeLP-Diabetes website, and then the structured HDSO programme. “My health record” section of the HeLP-Diabetes website gives users the opportunity to record their care plan, test results, appointments as well as their weight, waist circumference diet and other personal observations. The “Staying healthy” section of the HeLP-Diabetes website gives users information about making healthy lifestyle changes like eating well, being physically active and moderating alcohol intake. The overall number of page visits suggests that a structured pathway
is a popular choice for users, but there is also high use of sections which allow users to interact, record personal information and learn about lifestyle. This is consistent with reviews which suggest web-based interventions which increase the personal relevance of the health messages given increase engagement (359, 362). The findings are also consistent with one of the themes of my qualitative data from Chapter 6 which was that personalisation may facilitate improved engagement.

Data on visits to HeLP-Diabetes and the structured HDSO programme were combined. HDSO was considered to be one section of the website as a whole, alongside the other sections of the website (including “Staying healthy”, “My health record” etc). As an alternative, visits to the HDSO programme could have been analysed separately, and visits to the four modules of the structured programme could have been analysed individually. I chose to compare visits to HDSO with the other sections of the HeLP-Diabetes website primarily because one of the aims of the study was to compare use of HDSO with other sections of the HeLP-Diabetes website, to see if people preferred structured and unstructured education. If the other sections of the HeLP-Diabetes website all received more visits than the HDSO section, this might suggest that people prefer unstructured learning. But I found that HDSO was the third most visited section of the eleven non-mandatory sections of the website, suggesting that it was popular. Categorising HDSO as a section of the HeLP-Diabetes website also reflected real life use of the website for users, as they were referred to use HeLP-Diabetes as a whole package, including the structured and unstructured components, and could access HDSO once they logged in and visited the homepage of the HeLP-Diabetes website. All the other sections of the HeLP-Diabetes website were also available to users from the home page.

7.6.4 Implications

The findings of this study suggest that HeLP-Diabetes and HDSO can be used by people from different demographic groups, and hence it is possible for digital health intervention to be designed to narrow the digital divide. This is
important to enable equity of access to health information and support, and to prevent widening health inequalities.

As discussed previously, barriers to equitable use of digital eHealth interventions include (1) lack of access to information technology; (2) adequate skills to use the technology including health and computer literacy; (3) the motivation to go online and use digital interventions; and (4) lack of trust in internet security. The success of the intervention may therefore come from addressing some of these barriers:

1. The intervention was designed carefully using participatory design techniques, extensive user input, consideration of literacy levels and use of audio-visual media (141). This enabled people with low health and computer literacy to use the intervention, and this was reflected in the data which showed that nearly a third of people who registered to use the programme had no qualifications beyond secondary school, and there was no association between education level and use of the programme.

2. Motivation and lack of trust may have been, at least partially, addressed by integration of the programme into routine NHS care. Health care professionals working with the target population were able to discuss and recommend the programme, which may have increased patients’ motivation to access and engage with it. Recommendation from a trusted source may have helped address patients’ fears about security, and the affiliation of the programme with an academic institution may also have helped.

Access to information technology was not addressed by the intervention, and this is a challenge that needs to be tackled by both the government and developers if plans to digitalise the NHS are to proceed. The evidence that smartphone use is increasing more rapidly than other devices, and that people from low socioeconomic groups prefer using smartphones to access the internet, provides an opportunity for developers to increase access to digital health by designing mHealth interventions for this user group. Further research into the delivery of HeLP-Diabetes as smartphone application, as also suggested by the qualitative findings in Chapter 5, is needed.
7.7 Conclusion

This study of the use of HDSO and HeLP-Diabetes in routine NHS care suggests that it is possible to design digital health interventions that can be used by different demographic groups and narrow the digital divide. Developers of digital health interventions should be mindful of the needs of different demographic groups in their design process, and involve users of different backgrounds at each stage of development. Research on evaluation of digital health interventions should include collection of data on the demographic profile of users, and the use (or other engagement measure) of the intervention by different demographic groups. Access to information technology, increasing skills in using information technology (computer literacy), and improved internet security also need to be addressed if the digital divide is to be overcome.
Chapter 8. Reducing Attrition

8.1 Chapter summary

Chapter 4 described the evaluation of the first iteration of the HDSO programme, and Chapter 5 described the subsequent changes made to the programme to improve uptake and completion (reducing the number of sessions in the programme; reducing the number of questionnaires; inviting all patients with T2DM to register; and online registration). As well as these changes made to the programme, I developed other strategies for reducing attrition and improving completion rates which I tested during the evaluation of the second iteration of the HDSO programme. These strategies included telephone reminder calls to patients, and incentives.

I have started this chapter by reviewing some of the evidence for strategies to reduce attrition from online self-management interventions for long-term conditions. I have then described the strategies I implemented, and finally I have presented the outcomes from implementing these strategies. I have also included the protocol for a pilot randomised trial of personalised emails, and explained my reasons for not conducting the study.

8.2 Background

8.2.1 Defining attrition

eHealth interventions have many potential advantages to face-to-face alternatives, including convenience and anonymity. However, researchers have found adherence to eHealth interventions to be a challenge. Some eHealth interventions have seen attrition rates of up to 80%, and it has been suggested that attrition is one of the fundamental challenges of evaluating eHealth interventions (240).

Attrition has been defined as either dropout attrition and nonusage attrition in studies of eHealth interventions (240). Dropout attrition refers to low retention of study participants and loss to follow-up (240, 363). Nonusage attrition refers to low adherence due to study participants not using or not continuing to use
an intervention (240, 363). Non-usage attrition is illustrated in Figure 8-1 below. The curves show that the proportion of users of two eHealth interventions drops after the initial interaction (240).

Figure 8-1: Nonusage attrition curves for two studies of eHealth interventions. The number of completed modules are plotted against the proportion of participants completing them.

As patients registering for the HDSO programme were using it as a NHS service rather than joining a research study, it was nonusage attrition (low
adherence) that were challenges for the HDSO programme. Non usage attrition is the type of attrition that I have discussed in this chapter.

8.2.2 What is the evidence that attrition from eHealth interventions exists?

The evidence for attrition from eHealth interventions is mixed. Systematic reviews of attrition from internet interventions for psychological disorders and problem drinkers (258, 364, 365) have found that adherence rates were 30-50%, and compared favourably with face-to-face programmes. In contrast, Wangberg et al (366) collected data on adherence rates in three internet-based trials and reported only 0.8% of people making it to the end of a one-year intervention for smoking cessation, and only 2% of people reporting having used an internet-based personal health record more than once. The trials involved three different internet-based interventions: one for T2DM self-management support, one for smoking cessation support and one offering an online personal health record. Logging of web use, number of logins and time spent at the site, were used as measures of adherence in two of the trials, and authentication of SMS messages was used as the measure of adherence in the third trial. In all three trials many participants never used the intervention, many participants used the interventions only once or twice, and a few used the interventions to completion (0.8% in the smoking intervention trial) (366).

There is evidence of attrition from interventions for panic disorder (86), depression (87), weight loss (88, 89), smoking cessation (90-92), problem drinking (93), and other diabetes self-management programmes (94). The interventions which contained modules for people to work through, similarly to the HDSO programme, found a small proportion of the people who registered completed all the sessions. 1.03% completed all 12 sessions of a web-based cognitive behavioural therapy (CBT) programme for panic disorder (367), and 15.6% completed two or more modules of a web-based CBT programme for depression (87). Studies of other online diabetes self-management interventions have found that use of the programmes decreases over time (84, 94). The authors of the CBT studies suggested that the high attrition may
reflect the usability of the site, the acceptability of CBT-type interventions, and users’ commitment to change and symptom level, amongst other factors (87). Intervention factors that affect attrition are discussed further below.

The findings from these studies suggest that attrition can be a problem for eHealth interventions. There are other issues raised in the literature. The study of the D-Net intervention for T2DM (94) found improvement in most outcomes despite decrease in use of the intervention over time. The Wangberg study of the tailored self-efficacy intervention found no relationship between time spent on the site and improvement in self-care and perceived usefulness (84). The relationship between use of interventions and outcomes is discussed further below.

A review of the effectiveness of prompts to promote engagement with digital interventions (227), suggested that the small effect sizes seen in studies of the effectiveness of digital interventions may have been a result of non-use, or insufficient use, due to lack of engagement. Technology-based strategies were found to have a borderline positive effect on engagement, compared to no effect, and strategies to reduce attrition from digital interventions are discussed further below.

The studies described above suggest a mixed picture for adherence to eHealth interventions. Some studies suggest reasons for poor adherence may be due to the patient (e.g. commitment to change), or the intervention (e.g. usability of the site) (368). Attrition may not be a problem that is unique to digital interventions, but it may be better reported in the eHealth literature. For example, patients are regularly referred to face-to-face services such as physiotherapy in the NHS, but less data is collected on attendance at these services. Attrition levels (non-attendance at the service following referral) may actually be quite similar. NHS Digital uses the Hospital Episodes Statistics (HES) data to report data on attendances, but does not include data on referrals. HES showed that in 2016-17 the ratio of non-attendances to attendances for outpatient physiotherapy was 0.1 (369). There are no data available on the number of DNAs and attendances.
8.2.3 Why is attrition a problem for eHealth interventions: the relationship between attrition and outcomes

Attrition is a problem for eHealth interventions because their aim is to affect meaningful changes in behaviours, and if people stop using them there is a risk that this will not be achieved. We do not know for how long or how frequently people need to use eHealth interventions to affect meaningful changes, and what the relationship between adherence and outcomes looks like. Systematic reviews have been undertaken which suggest there is an association between adherence to eHealth interventions and outcomes. A systematic review of the impact of adherence on the effectiveness of e-therapies (347) found that interventions targeting physical outcomes showed a dose-response relationship. The authors used several measures of adherence: number of logins, completed modules or activities, visits made to forums, posts made to the forum, pages viewed and printed, and self-reported completion of activities away from the program or offline (347). All measures of adherence were correlated with improvements in physical outcomes, similarly to the dose-response relationship seen in medication therapy. However this conclusion is made weaker by the heterogeneity of the outcome measures. Number of logins correlated best with physical outcomes, and module completion correlated best with psychological outcomes (347). A systematic review of website-delivered physical activity interventions found that interventions with more than five “contacts” (email, weekly module, chat session, or guidance from online coach) had more positive outcomes in physical activity (88).

Data from the randomised controlled trial of the HeLP-Diabetes website also suggests an association between exposure to the intervention and outcomes. The overall mean reduction in HbA1c was −0.24% (95% CI −0.44 to −0.049; p=0.014) (143). Causal analyses estimated that the ‘high usage’ group (those who accessed the website on more than the median of 4 days), could on average reduce HbA1c by −0.44% (95% CI −0.81, −0.06) and PAID distress scores by −2.8 (95% CI −7.2, 1.7) over 12 months (141).
It is possible that the association between exposure and effect is due to reverse causality, which is when the user experiences better outcomes so becomes more engaged. This makes it harder to confirm that increased use of an intervention results in greater effect. It is also possible that early improvement could lead to disengagement as the user may feel they have learned all they need to know, and do not need to keep using the intervention. However, on balance it is likely that there is at least an association between exposure and effect. What dose of the intervention is needed to give the intended outcome (the effective dose) is also under question. Although some eHealth interventions are designed for participants to complete from start to finish, such as a programme with weekly modules, it may be that participant activity does not need to match the usage pattern for which the intervention is designed. The discussion about what constitutes ‘effective’ or ‘sufficient’ engagement is expanded on in Chapter 11.

In order to improve engagement, it is important to consider factors that influence attrition, and strategies that might be implemented to improve attrition, as discussed below.

8.2.4 Factors that influence attrition

8.2.4.1 Features of the individual users

Features of the individual users that influence attrition can be categorised as demographic, clinical or psychological. These categories reflect the hub of the behaviour change wheel (described in Chapter 3), which identifies the conditions necessary for behaviour change (171). As discussed in Chapter 7, there is concern that some groups are less likely to use eHealth interventions than others, leading to a potential digital divide. There are studies which suggest that demographic features may be related to frequency of logins (240, 363). In the secondary analysis of data from an online trial of an alcohol intervention being older, female, having a university degree, and not having children were all associated with more frequent logins and provision of follow-up data (363). Lower socioeconomic status and less contact with a change agent have been suggested as predictors of discontinuation of use (240, 370).
Data on the demographic and clinical features of users of HDSO were therefore collected to look for evidence of a divide. The data presented in Chapter 7 showed that there were no particular demographic groups who were more likely to register for or use HeLP-Diabetes and HDSO. Nor was there any evidence of preferential use of any of the sections of the website. The data in Chapter 6 showed that despite problems with uptake and completion, there were no demographic and clinical features associated with completion of the programme, other than duration of diabetes, and having been offered and attended face-to-face education.

**8.2.4.2 Features of the intervention**

The characteristics of the intervention also affect attrition. A model of diffusion of innovation has been suggested by Rogers (370), which discusses how new ideas are spread and adopted. Rogers suggests that characteristics of the innovation play a role in the decision to stop using it. For example, users are more likely to stop using an innovation if it is not perceived as creating any benefit (relative advantage), or if there are usability problems (complexity) (240).

**8.2.4.2.1 Reminders**

Other factors which influence attrition are reminders. Sending reminders is a way of providing support. Reminders can be given in person, via telephone, text message or email. They can come from another person, or they can be automated.

**Reminders from humans**

Sending people reminders is one way of providing support from another human. Reminders which afford people personal contact, and buy-in from change agents (people who promote the innovation, such as health professionals), can encourage people to continue using an innovation (240). A 2011 review looking at methods to promote exposure to internet interventions promoting a healthy lifestyle, found that email and telephone contact were related to more logins to the intervention website. However, a variety of behaviour change techniques and exposure-promoting methods...
were used, and the results were too heterogeneous to do a meta-analysis. (226).

A 2011 paper by Mohr et al explored why human support may enhance adherence to eHealth interventions (371). The authors proposed a theoretical model called “Supportive Accountability” which is based on organisational psychology, motivation theory and computer-mediated communication research, and can be used to guide research on human support components in eHealth interventions (371). The concept of accountability is central to the model (see Figure 8-2) and refers to the expectation of being called up to justify one’s actions or inactions (372).

**Figure 8-2: Model of Supportive Accountability**

Reproduced from:
Mohr D, Cuijpers P, Lehman K
Supportive Accountability: A Model for Providing Human Support to Enhance Adherence to eHealth Interventions
J Med Internet Res 2011;13(1):e30
DOI: 10.2196/jmir.1602
PMID: 21393123
PMCID: PMC3221353
This is an open-access article distributed under the terms of the Creative Commons Attribution License (http://creativecommons.org/licenses/by/2.0/), which permits unrestricted use,
There are several factors which contribute to accountability, including the presence of another human being in person, by telephone or by email (social presence). Each has its own advantages, for example text messages have the advantage of reaching users at any time or place and do not require login to access. But text messages can also be seen as intrusive for the same reasons (373). Emails provide limited cues to patients which can lead to patients forming a more positive impression of the coach. People may also find it easier to discuss difficult topics via email. Talking to patients on the telephone can provide a greater presence, but is time-consuming especially if multiple calls are needed to get in contact with the intervention user.

The model of supportive accountability proposes that clarity about what is expected from the user facilitates adherence. Expectations that are process-focused e.g. completion of My Health Record or number of logins to site, are more helpful as they focus on what the patient is actively doing. Performance monitoring can be helpful if the aim is to provide feedback and an opportunity for self-reflection. Legitimacy of the coach is also vital. The coach must be seen as trustworthy and having the necessary expertise. There is an expectation of reciprocity and defined patient and coach roles.

Motivation has been defined as giving behaviour direction or goals, and determining the strength or energy behind behaviour (371). The literature on human motivation suggests that it originates from internal (or intrinsic) and external sources, that can complement or compete with each other to influence behaviour (374). Actions which are motivated by external rewards are extrinsically motivated, through a neural learning system which is reinforced by outcomes. Less is known about intrinsic motivation, but it is thought that actions are intrinsically motivated if we engage in the behaviour for its own sake, without attempting to gain external rewards (375). Self-determination theory (SDT) is an established theory of motivation that focuses on self-determined, intrinsic motivation. But it also suggests that external
factors can modify intrinsic motivation, and that the determinants of motivated behaviour lie on a spectrum from internal to external. In the context of providing support to increase adherence to eHealth interventions, patients with higher levels of intrinsic motivation may not need support to continue using interventions. Patients without high levels of intrinsic motivation may need facilitative support and help with self-monitoring, self-reflection and problem-solving in order to continue using interventions (371).

**Automated reminders**

Automated reminders provide a cost- and resource-effective way of providing contact with intervention users. However, evidence for effectiveness at improving adherence is poor. A 2016 review of the effectiveness of prompts (automated and non-automated) to increase use of digital interventions found that studies reported borderline small-to-moderate positive effects for the technological strategies to improve use of interventions, as supposed to using no strategy (227). However high heterogeneity was found again, there were small sample sizes and there was a lack of statistical significance in the analysis of continuous outcomes (227). Three trials included in a study of adherence in internet-based interventions resulted in increased use of the intervention when automated email reminders were sent to participants (366). Other reviews have suggested that automated systems are significantly less effective at enhancing adherence (376, 377), than reminders that provide human support.

**8.2.4.2.2 Incentives**

Another strategy for improving engagement is the use of incentives. Incentives have potential as an external reward that could increase internal motivation.

There is some evidence to suggest that incentives are effective at improving retention in randomised trials (378), and questionnaire responses (379). A systematic review of strategies to improve retention in randomised trials found that small monetary incentives (GBP 5-20) improved the return of trial-related postal questionnaires, compared with no offer of incentive (378). The payment was small so that it was not perceived as payment but as a token of
appreciation. Non-monetary incentives (e.g. gifts such as pens, certificates, charity donations, or offer of study results) showed no effect (378). The authors suggested that this may be due to how gifts are valued by participants, and whether they are seen as adequately compensating participants’ time. A review of methods to improve response to postal and electronic questionnaires found that the odds of response at least doubled when monetary incentives were used. The amount of money offered varied, and the relationship between questionnaire response rate and amount of money was not linear. The odds of response were also increased with a non-monetary incentive (379). The non-monetary incentives included key-rings, lottery tickets and offer of study results. Although these two reviews looked at response rates in trial populations, it is plausible that similar incentives may also work in the context of engagement with interventions.

Incentives have been used to encourage behaviour change such as smoking cessation. They can be used to encourage recruitment onto a programme (incentives for participation in the intervention) or to reward achievement (incentives for the desired behaviour change). A variety of incentives have been used including monetary incentives, or gifts such as pens, bags, lottery tickets or luxury goods. NHS Tayside in Scotland used an incentive scheme to encourage pregnant mothers to stop smoking in 2007. ‘Give it Up for Baby’ was a scheme that offered £12.50 in grocery vouchers for negative weekly carbon monoxide breath tests (380). 140 women stopped smoking in the first year of the programme, and higher engagement and quit rates were achieved than other non-incentive based smoking cessation interventions for pregnant women in Scotland (380). However, the long-term effectiveness, particularly after the incentives have been withdrawn, has not been determined. If incentives are targeted at adherence to the intervention rather than the behaviour, they may not lead to long-term behaviour change.

A Cochrane review of incentives for smoking cessation has shown weak evidence for quit rates with incentives (381). Only one out of nineteen studies found higher quit rates for the incentive group compared to the control group beyond six months. This trial offered participants significant monetary
incentives (up to 750 USD) for prolonged abstinence (382). The review showed some evidence that incentives improved recruitment onto the intervention programmes (381).

More research in the use of incentives for health behaviour change is needed. It has been argued that rewards are experienced as controlling and can reduce intrinsic motivation (383). Other researchers argue that the effectiveness of incentives could be due to the way they help move the rewards of healthy behaviours forward in time, and serve as a proxy for the reward of the long-term outcomes. As noticeable positive changes in outcomes start to appear, they can drive motivation for self-care from being externally motivated (by rewards) to intrinsically motivated (384).

8.2.5 Strategies used to reduce attrition from HDSO

I decided to test two strategies to try and increase the number of people completing the programme. The strategies I used were telephone reminders and an incentive.

8.2.5.1 Telephone reminders

I chose reminders because the theories of supportive accountability, and self-determination, suggest that reminders can improve adherence to eHealth interventions by acting as an external factor which modifies intrinsic motivation to perform a behaviour.

I also based my decision on the evidence to support these theories. I found evidence that reminders provided by telephone, email or text message improve adherence and reduce attrition to a variety of eHealth interventions (87, 226, 227, 366). I chose telephone instead of email, because automated email reminders were already being sent to patients (as described in Chapter 3). Telephone calls also meant personal contact with people, which, as the model of supportive accountability suggests, provides a social presence, helps people with self-monitoring, and adds expertise and trustworthiness, all of which contribute towards greater adherence.
8.2.5.1.1 Incentives

The second strategy I chose to help improve patient adherence was incentives. As described above, there is some evidence that participants are more likely to continue using an intervention if they perceive a relative advantage to doing so (240, 370). Incentives can act as an external reward which increases intrinsic motivation by acting as a proxy for achieving longer-term outcomes. Offering an incentive was a way to give patients an additional benefit to completing the HDSO programme, and to increase their intrinsic motivation. The qualitative data collected thus far suggested that a way to increase perceived value of completing the programme and motivation to do so, was needed.

Characteristics of effective incentives

Motivation theories like the SDT, suggested that incentives that can modify intrinsic motivation should be used. Some incentives could be seen as controlling and do not increase intrinsic motivation. Incentives which support self-reflection and problem-solving, may encourage people with less intrinsic motivation to continue using an intervention.

The evidence from successful use of incentives suggested that small monetary incentives, which are not perceived as payment but as a token of appreciation, are effective. Non-monetary incentives such as key-rings, lottery tickets, offer of study results and grocery vouchers have also been effective in improving adherence to the intervention. It seemed from the evidence that small rather than large incentives, which were perceived as a token of appreciation rather than a payment or controlling, were more effective. All of these options were considered as incentives for the HDSO programme.

Selection process for incentives used in the study

I considered the incentives with evidence of effectiveness listed above, and ideas that I developed with the HeLP team which were derived from the resources we had available to us. These included incentives for health professionals to encourage them to inform patients about the programme, and incentives for patients to encourage them to complete the programme.
Incentives for health professionals

I considered incentives for health professionals as well as patients. This was because implementation theories like the NPT (see Chapter 2), suggest that successful implementation of new interventions requires making them routine practice (embedding) within the health service, by understanding what health professionals do and how they work. The intervention then needs to be sustained within the health service by embedding it into the social context (integration). For HDSO to be successfully implemented in the health service, we needed to understand the health professionals who were offering it to patients, how they worked and how to embed it within their routine practice and social context.

We considered holding education events in GP surgeries where the DSNs working with the HeLP team could provide education on diabetes self-management and explain the HDSO programme and how to refer patients to it. This could also have been an opportunity to talk to health professionals about how we could make it easier for them to fit the HDSO into their routine practice and social context.

The DSNs contacted practice managers to ask for expressions of interest. Although there was interest in the events, there were logistical problems with finding a time that was convenient for both staff at the surgeries and the DSNs. Also, there are a large number of practices within each CCG and not all practices could be visited to deliver an event. It was therefore decided against offering educational events.

Incentives for patients

Incentives for patients can come in monetary and non-monetary forms. We did not have the budget to offer monetary incentives, and did not feel it was ethical to do so anyway. Non-monetary rewards such as pedometers were considered but not offered to patients, again due to budget constraints. Once again I considered the resources available to me, and recognised the expertise we had within the team as a valuable commodity. I knew from my telephone calls with patients that dietary information was perceived as highly
valuable to them. I thought about how I could provide personalised dietary advice to patients. There was an experienced diabetes dietician who worked with the HeLP team to develop content for the HeLP-Diabetes website and forum. I asked the dietician if she would offer patients who completed the programme a ten minute phone call answering questions they had about their diet and providing personalised advice. The dietician agreed, and as this did not require any additional resources or budget, it was decided to offer the telephone calls with the dietician as an incentive for patients to encourage them complete the programme.

In the next section I have explained how I implemented the telephone reminders and incentive, and how I evaluated the impact of these measures on adherence to the programme.

8.3 Aims & Objectives

The aim of this study was to determine the impact of strategies to reduce attrition from the HDSO programme. Specific objectives were to determine:

1. The impact of telephone reminders on the proportion of active users of the programme, and the proportion of completers.
2. The impact of an incentive (offer of dietician telephone consultations) on the proportion of active users of the programme, and the proportion of completers.

8.4 Methods

8.4.1 Study design

This was a single-arm study of participant activity and programme completion pre- and post-intervention, using data collected via the online programme.

8.4.2 Ethics

The evaluation of the first iteration of HDSO had ethical approval from the Health Research Authority (reference number 159488, see Appendices A-C).

This study used data collected as part of routine service delivery. The use of the data on registrations and patient activity generated through the online
programme was permissible under the HRA clause that secondary use of information collected in the course of normal care is generally excluded from REC review.

When contacting people by telephone, I explained the purpose of the calls and gained verbal consent if people were happy to proceed. I explained that I was taking notes and that these would be anonymised in order to maintain confidentiality.

8.4.3 Telephone reminders

8.4.3.1 Participants

I selected patients who had been inactive (had not logged into the programme) for over 2 weeks for telephone reminders. I selected this group of patients as the data I had collected from the previous studies showed that this was predictive of non-usage of the intervention.

8.4.3.2 Recruitment

I identified who had been inactive for over 2 weeks by analysing the database of patient activity every week and filtering patient ID numbers by date of last activity. Each week I made a list of all the registered patients who had not been active for over 2 weeks, and contacted these patients.

8.4.3.3 Intervention

As illustrated in Figure 8-3, once I identified patients who had been inactive for over 2 weeks, I made three once weekly phone calls to each of them. Three phone calls were made so that if I could not speak to someone the first time I called, there were two more opportunities to speak to them. When I was able to speak to someone the first time I called them, the second and third calls allowed me to support the user with self-monitoring (a feature which contributes to adherence according to the theoretical model of Supportive Accountability).

Telephone calls were scripted with questions based on the theory of motivational interviewing (see Table 8-1 for script). Motivational interviewing (MI) is a method for interacting with patients to enhance behaviour change
which has strong evidence of effectiveness, particularly in substance abuse. It focuses on readiness for change and understanding the client’s view. Techniques include listening reflectively, eliciting motivational statements, examining both sides of ambivalence and reducing resistance by not forcing change prematurely (385).

The script for the telephone calls followed these principles because I wanted to understand people’s views on why they couldn’t start or complete the programme, understand how ready they were to use the programme and help them to start using the programme if they were ready.

Table 8-1: Script for telephone calls to inactive users

<table>
<thead>
<tr>
<th>Patient ID:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of call:</td>
</tr>
<tr>
<td>Barriers: Have you had any problems getting started with the programme? Is there anything stopping you?</td>
</tr>
<tr>
<td>How could we help you get past some of the difficulties you are facing?</td>
</tr>
<tr>
<td>What would you have to do differently to use the programme regularly?</td>
</tr>
<tr>
<td>Importance: On a scale of 1 to 10 how important is it for you to learn about your diabetes? Why did you choose that number?</td>
</tr>
<tr>
<td>What would you need to happen to move from [score_given] to [higher_score]?</td>
</tr>
<tr>
<td>Confidence: On a scale of 1 to 10, how confident do you feel about using HeLP-Diabetes:Starting out? Why did you choose that number?</td>
</tr>
</tbody>
</table>
What would you need to happen to move from [score_given] to [higher_score]?

Calls expected to last up to ten minutes, and I made notes on people’s responses in a spreadsheet with an ID number and the date of the call. Telephone calls were ceased once the patient became active (logged into the programme) or after three phone calls. Figure 8-3 illustrates when telephone calls were initiated (if a user was inactive for 2 weeks or more), and when calls were ceased (after 3 calls).

**Figure 8-3: Flowchart illustrating when telephone calls to users were initiated and ceased**

- **ALL**
- **ACTIVE**
- **INACTIVE**

- Participant responds by progressing
- Weekly automated email reminders
- Participant completes programme
- Weekly automated email
- Participant doesn’t progress
- Active after <2 weeks
- No activity >2 weeks
- Participant responds by progressing
- Total of 3 x weekly phone calls to remind participant about the programme & encourage completion
- Participant doesn’t progress
- No further telephone calls

Participant responds by progressing

Weekly automated email reminders

Active after <2 weeks

No activity >2 weeks

Participant responds by progressing

Total of 3 x weekly phone calls to remind participant about the programme & encourage completion

Participant doesn’t progress

No further telephone calls
8.4.4 Incentive: Offer of dietician telephone consultations

8.4.4.1 Participants
The dietician telephone consultation was offered by email to all patients registered with the programme (see recruitment).

8.4.4.2 Recruitment
I developed an email offering the dietician telephone consultation to all registered users. I sent this to the dietician to review and then to all the members of the HDSO team to confirm they were happy. I then emailed this message to all registered users of the programme once a month. I decided to send this email to notify programme users of the offer, and I chose once monthly emails as participants were already receiving weekly automated reminder emails. After the first emails were sent, I identified programme completers each week and informed the HDSO Programme Manager of their identification number. The Programme Manager contacted the completer by email to arrange a date and time for the telephone consultation with the dietician.

8.4.4.3 Intervention
The dietician telephone consultation consisted of a ten minute phone call in which the dietician supplemented the learning from the programme by answering participants’ questions about eating well with T2DM, and offering personalised advice. Participants were informed that the dietician would not give advice regarding medication or complex dietary needs such as allergies or coeliac. Figure 8-4 shows the email that I sent out to programme users offering the dietician telephone consultation.
8.4.5 Data collection

I collected data on user activity in order to address the objective of the study (the impact of the telephone reminders and incentive on user activity). The time and date of every login was automatically collected by the server side of the programme, as well as the webpage viewed by the user (name of weekly session and part). As for study 2, I used these data to calculate how many users were ‘active’ (defined as having completed at least one part of one session), and how many users completed all four sessions of the programme.

I also recorded notes from the telephone calls, and feedback from the dietician consultations. The notes from the telephone calls were responses to the scripted questions given in Table 8-1. I asked programme users who received a dietician consultation to complete the following feedback form:

---

**Exciting new offer from HeLP-Diabetes!!**

Complete your HeLP-Diabetes: Starting Out course to win a 10 minute one-to-one telephone consultation with our experienced Specialist Diabetes Dietician!

Carole Martin is a highly specialised diabetes dietitian with 33 years of experience working with patients in the NHS, including the Royal Free hospital. She has an interest in diabetes and a special interest in education of patients with Type 1 and Type 2 diabetes.

Carole can answer your questions on eating well for diabetes to supplement your learning from the course and give you a bit more personalised advice.

This offer is available to the first 10 completers, so don’t delay!

**What is included?** A 10 minute one-to-one telephone consultation with a Specialist Diabetes Dietician. The Dietician will take your questions on how to eat well for diabetes. **What’s not included?** Please note that the Dietician will not be able to give advice regarding medication or complex dietary needs such as allergies or coeliac's.

Once you have completed all 4 sessions of the course and the final quizzes, the Educator team will be in touch to organise your individual consultation. If you have any questions or would like more information contact the team on educators@help-diabetes.org.uk

---
1. Overall, how would you rate your session with our dietician?

5 - Very good 4 - Fairly good 3 - Average 2 - Fairly poor 1 - Very poor

2. Please tell us what you liked about this session

3. What you would like us to change about this session?

4. What is the most useful thing you have learned from this session?

I also asked for free text comments from the dietician about the consultations, and added these to the user feedback spreadsheet.

**8.4.6 Data analysis**

I used the data on logins collected by the programme to calculate the proportion of people who registered for the programme who were (i) active (completed at least one part of one session); and (ii) completed all four sessions of the programme.

I compared the proportion of active patients (activity rate) and the proportion of completers (completion rate) before and after the telephone calls and offer of dietician telephone consultations to determine the impact of each intervention.

I did not formally analyse the notes I recorded from the telephone calls, because the aim of the study was not to explore user views, and I had already collected and analysed qualitative data on barriers to completing the programme in a previous study (See Chapter 5). I did use the notes as field notes to follow up in the interviews I was conducting concurrently as part of Study 2 (discussed in Chapter 6). Examples of the notes are given in the ‘Results’ section below.

The feedback I received from programme users and the dietician were not analysed formally either, but given in the ‘Results’ section below.
8.5 Results

8.5.1 Telephone reminders

In total, I telephoned 55 users, and was able to talk to 45 people (10 did not answer). 4 (8.9%) of the people I spoke to responded by logging onto the programme, and 2 (4.4%) completed the programme. 41 (91.1%) of the people I spoke to did not become active after receiving a telephone call.
Overall, the telephone calls did not improve the percentage of registered patients who used the programme (by completing at least one part of one session), or the percentage of people who completed the programme. The percentage of active users fell from 54.2% to 48.0%. The percentage of users completing the programme fell from 12.5% to 5.0% (see Table 8-2).

Table 8-2: Changes in activity and completion of the programme before and after the telephone reminders to inactive users

<table>
<thead>
<tr>
<th></th>
<th>Number active/all registered users (%)</th>
<th>Number of completers/all registered users (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before telephone reminders</td>
<td>13/24 (54.2)</td>
<td>3/23 (12.5)</td>
</tr>
<tr>
<td>After telephone reminders</td>
<td>48/100 (48.0)</td>
<td>5/100 (5.0)</td>
</tr>
<tr>
<td>95% Confidence interval of the difference</td>
<td>11.7, 90.5</td>
<td>-38.9, 56.4</td>
</tr>
</tbody>
</table>

An example of the notes I made during the telephone calls with users who had been inactive for over two weeks, is given in Table 8-3. These were not formally analysed, as the objective of the study was to determine the impact of the calls on user activity.
Table 8-3: Example of notes from telephone calls

<table>
<thead>
<tr>
<th>Patient ID:</th>
<th>1149</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of call:</td>
<td>26.1.16</td>
</tr>
<tr>
<td>Barriers: Have you had any problems getting started with the programme? Is there anything stopping you?</td>
<td>Worried about using the link to access the site &quot;I've messed it up before&quot;. Unable to work out what the problem is</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How could we help you get past some of the difficulties you are facing?</th>
<th>Send the link again and she'll ask her friend to help her. <strong>Phone again next week</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>What would you have to do differently to use the programme regularly?</td>
<td>Friend may need to help, comes over most days. Partner ill with cancer</td>
</tr>
<tr>
<td>Importance: On a scale of 1 to 10 how important is it for you to learn about your diabetes?</td>
<td>10</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Why did you choose that number?</th>
<th>&quot;I don't know that much, it took a long time to accept it&quot;</th>
</tr>
</thead>
<tbody>
<tr>
<td>What would you need to happen to move from [score_given] to [higher_score]?</td>
<td>n/a</td>
</tr>
</tbody>
</table>

"n/a"
Confidence: On a scale of 1 to 10, how confident do you feel about using HeLP-Diabetes:Starting out? | 7

Why did you choose that number? | "It's about right"

What would you need to happen to move from 7 to 8? | Unable to say

8.5.2 Incentive: Offer of diettician telephone consultations

18 people completed the programme during the study period, and were eligible to a diettician telephone consultation. All 18 were sent an email by the Programme Manager offering them the consultation and asking them about their availability. Of these 18 people, 4 took the offer and had a diettician consultation (an uptake rate of 22.2%).

An increase in the percentage of users completing the course was seen during the period of time that the diettician consultation was offered (5.0% to 8.4%), but the percentage of people who were actively using the programme did not increase (48.0% to 29.8) (see Table 8-4).

Table 8-4: Changes in activity and completion of the programme before and after the offer of diettician telephone consultation incentive

<table>
<thead>
<tr>
<th></th>
<th>Number active/all registered users (%)</th>
<th>Number of completers/all registered users (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before offer of diettician telephone consultation</td>
<td>48/100 (48.0)</td>
<td>5/100 (5.0)</td>
</tr>
<tr>
<td>After offer of diettician telephone consultation</td>
<td>82/275 (29.8)</td>
<td>23/275 (8.4)</td>
</tr>
<tr>
<td>95% Confidence interval of the difference</td>
<td>-76.7, 154.5</td>
<td>-14.9, 28.3</td>
</tr>
</tbody>
</table>
No completed feedback forms were received from programme users who had a dietician consultation. Feedback from the dietician was received for two of the people she spoke to. This is given below:

User 1D 1285

“[1285] seemed a really nice guy. His diet is very good. He told me that he had lost some weight. If I remember rightly, I advised him to stop fruit juice & spread his fruit intake.”

User ID 1312

“[1312] seemed to be doing everything right, including activity sessions x3/week. I think I suggested taking that up to the next level i.e. x5/week.”

Overall feedback

“I think they both found it useful.”

8.6 Discussion

8.6.1 Principal findings

This study aimed to determine the impact of two strategies to reduce attrition from the HDSO programme. I contacted 55 people who had been inactive for over two weeks. Of these 55 people, 4 (7.3%) became active by logging on to the programme and 2 (3.6%) of the 4 who became active went on to complete the programme. The remaining 51 users continued to be inactive. The percentage of people who were active decreased from 54.2% to 48.0%. The percentage of people who completed the programme decreased from 12.5% to 5.0%.

4 out of 18 people (22.2%) who were eligible to receive a dietician consultation took up the offer. The percentage of people who were active decreased from 48.0% to 29.8% and the percentage of people who completed the programme increased from 5.0% to 8.4%.
8.6.2 Comparison with existing literature

The finding of a decrease in activity rate with telephone reminders is inconsistent with findings from two systematic reviews of strategies to increase use of digital health interventions. A review of intervention characteristics which increase exposure to internet-delivered healthy lifestyle interventions found that the results were too heterogeneous to do a meta-analysis, but a qualitative integrative analysis suggested that telephone contact resulted in more logins to the intervention website (226). A review of the effectiveness of prompts to increase use of digital interventions found borderline small-to-moderate positive effects for the technological strategies (including telephone calls and emails) to improve use of interventions, as supposed to using no strategy (227). It may be that my results were inconsistent with the first review because it measured logins, rather than completion of parts of the course as I did in my study. My findings may be inconsistent with the second review due to a smaller sample size.

My findings are also inconsistent with a systematic review of factors that influence user engagement in internet-based behavioural interventions for chronic illness, which found that interventions that included functionality for support from clinicians or peers could meet specific needs of individual, and that coaching showed particular promise (362). My findings may have been inconsistent with this, as I did not take a formal coaching approach. Coaching in health has been described as "a behavioural intervention that facilitates participants in establishing and attaining health-promoting goals in order to change lifestyle-related behaviours, with the intent of reducing health risks, improving self-management of chronic conditions, and increasing health-quality of life" (386). A 2018 systematic review and meta-analysis of RCTs of personal health coaching as a T2DM self-management intervention strategy found that coaching had a favourable impact on HbA1c at up to 18 months (387). I did use principles of motivational interviewing as a basis for the questions I asked in my telephone calls, but I was not trained in coaching and did not use any other coaching techniques.
A review of efficacious components of technology-based weight loss interventions (388) found one study that showed that regularly scheduled contact with a health counsellor by text message or telephone call was an effective supplement to the main intervention and improved website utilisation (389). In this study, a trained dietician acted as a health coach and provided two 20-minute face-to-face sessions and two 20-minute telephone sessions where participants were given counselling on their behaviour goals. My findings were inconsistent with this study because I did not provide health coaching, counselling, face-to-face contact or as much time with programme users. I did not build a therapeutic relationship with programme users like that of the health coaches in this study may have developed, and this may have affected how people responded in terms of use of the programme.

In contrast, several web-based weight loss trials are consistent with my findings and have found that increasing support does not improve usage (340, 390, 391). This may be because the support really did not have an effect, or it may be that these studies did not compare truly unsupported interventions with supported interventions, and the support offered may not have focused on improving engagement and increasing activity (392).

My finding of an increase in the percentage of people completing the programme with the offer of a dietician telephone consultations as an incentive, is inconsistent with findings from a Cochrane review of incentives for smoking cessation (381). This review found that only one out of nineteen studies resulted in higher quit rates for the incentive groups compared to the control groups beyond six months. My findings may have been inconsistent with the Cochrane review because it was looking at long-term outcomes (quit rates beyond six months), whereas my review looked at short term outcomes (use of the structured education programme after the offer of an incentive).

A study of financial incentives for health insurance plan members in the United States to complete an online wellness and self-management programme found that financial incentives were not sufficient to result in participation in the programme (393). Of the users who did use of the programme, 38.96% of people continued using it even after they had received both incentives. This
suggests that this group found the programme useful, and it may have been their own internal motivation which encouraged programme use rather than the incentives (393). My findings that the percentage of people who used the HDSO programme did not increase, but the percentage of people who completed the programme did increase were consistent with this study, and suggest that the people who used it found it useful despite the incentive and completed the programme as a result of their own internal motivation, which may or may not have been modified by the incentive.

8.6.3 Strengths and limitations

This was an early phase study which provided some good descriptive data on programme usage and adherence before and after telephone reminders and incentives for users. However there were several methodological flaws, and the results were therefore only indicative of the impact of these strategies and further research is needed.

A strength of the study was the external validity. The data were collected during the implementation of the HDSO programme in routine clinical practice in the NHS. As discussed in chapters 6 and 7, data collected from routine practice is more representative of real-world patients. Randomised controlled trials have strict inclusion and exclusion criteria which often exclude people who represent a large proportion of the disease population such as the elderly, or patients with co-morbidities and would therefore be expected to have limited external validity (356).

There are however several limitations to studies set in clinical practice. I collected observational data on the change in number of people who actively used the programme and completed it. Due to the context of the study (implementation in the NHS) I could not use randomisation, and therefore could not compare people receiving telephone reminders and the offer of a dietician consultation with a control group. The advantage of having a control group is greater accuracy of the reported treatment effect due to reduction in bias. This is an important limitation in this study as the aim of the study was to determine the effect of telephone reminders and the offer of a dietician
consultation. If I were able to repeat the study in a research setting rather than a clinical setting, I would randomise participants so that I had an intervention and control group, and I would compare the effect of the telephone reminders and offer of dietician consultation with the control group to look for a difference, rather than comparing the effect before and after these strategies were introduced.

It is possible that there were confounding factors which affected activity and completion rates, other than the telephone reminders and offer of dietician consultation, which I did not identify. For example, theories of motivation such as the self-determination theory described in the introduction, suggest that behaviour can be internally or externally motivated. Actions are intrinsically motivated when people engage in the behaviour for its own sake, without regard to external factors like support or reward. However the determinants of motivated behaviour lie on a spectrum from internal to external, and so external factors may modify intrinsic motivation and encourage the desired behaviour. In relation to this study, the people who did not use or complete the programme, may have had less intrinsic motivation. They may have needed more support and a greater reward than I offered through my telephone calls and incentive of a dietician consultation. The calls and incentive may not have been enough to increase their intrinsic motivation to complete the programme. Or, offering a dietician telephone consultation on completion of the programme may not have been appropriate for people with less intrinsic motivation, as completing the programme in order to speak with the dietician may have seemed too unachievable. It may, therefore, have been more effective to offer this to anyone who was interested in talking to a dietician, even those who had not completed the programme. Speaking with the dietician may have helped increase their intrinsic motivation, and subsequently encouraged them to complete the programme.

The people who completed the programme may have had greater intrinsic motivation, and may not have needed or been influenced by the telephone calls and offer of incentive, and would have completed it anyway. This means
that the less intrinsically motivated people needed to be targeted more effectively.

Another limitation of the study was the small number of participants. 55 participants were contacted to determine the impact of telephone reminders, and 10 of these did not answer the phone and only 4 became active by logging onto the HDSO programme and completing at least one part of one session. 18 participants were eligible to a dietician telephone consultation, but only 4 of these took the offer. This is a small number of patients to draw conclusions from, particularly given the lack of randomisation described above. However, the small sample size was due to the fact that the research was carried out during implementation of the programme in the NHS and therefore meant I could only involve the number of registered users, and I could not recruit more participants to reach a specified sample size. If I were to repeat the study in a research setting rather than a clinical setting, and if I had more time and resources, I would include everyone registered for the HDSO programme in the study, not just those who were inactive, in to increase the sample size. I would also use a more formal coaching approach with more tailoring of the advice and encouragement, or employ trained health coaches to conduct the telephone calls. The purpose of coaching is to provide education, feedback and support to enhance self-awareness, motivation and self-efficacy (394). A coach helps the client to access the motivation they need to initiate and maintain healthy behaviour changes (395). Reviews of health coaching for T2DM and other long-term conditions show promising results for improvement in key lifestyle behaviours like diet and exercise (387, 394-396). However, in this study I was limited by the fact that I was conducting the research on my own without a team of trained health coaches. I therefore had a limited amount of time carrying out the phone calls, and could not offer more tailoring and education, and I could not call everyone who was registered to use HDSO.

In this study I had to weigh up the benefits and disadvantages of the telephone calls. There are many possible opportunities for using telephone calls to engage patients with the programme, including providing support and feedback. But one disadvantage is that telephone calls are time-consuming. I
decided to carry out the telephone calls so that I could provide some support with self-monitoring use of the programme, but I could not put more time into providing more extensive coaching or to call more users.

If I were to repeat the study with a bigger budget, I would also consider incentivising the health professionals who worked in the CCGs where the programme was available, so that they encouraged people to register for and use the programme. I considered doing this by offering GP practices education sessions with the DSNs, but this proved impractical. Given more time and money we may have been able to organise these sessions, which may have meant greater opportunity to understand how to embed and sustain the programme in routine practice, in keeping with implementation theory such as NPT, and would have allowed health professionals to benefit by receiving education about T2DM management. The qualitative findings from chapter 6 suggested that health professional engagement is important for patient engagement with the programme. Health professionals can give an explanation of the benefits of the programme and encourage people to use it, and encouragement from a familiar and trusted GP or nurse may have been more effective than encouragement from unfamiliar individuals such as myself or a health coach employed to conduct the calls.

8.6.4 Implications for research and practice

Further research is needed to determine the relationship between telephone reminders and adherence with an online structured self-management programme for T2DM, and the relationship between dietician telephone consultation incentives and adherence with an online structured self-management programme for T2DM.

Further research is also needed into whether telephone is the most effective modality for reminders, and how the number, frequency and nature of the telephone calls affects adherence.
8.7 Conclusion

The study of telephone reminders and offer of dietician telephone consultation incentive showed that programme use did not increase as a result of these strategies. An increase in the proportion of people completing the programme was seen after the offer of dietician telephone consultations, but not after the telephone reminders. More research is needed on strategies to reduce attrition from the programme, and in the next chapter I have described a protocol for a pilot randomised trial of personalised email support.
Chapter 9. Protocol for pilot randomised trial of personalised emails

9.1 Chapter summary

In this chapter I have described the rationale for a randomised trial of personalised email support for HDSO users. I have also described a protocol for a pilot randomised trial of personalised emails to determine protocol fidelity and generate initial data on the potential effectiveness of personalised email support. I intended to carry out the study and include it in my PhD, but due to ethical and time constraints I was unable to. I have described why I was unable to carry out the pilot trial in the final section of this chapter. I have included the protocol to illustrate my learning and thought process.

9.2 Background

The study described in Chapter 8 about the effect of telephone reminders and offer of dietician consultation incentive was limited in part by time and resources. It was also methodologically limited by lack of randomisation. Evidence suggests that adding human support can limit the reach of web-based interventions. But we need to identify lower-cost forms of adding support, to make it more feasible to offer to patients (392). Email is less time and resource intensive than telephone calls, but it still offers the opportunity for tailoring communication to users with personalised messages, and may therefore be a more appropriate strategy for reducing attrition from HDSO. The concepts of tailoring and personalization in the context of eHealth are discussed in more detail in the next section.

9.2.1 Tailoring content

Tailoring content has been suggested as a method of enhancing adherence to eHealth interventions. A definition of tailoring that has been used in behaviour change research is: “the provision of information, advice and support that is individualised to the user based on their known characteristics, behaviours or scores on relevant theoretical constructs” (397). Theories of persuasion and attitude change suggest that tailoring increases personal relevance, thus increasing motivation to process the argument presented by
the intervention (398). Tailored information is more likely to be read and remembered and be positively perceived by users of the intervention (397, 399, 400). The arguments themselves must be convincing (401), should avoid producing negative reactions and be congruent with prior attitudes or beliefs (402).

Reviews and meta-analyses of the literature on health behaviour change interventions report benefits from tailoring when compared to not tailoring (403-406). A 2009 review by Lustria et al (407) explored the effect of tailoring by researching the mechanisms for individualizing messages used in computer-tailored behavioural interventions. They found that three tailoring mechanisms were used (feedback, personalization or adaptation) to make messages personally relevant. Feedback was the most commonly used mechanism. It was also used in combination with personalization or adaptation, for example by including personally identifiable characteristics in the messages, making references to self-reported outcomes, or directing users to customised content (407). The Stages of Change Model (408) was commonly used, particularly for health behaviours that involve motivational readiness such as smoking cessation. However it was unclear how the stages were assessed. The Stages of Change Model argues that behaviour change interventions should be tailored to an individual’s current stage (409). There have been doubts about the validity of this model. Robert West has suggested that use of the model might lead to effective interventions not being offered to people who would have responded e.g. ‘pre-contemplators’ who are perceived as being unmotivated to change. However, pre-contemplators may still respond to triggers in the right situation (410). A review of the effectiveness of stage-based interventions to promote smoking cessation found that stage-based interventions are no more effective than non-stage based interventions or no intervention at all (411). West argues that mass, untailored help and encouragement should be offered to everyone.

A 2012 review of design features in effective eHealth interventions identified tailoring as one of four core interactive design features that mediate effects on health outcomes, alongside social context and support, contacts with the
intervention and self-management (412). Information appeared to be more effective if tailored, and if more than one way of delivering tailoring was used (412).

9.2.2 Personalised emails

One way of providing tailored support is the use of personalised emails to users. Emails are discussed in the review of technology-based strategies for promoting engagement by Alkhaldi et al (227). Emails were the most commonly used strategy in the included studies, compared to telephone calls and text messages, or a combination of the three. Most of the studies used emails at regular intervals. Two studies used automated emails, and nine used emails sent by therapists, counsellors, non-clinical staff, researchers, trained coaches and trained peers. The emails either offered assistance with the intervention, described the content of the intervention, linked to specific pages, reminded users to complete sessions or provided help and support with health or engagement with the intervention.

Two of the studies of emails reported no effect due to the level of personalization being too low (413, 414). The first of these two studies was a 2012 study by Santucci et al. looking at the effect of email session reminders to students using a computerised cognitive behavioural therapy (CBT) programme for anxiety and depression. Students in the session reminder group were sent weekly emails by study staff reminding them to complete the programme session for the week, and students in the no reminder group received no contact from study staff. Results showed that session completion did not differ between the session reminder and no session reminder participants. The authors suggest that the use of email may have been too low intensity, as compared with a telephone or postal reminder. There may have been a lack of personal connection between the participants and study staff, or the students may have been receiving too many emails already (413).

The second study was a 2012 study by Schneider et al. looking at the effect of periodic email prompts on visits to an internet-delivered lifestyle intervention targeting diet, physical activity, smoking and alcohol (414). Participants
allocated to the email prompt group received an email prompting to revisit the site at 3 months from their baseline visit. The emails consisted of a personalised greeting, information about monitoring of progress on the site, and an opportunity to receive additional information on a health behaviour of choice. The email also contained personal login details and the research team’s contact details. 6.3% of participants responded to the prompt email by revisiting the site after 3 months, and this was significantly higher than the percentage of participants in the no reminder group (0.0%, p<0.001). However after multivariate analysis the effect became non-significant. The authors concluded that the level of personalization may have been too low, and the emails may have been sent too long after the baseline visit (414).

Two other studies included in the Alkhaldi review used personalised feedback as part of internet-based treatment for social phobia and depression with guided and unguided self-help (415, 416), and had mixed results. The social phobia study compared a 10-week web-based unguided self-help treatment with weekly email support from a therapist, and a third condition where participants were allowed to request the weekly email support. The weekly emails consisted of an initial introductory email and then feedback on behaviours and progress through the programme. This included recognition and reinforcement of the participant’s independent work, and the offer that they could contact the therapist at any time with questions. If there had been no activity for a week the therapist offered assistance and asked about problems with the programme (415). All three groups improved significantly from pre- to post-treatment for self-reported measures. However level of support did not affect self-reported measures, dropout rates or adherence to the programme (415).

The second study compared a group receiving the programme without any support from a therapist, with a group receiving the programme plus scheduled email contact with a therapist (416). The email contact consisted of weekly feedback on participants’ programme usage in the past week, and any questionnaire scores. It was relatively generic and focused on recognition and reinforcement of independent work, as in the social phobia study (415).
was no difference between self-reported measures (including Beck Depression Inventory) (417) in the guided and unguided groups. However programme usage did differ between the two groups. The mean number of lessons completed by the unguided group was 6.8, and then mean number of lessons completed by the guided group was 8.52. 36% of participants in the unguided group completed the programme, and 56% of the guided group completed the programme (416).

Similarly, an increase in completion rate was seen in a randomised trial of self-guided internet treatment for anxiety and depression by Titov et al. (418). Groups with or without automated emails were compared. Participants in the email group received two emails per week which were triggered at set times including on completion of a lesson or after 7 days of not having completed a lesson. Each email was limited to two or three paragraphs of three or four sentences, and reminded participants about content on the site, reinforced progress, and explained that progress can be challenging and slow. The completion rate for the intervention were higher in the email group than in the group without emails (36% compared to 58%) and treatment satisfaction levels were high (418).

Overall, these studies point towards personalised emails having the potential to improve engagement with digital interventions. However, there are uncertainties around optimal timing, frequency, and content, and whether the findings from mental health (described above) generalise to DSME.

9.3 Aims & objectives

My aim was to build on the findings from the study of reducing attrition in the previous chapter, by conducting a pilot randomised trial to determine if personalised email support for users of the HDSO programme was more effective at reducing attrition than no support.
Objectives

The protocol was for a pilot trial to:

1. Determine protocol delivery and fidelity (can personalised email support be delivered as described in the protocol, or do adjustments to the intervention protocol need to be made?);

2. Generate initial data on the potential effectiveness of personalised email support, including:

   (a) The difference in activity rate (proportion of people who have completed at least one part of one session of the programme) between the personalised email support group and the group without personalised email support;

   (b) The difference in completion rate (proportion of people who have completed all 4 sessions of the programme) between the personalised email support group and the group without personalised email support.

9.4 Methods

9.4.1 Design

A pilot online two-arm individually randomised trial.

9.4.2 Ethics

The HDSO programme was commissioned by four Clinical Commissioning Groups (CCGs) in England. It was offered to patients as a NHS service. Patients consented to receive emails and have their pseudonymised activity data collected as part of the terms of the programme when they registered. They were able to unsubscribe from emails at any time.

Patient data were collected by the online programme and automatically pseudonymised with identification numbers. The pseudonymised data were then downloaded to Excel for analysis. No identifiable information was downloaded.
Ethical approval was granted for the interviews conducted during the evaluation of the first and second iteration of the HDSO programme from the Health Research Authority (reference number 159488, see Appendices A-C). I gained ethical approval for a pilot randomised trial of personalised emails after I submitted a substantial amendment (Amendment number: 15/SS/0078/AM04 SA02). I submitted the study protocol as described below.

The consent form and participant information sheets can be found in Appendices N and O.

### 9.4.3 Participants and Setting

I proposed to invite the most recently registered for the HDSO programme to the study, and to randomise them to either the personalised emails (intervention) or no personalised emails (control) group.

HDSO was commissioned as a service by four CCGs across England. Patients were referred to the programme by health professionals and accessed it by self-registering on the home page. Patients consented to receiving automated emails from the programme team at registration. Details of automated emails sent to all registered patients are described below (see ‘Control’). Once self-registration was completed, login details were sent and the HDSO programme and HeLP-Diabetes website were immediately available.

### 9.4.4 Sample size

An adequate sample size is necessary to determine a statistically significant treatment effect in clinical trials, and sample size calculations can be used to calculate the minimum number of participants needed (419). If a sample size is too small, it may not be possible to detect an existing effect, and sample sizes that are too large waste time and resources (420).

Pilot trials have different objectives to main trials and sample sizes therefore do not necessarily need to be calculated in the same way (419). Reviews of pilot and feasibility studies have found that there is inconsistency in the literature of the definition of the terms “pilot” and “feasibility”, and their
objectives (421-424). Eldridge et al. developed a conceptual framework for defining pilot and feasibility studies by conducting a large Delphi survey, an international expert consensus meeting and a review of 27 empirical pilot or feasibility studies (421). They have suggested that the objective of feasibility studies is to ask if the trial can be done, and if so how. Pilot studies have the same objective and test the procedures of a future study at a smaller scale (421). Pilot studies could be considered a sub-set of the overarching theme of feasibility (421). The National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre (NETSCC) have published guidance which offers a similar definition, as follows: “a version of the main study that is run in miniature to test whether the components of the main study can all work together” (425). Components of the main study that are important to test in a pilot study include recruitment, randomisation, treatment and follow-up assessment (426).

The decision about sample size for a pilot study can therefore be more pragmatic than a sample size calculation for a main trial, but it still needs to be justified, and needs to be sufficiently large that the probability of detecting problems in the processes of the trial is high (427). An audit of pilot and feasibility trials being run in the UK was conducted by Billingham et al in 2012 using data from the United Kingdom Clinical Research Network (UKCRN) Database (422). This added to the results of earlier reviews by Arain (423) and Lancaster (424) of pilot studies published in seven major medical journals. Arain found that only 35% of the included trials performed and documented sample size calculations (423). Billingham found that none of the 79 included trials stated a justification for the target sample size (422).

This study aimed to test the procedures for a phase III RCT of the effectiveness of personalised email support at reducing attrition from the HDSO programme, compared with no personalised email support. A formal sample size calculation that would be used in a phase III RCT as described above, was not necessary for this study as it was a pilot trial with the aim of determining protocol fidelity and generating initial outcome data. I wanted to determine if delivering personalised email support was feasible, if it might be
effective at reducing attrition rate, and if any changes needed to be made to the intervention protocol to make it more effective at reducing attrition, prior to a phase III RCT. The trial would be used as a developmental tool for a future trial and a small sample of 20 participants (10 in each group) would be used to test procedures. This number was chosen for pragmatic reasons. It was feasible to write and send emails to this number of people, whilst also being enough people to be able to compare activity rates in each group, particularly if some did not respond or use the programme.

9.4.5 Randomisation and blinding

The plan was to randomly allocate participants to HDSO with personalised email support or HDSO without personalised email support at a ratio of 1:1 using a computer-generated list.

Randomisation would have occurred at the individual level. I could not be blinded to trial arm assignment and participants could not be blinded to their allocated intervention.

9.4.6 Control

All participants would have been registered to use the HDSO intervention. I have described HDSO in detail in Chapters 3 and 5 of the thesis, and summarised it here. The programme consists of four sessions, each of which contains 3 or 4 parts taking 15-20 minutes each to complete. Users are encouraged to complete a session a week. There are self-assessment questionnaires in sessions 1 and 4 of the programme, and users are asked to complete and review goal-setting tasks as they work through the programme.

All users received regular automated emails. Automated emails were triggered on completion of the questionnaires, on completion of a session, and on completion of the programme. The email users received after completing the questionnaires provided personalised feedback based on the level of emotional distress and self-efficacy in self-managing indicated by their questionnaire scores. This helped them to assess which of their health behaviours needs modifying.
Automated reminder emails were also triggered for all registered users who did not start the programme within 7 days or who did not access the programme for more than 7 days. Three weekly reminder emails were sent, and then a final email after 6 weeks of not accessing the site.

Participants in the control arm would have received regular automated emails, but would not have received the additional personalised support emails.

9.4.7 Intervention

Participants in the intervention arm would have received personalised emails instead of the automated emails described above.

9.4.7.1 Email frequency and timing

The personalised emails would be sent at registration, and then at weekly intervals for four weeks.

9.4.7.2 Email content

9.4.7.2.1 Development process

I went through a series of steps for developing the email content. First, I identified the objective of the personalised email support (to improve engagement with the structured education programme), and then I identified the factors that need to be addressed by the emails in order to meet the objective of improving engagement (428).

I interviewed patients and health professionals in Study 2 about barriers to using or completing the programme (See Chapter 6). Four main themes emerged from the qualitative data, including one theme on patient non-prioritization of the programme. I used the sub-themes on patient non-prioritization to inform the list of factors that needed to be addressed by the emails in order to improve engagement (See Table 9-1).
Table 9-1: Summary of qualitative data on factors affecting patient non-prioritization

<table>
<thead>
<tr>
<th>Major theme</th>
<th>Sub-themes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient non-prioritization</td>
<td>Competing priorities</td>
</tr>
<tr>
<td></td>
<td>Not being ready for information</td>
</tr>
<tr>
<td></td>
<td>Perceived relevance</td>
</tr>
<tr>
<td></td>
<td>Perceived need</td>
</tr>
</tbody>
</table>

Next I mapped each of the sub-themes with email features that could be used to address them (See Table 9-2).

Table 9-2: Email development principles

<table>
<thead>
<tr>
<th>Objective of the personalised email support</th>
<th>Factors affecting patient non-prioritization that needed to be addressed by the personalised email support</th>
<th>Features of the personalised emails that could address patient non-prioritization</th>
</tr>
</thead>
<tbody>
<tr>
<td>To motivate users to start using or continue using the programme</td>
<td>Competing priorities</td>
<td>Acknowledge personal context and competing priorities. Suggest individualised ways to navigate barriers e.g. using programme flexibly to fit around other demands.</td>
</tr>
<tr>
<td>Motivation Issue</td>
<td>Feature Description</td>
<td></td>
</tr>
<tr>
<td>----------------------------------</td>
<td>----------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Not being ready for information</td>
<td>Highlighting short-term and long-term benefits of the programme.</td>
<td></td>
</tr>
<tr>
<td>Perceived relevance' perceived need</td>
<td>Encouraging reflection on personal goals.</td>
<td></td>
</tr>
<tr>
<td>Competing priorities</td>
<td>Feeding back to users to congratulate them about their continued progress or to remind them to maintain progress.</td>
<td></td>
</tr>
</tbody>
</table>

**Theories of motivation**

Reviews suggest that interventions based on behaviour change theory tend to have larger effects (172). I therefore used theories of motivation as a guide for how to enhance motivation (398). I mapped theories including self-determination theory, temporal self-regulation theory and theories of volition and self-regulation to each of the necessary email features proposed above. Based on the guiding theory, I created examples of messages that could be included in the emails (See Table 9-3).
Table 9-3: Theories of motivation and example email components

<table>
<thead>
<tr>
<th>Features of the emails necessary to address user behaviours/beliefs</th>
<th>Guiding theory</th>
<th>Example of corresponding email component</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acknowledge personal context and competing priorities. Suggest individualised ways to navigate barriers e.g. using programme flexibly to fit around other demands.</td>
<td>Self-determination theory: motivation can be enhanced by supporting individuals' need for autonomy. A sense of autonomy is enhanced by providing choice and flexibility within a structured programme (398, 429-431).</td>
<td>I can see that you have not yet managed to start week 1 of the programme. Is there anything in particular that is stopping you from starting the programme? Can we help you to work out a more flexible way of using the programme that fits with your schedule?</td>
</tr>
<tr>
<td>Highlighting short-term and long-term benefits of the programme.</td>
<td>Temporal self-regulation theory: decision to change behaviour is motivated by weighing up immediate costs of performing the behaviour (time, energy) against the longer-term benefits. Feedback on immediate benefits more appropriate initially, then longer-term benefits later on (398, 432).</td>
<td>How confident do you feel right now at managing your diabetes? And how much do you think it affects your life? The quizzes that are coming next will generate immediate feedback that will help you answer this, and help you identify which topics will be helpful later on in the course. Are there any topics that you can think of now that you are interested in learning more about?</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Encouraging reflection on personal goals.</td>
<td>Self-determination theory: autonomy is enhanced by encouraging users to reflect on personal reasons for registering for the programme, and how this fits with core values e.g. long-term health (398, 433).</td>
<td>I can see that you have not yet managed to start week 1 of the programme. This might be a good time to think about your reasons for signing up to the programme—was it to lose weight, or be more active?</td>
</tr>
</tbody>
</table>
Feeding back to users to congratulate them about their continued progress or to remind them to maintain progress.

Theories of volition and self-regulation: feedback on goal progress can facilitate self-regulation of goal-directed behaviour. Users’ satisfaction with goal progress and feedback can enhance motivation (183, 398, 434).

You’ve finished week 3 and successfully completed your activity goal, well done! How do you feel about achieving your activity goal already? And how does this make you feel about setting yourself more activity goals for the future?

All emails would have addressed the user by their first name. In the first email at registration I would have introduced myself and the frequency of the emails. In each of the subsequent weekly emails I would have given feedback to the user about their progress through the course, recognizing and reinforcing progress made. I would have provided personalised responses to the information participants disclosed in their emails about their barriers to progressing through the programme. In all emails I would have provided my contact details and offered to answer non-clinical questions or addressed concerns by telephone or email.

9.4.8 Data collection

The following data would have been collected to determine intervention protocol delivery and fidelity:

- Number of personalised emails sent per participant;
- Number of responses to personalised emails received per participant;
- Frequency of emails sent;
- Level of personalization of emails (whether or not participants disclose personal information to allow for personalised support);
The following data would have been collected to determine potential effectiveness of personalised email support:

- The activity rate (proportion of people who have completed at least one part of one session of the programme) in the personalised email support group compared to the group without personalised email support.
- The completion rate (proportion of people who have completed all 4 sessions of the programme) in the personalised email support group and the no personalised email support group.

Descriptive data would also have been collected including age; gender; ethnicity; education level; duration of diabetes; diabetes management; IT skills; offered face-to-face education; attended face-to-face education of each participant.

Data would have automatically been collected online through the HDSO programme. Data were collected from all registered users on date of registration, date of most recent login and most recent module completed.

### 9.4.9 Data analysis

The mean number of personalised emails sent per participant would have been calculated, as well as the mean number of responses to personalised emails received per participant. The mean number of days between each email sent to participants would have been calculated.

A qualitative approach would have been taken to the analysis of the level of personalization that was feasible, and the information received from participants. The content of emails sent and received would have been analysed thematically. A thematic analysis would have been used as it allows exploration of participant views and experiences, and can generate unanticipated insights (277). This was appropriate as I was interested in participant engagement and how email support could be used to facilitate improved use of the programme. I hoped that thematically analysing the emails would allow me to explore which aspects of the emails participants found helpful, which aspects they did not find helpful, and what kinds of issues participants needed support with to improve their engagement.
The proportion of people who completed at least one part of one session of the programme would have been calculated and compared for each arm of the study. The proportion of people who completed all 4 sessions of the programme would have been calculated and compared for each arm of the study. I would have been determined if there was a significant difference in activity and completion rates between the groups using a Wilcoxon test. Statistical analysis would have been carried out using SPSS version 22.

9.4.9.1 Descriptive data

Mean age and standard deviation of the participants would have been calculated and compared for the group receiving personalised email support and for the group not receiving personalised email support.

The remaining baseline descriptive data would have been grouped into the following categories, summarised and compared for the group receiving personalised email support and for the group not receiving personalised email support.

- Gender
  - Male
  - Female
- Ethnicity
  - White (including White English/Welsh/Scottish/Northern Irish/British, White Irish or White Other)
  - Black/Black British (Caribbean, African, and Other)
  - Asian (Chinese, Indian, Pakistani, Bangladeshi, or Other)
  - Other
- Education level
  - School leaver
  - A Level
  - Degree or equivalent
  - Postgraduate or equivalent
- IT skills
  - Low Intermediate
  - High
- Duration of diabetes
  - Less than a year
  - 5-10 years
  - Over 10 years
- Offered face-to-face diabetes structured education
  - Yes
9.5 Reasons for not conducting the study of personalised emails

I decided not to conduct the pilot randomised study of personalised emails due to the requirement of the HRA ethics committee for patients to be invited to the study by email, and to ‘opt-in’ to the study and give consent if they were interested in taking part. The patients who registered for the HDSO programme were using it as a NHS service rather than taking part in a research study. This meant that the population registered for the programme were not selected and were representative of the general population. This was illustrated by the data I collected in previous studies, and I have reflected on this in Chapters 6, 7 and above. I therefore initially proposed to the ethics committee that I include the last 20 people who registered for the programme without requiring them to opt-in and provide consent. I felt this was justified as everyone who registered for the programme already received regular emails as part of the programme procedures. However I was unable to get ethical approval to randomise programme users without their consent. Another option may therefore have been to send 20 participants personalised emails and collect data on impact on attrition from the programme, as I did with the telephone reminders and offer of incentive in the previous chapter. However, the study would again be limited by lack of randomisation. I also ran out of time to explore this second option due to changes with the commissioning of and a limited amount of time to be able to continue accessing usage data.

9.6 Conclusion

I designed a protocol for a pilot randomised study of personalised emails and submitted it to the ethics committee, but ethical approval was only gained for opt-in patient recruitment and consent. This would have limited the potential generalisability of the results. I therefore decided not to carry out the study and
determine the evidence for personalised emails. Further research on personalised emails as a strategy for reducing attrition is still needed.

Chapter 10. Recommendations for the final intervention

10.1 Chapter summary

In this chapter I have described the final intervention at the end of my research process. I also synthesised the key findings from the four studies I have conducted, to inform recommendations for further optimisation of the programme.

10.2 Introduction

10.2.1 The HeLP-Diabetes: Starting Out development and evaluation process

The preceding chapters have described the development of a first iteration of the programme, its evaluation and optimisation, to produce a second iteration of the programme. This second iteration has also been evaluated, and methods for improving adherence have been considered and evaluated. In this chapter, I have used the data and learning I have accumulated from these processes of development and evaluation to describe the final intervention, and formulate a set of recommendations for further optimisation of the programme. This is in keeping with guidance on developing and evaluating complex interventions (107), and addresses my final research objective.

A description of the final intervention is given first, followed by recommendations for further optimisation of both the intervention and the delivery package.

10.3 Description of the final intervention

10.3.1 Online registration

Online self-registration was introduced during the evaluation of the second iteration of the intervention, so that patients could register to use the programme themselves online. This replaced a telephone registration system,
in which patients waited to be contacted by telephone by the HeLP administrator after they had returned their notification of interest. With the online registration process, people did not have to wait for the HeLP administrator to get back to them, and they could start using the programme immediately.

The data collected on registration numbers and demographics, before and after self-registration was introduced in January 2017, support the decision to introduce online registration. These data are represented in Figure 10-1 and Table 10-1.

As can be seen in Figure 10-1, the number of people who registered for the programme per month increased from 32 in December 2016 to 142 in January 2017, an increase of more than four times the number of registrations in December 2016.

**Figure 10-1: Number of people who registered for HDSO per month 11/2015-01/2017**

When I looked at the demographics of the people who registered for the programme after self-registration was introduced, I noticed that the
percentage of people aged less than 60 had increased slightly, as did the percentage of female users. However the percentage of people with less education and basic IT skills did not decrease. The percentage of people from minority ethnic groups increased. The diabetes duration, education level and treatment did not change.

**Table 10-1: Demographic and clinical characteristics of people registered to use HDSO before and after self-registration**

<table>
<thead>
<tr>
<th></th>
<th>Number of Registrations</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>6.9.16 (before online self-registration)</strong></td>
</tr>
<tr>
<td><strong>AGE</strong></td>
<td></td>
</tr>
<tr>
<td>Age &lt;60</td>
<td>100 (44)</td>
</tr>
<tr>
<td>Age &gt;60</td>
<td>129 (56)</td>
</tr>
<tr>
<td><strong>GENDER</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>100 (46)</td>
</tr>
<tr>
<td>Female</td>
<td>116 (54)</td>
</tr>
<tr>
<td><strong>ETHNICITY</strong></td>
<td></td>
</tr>
<tr>
<td>White British</td>
<td>96 (42)</td>
</tr>
<tr>
<td>Not White British</td>
<td>133 (58)</td>
</tr>
<tr>
<td><strong>EDUCATION</strong></td>
<td></td>
</tr>
<tr>
<td>School leaver</td>
<td>75 (34)</td>
</tr>
<tr>
<td>A Level or higher</td>
<td>146 (66)</td>
</tr>
<tr>
<td><strong>IT SKILLS</strong></td>
<td></td>
</tr>
<tr>
<td>Basic</td>
<td>63 (33)</td>
</tr>
<tr>
<td>Intermediate</td>
<td>80 (42)</td>
</tr>
<tr>
<td>Advanced</td>
<td>48 (25)</td>
</tr>
<tr>
<td><strong>DIABETES DURATION</strong></td>
<td></td>
</tr>
<tr>
<td>&lt; 1 year</td>
<td>62 (29)</td>
</tr>
<tr>
<td>&gt;1 year</td>
<td>150 (71)</td>
</tr>
<tr>
<td><strong>DIABETES EDUCATION</strong></td>
<td></td>
</tr>
<tr>
<td>Offered face to face diabetes education</td>
<td>104 (46)</td>
</tr>
<tr>
<td></td>
<td>First iteration</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>Not offered face to face diabetes education</td>
<td>124 (54)</td>
</tr>
<tr>
<td>Attended face to face diabetes education</td>
<td>26 (12)</td>
</tr>
<tr>
<td>Not attended face to face diabetes education</td>
<td>200 (88)</td>
</tr>
<tr>
<td>TREATMENT Managed by lifestyle alone</td>
<td>69 (30)</td>
</tr>
<tr>
<td>Takes tablets and/or insulin</td>
<td>158 (70)</td>
</tr>
</tbody>
</table>

These results suggested, that although self-registration may have attracted younger people and more men, it did not reduce the number of people from ethnic minority groups, people with less IT skills and people with less education registering for the programme. Therefore, self-registration proved to be a better method of registering users.

### 10.3.2 Number of sessions and questionnaires

After the evaluation of the first iteration, the number of sessions in the programme was reduced from eight to four, and the number of questionnaires was reduced from three to two. These changes were made after looking at the data on attrition from the programme (54.2% of people started the programme but did not complete it, and 33.3% of people didn’t start the programme). Qualitative data gained from calling people registered to use the programme suggested lack of time was a limitation to engagement. The reduction in the number of sessions and questionnaires was aimed at addressing this limitation. Evaluation of the second iteration of the programme, with these changes made, produced data which showed that attrition remained a problem (14.4% of people started but did not complete it, and 76.2% did not start the programme). This suggested that there were other factors, in addition to the length of the programme and questionnaire burden, which affected attrition.
Overall I concluded that it was the correct decision to shorten the programme, and recommend the current session format for a fully optimised programme.

The factors other than programme length that may have affected attrition were explored in the qualitative interviews conducted during the evaluation of the second iteration of the programme. These included lack of time discussing structured education with health professionals; and patients not being ready for information or perceiving it as necessary or relevant. These challenges and recommendations for addressing them are discussed in the next sections. I have discussed utilising staff other than GPs and Practice Nurses to discuss structured education with patients, as a way of allowing more time for this discussion.

The attitude that some patients had that self-management education is not necessary or not relevant is difficult to address with programme changes. The transtheoretical model of behaviour change suggests that people need to be at the stage of “action” to actively engage in a new behaviour (435). People who consider self-management education to be unnecessary or irrelevant may be at the pre-contemplative stage (not intending to make any changes) of the model (435). The theory suggests that people can move backwards and forwards through the stages, and it is not a linear process. There has however been criticism of the model, as discussed in Chapter 8, including the role of contextual factors in encouraging behaviour change which the model does not account for (410).

One way of addressing the problem of some being not feeling ready, is to offer structured education to all patients with type 2 diabetes, and not just those who are newly diagnosed. This gives people the opportunity to access it when they feel ready.

Another possibility, is that high attrition from the programme was seen because some people who registered did not want to work through the whole course immediately. They may have wanted to come back to the programme at a later date, and this may be a way that people like to use online resources. This will be discussed further in Chapter 11.
This concludes my description of the intervention that resulted at the end of my research. Next, I have illustrated the four sessions (and fifth bonus session) of the programme with a series of screenshots.

**Week 1 – Getting Started**

**Figure 10-2: Screenshot of Week 1 Part 1**

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**Part 1 - An introduction to type 2 diabetes**

Why should I do this course?

On average, your diabetes team spends 3 hours a year managing your diabetes.

You spend 8760 hours every year living with your diabetes.

The decisions you make have a much bigger impact on your health than those made by your healthcare team.

Even small changes in what you do can make a big difference to your health if you work them in to your daily life.

Over the next 4 weeks we will:

- show you how you can make a big difference to your health and well-being
- help you decide what is important for you
- help you achieve your personal goals

Each of the sessions takes about 90 minutes to complete in total.

The sessions are split into parts so you can do them in 15 minute chunks when it is convenient for you.

---

Week 1 contains four parts: an ‘Introduction to type 2 diabetes’, the ‘Self-assessment’ quizzes, and information and advice about ‘Eating well for diabetes’ and ‘Becoming more active’.
Week 2 – Self-management

Figure 10-3: Screenshot of Week 2 Part 1

Week 2 contains four parts: ‘Taking control’ (information on monitoring blood glucose levels and healthy behaviours, and quizzes on physical activity, medication use, alcohol intake and diet); ‘Protecting my body and mind’ (information about preventing problems with emotions, eyes, feet, infections, kidneys, nerves, sexual function, and abnormal blood sugar levels); ‘Handling feelings’ (information about how diabetes can affect relationships at work and at home, and videos of people with diabetes talking about how they approached these issues); and ‘Making changes’ (an exercise for reflecting on the quizzes in Week 1, and setting specific, measurable, achievable, realistic and time-bound (SMART) goals for diet, medicine, activity, drinking and other health behaviour changes).
Week 3 – Improving my health and well-being

Figure 10-4: Screenshot of Week 3 Part 1

Week 3 contains five parts: ‘Making the most of the NHS’ (information about the essential checks that all people with diabetes should receive, videos of people talking about their interaction with the NHS, and a link to the health record in HeLP-Diabetes where users can record appointments); ‘Medication’ (information about the purpose of medication, videos about the challenges and benefits of medications, advice for concerns about medications, a “My medicines” list, and information about commonly used medications in diabetes); ‘Reducing the risks of heart attack and stroke’ (an explanation of the importance of blood pressure, how it is measured, and heart disease and its treatment and prevention); ‘Update my goals and plans’ (a look back to the SMART goals); and ‘Understanding my moods’ (videos of people with diabetes explaining how they felt when they found out they had diabetes, and what they did to make themselves feel better).
Week 4 – Taking control of my diabetes

Figure 10-5: Screenshot of Week 4 Part 1

Week 4 contains 5 parts: ‘My diabetes review’ (videos about people’s experiences of diabetes care, and explanation of the diabetes care plan); ‘Looking after my feet’ (types of foot problems, preventing foot problems, foot checks and tests, and foot complications from diabetes and their management); ‘Review my goals and plans’ (another opportunity to review and update SMART goals); ‘Self-assessment’ (the end of programme quizzes) and ‘Moving on: the beginning of the end’ (advice about staying motivated and links to further information).
Week 5 – Bonus content

Figure 10-6: Screenshot of Week 5 Part 1

Week 5 contains supplementary content moved from the first iteration of the HDSO programme. This information includes working with health professionals, managing diabetes when ill, diabetes and social life, work, driving, reviewing goals and plans, and more on managing moods.

Next, I have listed recommendations for further changes to HDSO that I was not able to make within the constraints of my research, but could be made to optimise the programme and delivery package. These recommendations are based on the findings of my evaluations of the programme.

10.4 Recommendations for further optimisation of the intervention and the delivery package

10.4.1.1 Recommendations for improving uptake

Population impact depends on reach (uptake) as well as effectiveness of an intervention (436). Reach is an important measure of impact of a public health intervention (234), and has been defined as the proportion of the target population that participates in the intervention (234). Even if an intervention produces a large effect size, if it attracts a small proportion of participants it
will not necessarily have enough of a population impact (436). Reach is also an important consideration when assessing cost-effectiveness (63). Digital interventions have the potential to reach large numbers of participants, and have a low marginal cost per user.

The reach of a public health intervention is the result of (i) health system factors; (ii) patient factors; and (iii) intervention factors. Participation in the intervention, and hence reach, involves health professionals, as well as patients or the public, and the intervention features (63). There are multiple steps that are taken in order to achieve reach, including awareness of the intervention, access to it, taking up the offer of the intervention, and using it. Optimising reach requires working with health professionals to raise awareness of the intervention with patients, working with patients to encourage uptake and use, and making the intervention accessible to patients on multiple devices and integrating it with medical systems.

The following recommendations address challenges at the health system, patient and intervention level. Some of these challenges were within my control and some were not. One of the greatest challenges that was not within my control was the implementation of the programme in the NHS, and the impact on its success. As a reminder of the context to the research, I evaluated the programme whilst it was implemented in the NHS. This was a result of the HDSO programme being commissioned by four CCGs in London during the period of my research. As described in Chapter 6, uptake of the intervention in routine clinical practice was measured in these four CCGs (and Camden where it was being used for free after the HeLP-Diabetes implementation study), but the implementation models used in each CCG were specified by the commissioners, and varied between CCGs. My findings were that 791 people registered for the programme, and 74 people (9.4%) completed it. Although low, this figure compares favourably with National Diabetes Audit data showing that only 7.1% of patients referred to face-to-face education attend (250).

The programme was available to patients at all practices in the five CCGs that offered the programme. The HeLP team contacted CCG diabetes leads,
practice managers, GPs and Diabetes Specialist Nurses to inform them about the programme. Practices were also asked to identify eligible patients by searching the electronic records and to send out recruitment packs, but only nine practices did this. Some practices promoted the programme using posters and flyers in the waiting area, and others used text messages. Data were not collected on the process used at each practice or the corresponding number of participants recruited, because the programme was being offered as a service and not a research study. If this had been possible the data would have helped better understand which process worked well and which didn’t.

There were other challenges that it was possible to address, and these are discussed below.

Recommendations for challenges at health system level

10.4.1.2 Employing a Change Manager

I compared the number of patients who registered from each CCG (See figure 10-7). This showed that more patients registered from Lewisham than any other CCG.
I reviewed the differences in health system, patient and intervention factors between Lewisham and the other CCGs. The lowest number of patients came from Camden, perhaps because the programme was not commissioned there but was offered to the CCG for free after the end of the implementation study. Another key health system difference was that Lewisham employed a Change Manager to liaise with practices and patients to raise awareness of the programme. This included visiting practices to talk to staff about the programme, and seeing patients before or after their consultations to talk to them about the programme. This seemed to be a component of the delivery package which was effective at improving reach, and therefore I recommend it as an approach for a fully optimised intervention. Further research could be done to explore the impact of a Change Manager, and the effectiveness of the other ways that CCGs and practices used to inform patients about the programme, including text messages.
10.4.1.3 Training health professionals about structured education

The qualitative data from the evaluation of the programme during its implementation in the NHS, highlighted the importance of health professionals discussing the benefits of structured education with patients, and the reason for referral. Patients reported not being given enough information about structured education from health professionals. Some health professionals felt GPs and Practice Nurses lacked time and understanding of the nature of structured education programmes, to be able to discuss it in detail with patients. This may have influenced patients’ decisions to register for the programme, and to complete the four sessions once they had registered. The problem of lack of time in consultations is difficult to address, but it may be possible to address deficiencies in understanding of structured education by providing training for health professionals. This is currently offered in Lewisham by the community diabetes team and the Change Manager (delivered by the Community Diabetes Specialist Nurse), and could be more widely offered in other regions.

10.4.1.4 Allied health professionals referring patients to structured education

Another suggestion that came from the qualitative data, was involving staff other than GPs and Practice Nurses in referring patients to structured education, in order to reduce GP and Practice Nurse workload. One of the health professionals I interviewed suggested training healthcare assistants or administrative staff to refer patients to structured education. In the case of HDSO, the programme could be demonstrated to patients before or after their appointment with a GP or Practice Nurse. Patients could immediately be registered for the programme if they liked it and wanted to use it. This could even be extended to other allied health professionals (AHPs) such as pharmacists and dieticians. A systematic review of extended roles for AHPs (437) (including physiotherapists, occupational therapists and speech therapists) has been conducted to determine the impact on the health service of extending their roles to tasks like making referrals to other medical specialities. The authors found that literature on extended roles does exist but robust evaluations of the impact on patient outcomes and cost-effectiveness
are lacking. More research is needed into the effectiveness of extended roles for AHPs.

### 10.4.1.5 Patient champions

Participants suggested recruiting people who completed the HDSO programme to act as “patient champions” to discuss the benefits of the programme with peers and encourage their participation. The role of peer support for patients with type 2 diabetes has been explored in the literature. The World Health Organization (WHO) produced a report in 2008 on peer support programmes in diabetes stating that peer support appeared to be a “promising approach for diabetes management” (438). Their review of the research showed that peer-led face-to-face self-management support led to small short-term effects on outcomes including self-efficacy, self-rated health and cognitive symptom management. Peer-led online support had similar effects (438). A 2016 meta-analysis of HbA1c outcomes from peer support interventions also found a small (yet statistically significant) effect (439). They also found that these interventions may be particularly effective for minority ethnic groups like Hispanic groups (439). An important difference between these reviews and my recommendation, is that the interventions under examination in the reviews were peer-led. My recommendation for HDSO would be that peer-support is supplementary to the online programme, and is used to explain the programme to patients, register patients, or encourage continued engagement with the programme. Encouragement from completers of the programme was piloted for a short period, but did not have an impact. This may have been because communication from completers was made via the forum, and therefore was less effective as it depended on other users viewing the forum. Face-to-face interaction between patients who have and haven’t used the programme may be more effective, if the practicalities of organising meetings and compensating patient volunteers for their time could be arranged. However, results from the HeLP-Diabetes implementation study suggested that the practicalities are a barrier (141). Peer tutors were trained to register patients referred by HCPs in practices, and introduce them to the programme. It was hoped they would be able to spend more time with patients than HCPs were able to in time-limited appointments. All practices in
participating CCGs were offered the peer tutor, but no practices accepted the offer. Informal feedback suggested that the barrier to uptake was the additional work of referring patients to the peer tutor and organising meeting space within the practice (141). Therefore the recommendation to involve peer champions would need to be implemented with recognition that these barriers would need to be overcome for it to be successful.

**Recommendations for addressing challenges at the patient level**

10.4.1.6 **Offering the programme to all patients with type 2 diabetes**
The HDSO programme was developed for newly diagnosed patients (diagnosed in the last 9 months), but everyone with type 2 diabetes was offered the programme when it was evaluated during implementation in the NHS. This decision was taken as I concluded that, due to the low uptake rate of face-to-face education (7.1% (440)), there are people who have had diabetes for longer than 9 months who are in need of structured education. I also reviewed literature which argued that patients are not ready for structured education in the first year after diagnosis. This is discussed in more detail in Chapter 4. My recommendation for a fully optimised intervention would be to offer it to everyone with T2DM, and not just newly diagnosed patients. This is due to the need for structured education after the first year of diagnosis.

**Recommendations for addressing challenges at the intervention level**

10.4.1.7 **Access via smartphones**
Another finding that came from the qualitative data collected during the evaluation of the programme, was the need for the HDSO programme to be available as a smartphone application. Participants explained that they would find it useful to be able to access the programme when ‘on the go’ rather than when at a desk at home or at work.

In Chapter 7 of the thesis I discussed data from the Office for National Statistics (ONS) showing the increase in smartphone use (which has more than doubled since 2016). More than 7 in 10 adults use mobile or smartphones to access the internet (322). There is preferential use of smartphones over other computer devices by adults in low SES households (333). I argued that
providing public health interventions via smartphones may therefore have the potential to help decrease health inequalities. This is because they could help improve access to healthcare for adults from low SEs backgrounds.

A review of mobile phone and smartphone technologies for diabetes care and self-management conducted in 2015 by Garabedian et al, found only 20 studies with robust designs (randomised controlled trials) (441). 16 unique mHealth interventions were evaluated in these 20 studies, and 11 of the 16 interventions showed significant improvements in HbA1c, medication adherence, depressive symptoms, blood pressure and self-management tasks. Interventions that required involvement by patients and health professionals were more likely to be effective (441). Other reviews have also found improvements in glycaemic control (72, 442, 443). A review of computer-based diabetes self-management interventions for adults with type 2 diabetes found a larger effect size on HbA1c in the mobile phone subgroup (72).

Only 3 studies in the Garabedian review collected data on utilisation of the mHealth technologies, and these showed high rates of discontinuation. In one study 32% of participants discontinued using the intervention within 2 months (444), in a second study 66% of participants discontinued use after 6 months (445), and in a third study 38% of participants did not complete a course of six counselling sessions (446).

One study included in the review found that, despite the narrowing of the inequalities in smartphone ownership, there are inequalities in the use of mHealth technologies for health which persist. The study used a cross-sectional survey to examine smartphone ownership and downloading of health apps onto smartphones in Caucasian, Filipino, Korean and Latino American groups (447). They found that Koreans were most likely to own a smartphone, and internet access via mobile phones was more common than with desktop computers in this group. Odds of downloading health apps increased with education, and were reduced in the Latino and Korean groups compared to Caucasians, and increasing age (447).
Smartphones may therefore be useful for delivering public health interventions like HDSO, but attrition may still be a problem, and smartphone access may not be enough to narrow health disparities for ethnic minority groups, older people and people with less education. There may be other factors in the design of the intervention that do encourage engagement from these groups, as discussed in Chapter 7. The results from the analysis of usage of HDSO showed no difference in use by ethnic minority groups and people with less education. The greatest use was in the 51-60 year old age group. I therefore recommend access to HDSO via smartphones, but recognise that this may increase uptake within some demographic groups more than others. My data suggest that the programme is acceptable to older people, those with less education and people from ethnic minority groups on desktop and tablet devices, which provides evidence that the design of the programme was acceptable to these groups.

10.4.2 Recommendations for reducing attrition from HDSO

Recommendations for addressing challenges are at the intervention level include using reminders, incentives and tailoring.

10.4.2.1 Reminders

Telephone reminders were tested as a way of reducing attrition from the programme. As described in Chapter 8, a small study showed that calling people who had not logged on for over two weeks was not effective at increasing the activity rate or completion rate for the programme. There were, however, several limitations to the study. These included a lack of randomisation and the possible role of other contextual factors in influencing the behaviour of the participants. The participants may have had other priorities competing for their time, so that despite receiving telephone reminders, they were not able to use the programme. Due to the lack of evidence for telephone reminders from my study, and the time and resources required to provide telephone reminders for users, I would not recommend them for a fully optimised intervention. I proposed a study of personalised emails in Chapter 9 to determine if these could be more effective at reducing attrition. This is discussed in more detail below in the context of tailoring.
10.4.2.2 Incentives

I also explored the effect of offering an incentive to HDSO users. I found that when everyone who was registered for the HDSO programme was offered a telephone consultation with a dietician, the activity rate decreased from 48.0% to 29.8% and the completion rate increased from 5.0% to 8.4%. Again the study was limited to a small sample size (only 4 people took up the offer of a dietician consultation), lack of randomisation and the effect of contextual factors. Further research on the effect of incentives (which types of interventions are effective, when they should be offered, to who and how) in reducing attrition from the HDSO programme is needed before they can be recommended for the fully optimised.

10.4.2.3 Tailoring

As discussed in Chapter 7, the role of tailoring (or personalization) needs to be explored for recommendations to be made for the fully optimised intervention. Tailoring information was a suggestion that came out of the qualitative interviews I conducted during the evaluation of the second iteration of the intervention. There is evidence for tailored support from the model of supportive accountability, which suggests that having to justify one’s actions or inactions may be a motivator for improved adherence (371). Systematic reviews of technological-based prompts have shown some improvements in the use of digital health interventions (226, 227).

I designed a pilot randomised trial to determine if personalised email support for users of the HDSO programme is more effective at reducing attrition than no support. The intervention I proposed consisted of weekly emails, over four weeks, giving feedback to users about their progress through the course, recognizing and reinforcing progress made, and personalised responses to users’ emails about their barriers to progressing through the programme. I was unable to conduct the pilot trial due to ethical constraints, but this could be explored with further research.
10.5 Conclusion

In this chapter I have described the final intervention, and made recommendations for further optimisation of the intervention and the delivery package, including recommendations for optimising uptake and reducing attrition from the programme. The next chapter describes a protocol for a randomised trial to evaluate a fully optimised intervention.
Chapter 11. Overall discussion

11.1 Chapter summary

In this chapter I have revisited the overall aim and objectives of the PhD. I have discussed the seven objectives, and whether they were achieved. I have also summarised the four studies which make up my PhD and their findings. I have discussed the strengths and weaknesses of my research, including context and setting. I have identified the relationship between my main findings and the existing literature. Finally, I have considered the implications of my findings for policy and practice, and made suggestions for further research.

11.2 Aim and objectives of the PhD, and how they were achieved

The number of people living with type 2 diabetes (T2DM) is growing. Structured education reduces the risk of complications, and it is NHS policy that newly diagnosed patients are referred to a structured education programme. Uptake to group-based courses is low. The internet could help surmount barriers to accessing education. The aim of the thesis was to develop, optimise and formatively evaluate an online structured education programme for people newly diagnosed with type 2 diabetes (HeLP-Diabetes: Starting Out) leading to a programme with demonstrated acceptability and feasibility. The aim of the thesis was achieved through a series of four empirical studies addressing each of the eight objectives summarised in Table 12-1 and listed below.

The eight objectives of my PhD are summarised here to give an understanding of the pathway my research has taken, where the research has led, and where each chapter fits in. Each objective is mapped to a stage of the research, and a thesis chapter.
Table 11-1: Summary of development and evaluation of HDSO

<table>
<thead>
<tr>
<th>Thesis objective</th>
<th>Stage of research/development</th>
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<td>To develop an initial version of the programme (iteration 1)</td>
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<td>To revise the programme in light of these data (iteration 2)</td>
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<td>To determine uptake, usage and effect of the 2nd iteration</td>
<td>Evaluation of the second iteration</td>
<td>6</td>
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<tr>
<td>To describe the demographic characteristics of users, patterns of use, and</td>
<td>Evaluation of quantitative usage data</td>
<td>7</td>
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<tr>
<td>explore associations between demographics and usage patterns</td>
<td></td>
<td></td>
</tr>
<tr>
<td>To consider and evaluate different methods of improving</td>
<td>Optimisation</td>
<td>8</td>
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<td>adherence to the programme</td>
<td>Recommendations for final intervention</td>
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<tr>
<td>-----------------------------</td>
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<tr>
<td>To make recommendations on strategies for improving adherence and for a fully optimised programme suitable for evaluating in a phase 3 randomised controlled trial</td>
<td>Recommendations for further research</td>
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### 11.2.1 To develop an initial version of the programme (iteration 1)

This objective was achieved by organising selected content from the HeLP-Diabetes website into 8 sessions, with a spiral curriculum allowing people to build on knowledge they had acquired in previous sessions. I developed a causal model for the programme, and identified outcomes which could be measured with self-assessment questionnaires. I chose to measure diabetes knowledge, diabetes management self-efficacy and diabetes-related distress at the beginning and end of the programme using the Adknowl, DMSES and PAID questionnaires. I developed personalised feedback which was sent to people on completion of the questionnaires, and personalised email reminders sent to people after they completed a session or if they did not log on for a week or more. Goal-setting tasks were also included asking people to set specific, measurable, achievable, realistic, time-bound (SMART) goals.
Usability testing of the initial version of the programme was carried out, and changes made based on users’ suggestions.

11.2.2 To determine the uptake, usage and effect of this initial version

This objective was achieved by conducting a mixed methods evaluation of HDSO in 15 general practices in London, using questionnaires, usage data and interviews. Patients were offered the programme if they had been diagnosed with T2DM in the last 9 months. The programme was offered either by mailing recruitment packs to eligible patients, or during routine consultations. Uptake and usage were measured as the number of people who registered for the programme, and the number of people who started and completed it. Webpage visits were automatically recorded by the server side of the website, pseudonymised, downloaded to Excel and analysed to give the number of registrations, and proportion of people who started and completed the programme. The effect of the intervention was measured using the Adknowl, DMSES and PAID questionnaires giving indicators of diabetes knowledge, diabetes management self-efficacy and diabetes-related distress. An insufficient number of interviews were carried out to allow for data saturation and analysis. The qualitative data from the evaluations of the first and second iterations of the programme were therefore combined.

11.2.3 To revise the programme (iteration 2) in light of the data from the evaluation of iteration 1

The findings from the evaluation of the first iteration of the programme informed changes to the intervention. The quantitative results showed poor uptake and usage. I explored this further with a user experience study, and found that people reported having too little time to start or complete the programme, or expected it to take too long. Based on these findings, the following changes were made to the programme: (1) the number of session was reduced from eight to four; (2) the number of questionnaires was reduced from three to two; (3) patients were able to self-register online rather than waiting to be registered over the telephone by the HeLP team. All patients with T2DM were offered the programme, not just newly diagnosed patients,
because of the low uptake of face-to-face structured education and the number of patients who have not received structured education 9 months after their diagnosis.

11.2.4 To determine uptake, usage and effect of the 2nd iteration

This objective was achieved by conducting a mixed methods evaluation of the second iteration of the programme. The programme was evaluated during its implementation as a routine NHS service in five CCGs in London. Uptake and usage were again measured using data on registrations and session completion collected by the server side of the website. Effect was measured using the DMSES and PAID questionnaires to determine change in diabetes management self-efficacy and diabetes-related distress. Interviews were carried out with patients and health professionals to explore views of the programme and factors affecting its acceptability.

11.2.5 To describe the demographic characteristics of users, patterns of use, and explore associations between demographics and usage patterns

In order to achieve this objective, I carried out a retrospective analysis of the data on the use of the HDSO programme and HeLP-Diabetes website. I analysed the demographic characteristics of people who registered for the programme or website (both are accessed via a single registration process). I compared the demographic characteristics of people who visited the programme or website, and those who did not. I also looked for associations between demographic characteristics and number of visits to each section of the website or programme, to see if some sections were more popular with certain groups. I compared the number of visits to the HeLP-Diabetes website with the number of visits to the HDSO programme, to see if users preferred unstructured over structured learning.
11.2.6 To consider and evaluate different methods of improving adherence to the programme

This objective was achieved by considering various different ways of improving adherence to the programme, including telephone reminders and incentives. I decided to evaluate the effect of telephone reminders, and an offer of a dietician telephone consultation as an incentive, on adherence to the programme. I collected data on activity rate (proportion of people registered for the programme who visited at least one page) and completion rate (proportion of people registered for the programme who completed it). I compared activity and completion rates before and after the reminders and offer of incentive, to determine if they were effective at improving adherence to the programme.

11.2.7 To make recommendations on strategies for improving adherence and for a fully optimised programme suitable for evaluating in a phase III randomised controlled trial.

I achieved this objective by making recommendations for a fully optimised intervention, and for the research methods to evaluate it. These recommendations included increasing uptake of the programme by employing a Change Manager in each CCG, training health professionals on structured education, asking allied health professionals to refer patients to the programme, access to the HDSO programme via smartphones and personalised support.

11.2.8 To make recommendations for the research methods used in a phase 3 randomised controlled Trial

My recommendations were to conduct a cluster randomised feasibility trial of HDSO to explore whether a phase III randomised controlled trial to determine relative effectiveness and cost-effectiveness of an online structured education programme for type 2 diabetes compared with group-based education is feasible, and what the parameters of such a trial should be. I developed a protocol for a cluster randomised feasibility trial.
11.3 Summary of PhD findings

11.3.1 Study 1: Evaluation of first iteration of HeLP-Diabetes: Starting Out

The aim of this study was to determine the uptake, usage and effect of the first iteration of HDSO. The programme was offered to newly diagnosed patients (diagnosed in the last 9 months) in 15 GP practices in London.

24 people registered for the programme, 13 (54.2%) started it and 3 (12.5%) completed it, during the study. The mean age of patients who registered for the programme was 60.1 years (SD 3.1). 50% were male and 50% were female. 33% of registered patients were white British, 17% were white other, and 50% were BAME. 22% of registered patients had post-graduate degrees, 23% had undergraduate degrees, 22% had A Level qualifications and 23% had no formal qualifications beyond school leaving age.

The questionnaire scores from the three completers showed an increase in the mean knowledge and self-efficacy scores, but also in the distress scores. The number of completers (n=3) was insufficient to perform statistical analyses or draw any conclusions. The finding of an increase in mean distress was unexpected, but could be explained by a greater awareness of the illness, and its implications and the work of self-management.

The findings of this study led to changes to optimise the programme, and the development of a second iteration.

11.3.2 Study 2: Evaluation of the second iteration of HeLP-Diabetes: Starting Out

A mixed methods evaluation of the second iteration of HDSO was carried out in routine NHS practice in five CCGs in London. The aim of the study was again to determine uptake, usage and effect of the programme.

791 people registered for the programme, 603 (76.2%) started it and 74 (9.4%) completed it. Median distress scores were 2.5 points lower at week 4 than week 1 of the programme (p=.001). Median self-efficacy scores were 6 points
higher at week 4 than week 1 of the programme (p < .001). Both changes were found to be statistically significant. But the change in distress scores did not meet the minimal clinically important difference (MCID) of 4 points. The median baseline distress and self-efficacy scores suggested that baseline distress for completers was low, and baseline self-efficacy for completers was high. The qualitative findings suggested that health professional factors, patient factors and programme factors affected programme acceptability and engagement.

11.3.3 Study 3: Analysis of usage data & exploration of the digital divide

The aim of this study was to determine if there were demographic differences between people who registered for the website or programme and the target population (people with T2DM in inner London); if there were demographic differences between people who used the website or programme and people who did not; and if there were different patterns of use between demographic groups. I found that the characteristics of people who registered for the programme reflected those of the target population. The mean age was 58 years (SD=30), over 50% were from BAME backgrounds, and nearly a third (29.8%) had no qualifications beyond school leaving age. I found no association between use (visiting at least one page) of the website or programme and any demographic characteristic, apart from weak evidence of less use by the mixed ethnicity group (35.3%, OR=0.27, 95% CI=0.10-0.78). I found no evidence of differential use of the programme by demographic characteristic, apart from weak evidence for people with degrees and school leavers being more likely to use the “Living and working with diabetes” (p=0.03) and “Treating diabetes” (p=0.04) sections of the website.

11.3.4 Study 4: Strategies to reduce attrition

I evaluated the effect of telephone reminders and offer of dietician telephone consultation on usage and completion of the programme. I found that the completion rate increased after the offer of a dietician telephone consultation was made. The activity rate did not increase as a result of the telephone reminders or offer of dietician telephone consultation. Having reflected on
these results, I developed a protocol for evaluating personalised email support, which I described in Chapter 9.

11.3.5 Summary of overall findings of the thesis

Overall, the findings from the studies conducted for this PhD suggest it is feasible to develop, optimise and evaluate an online structured education programme for people newly diagnosed with type 2 diabetes, and deliver it in NHS primary care. The qualitative findings from the programme evaluation demonstrate its acceptability to patients. Patients appreciated the benefits of using an online programme, as supposed to face-to-face education, including being able to take their time to work through it; accessing information through videos as well as text, and watching videos of other people talking about living with the illness. People also liked being able to access support from the HeLP team over the telephone when they needed it.

The findings from the retrospective analysis of data on the use of the HDSO programme and the HeLP-Diabetes website, showed that there were no strong associations between demographic characteristics and registration and use of the programme. This suggests that the programme was acceptable to people from different demographic groups, including people of older age, less education and ethnic minority backgrounds. This was an important finding because of the concern about the “digital divide” (defined as the gap between those who do and do not make regular use of digital technologies and the internet (293, 294)) and the potential for DHIs to widen health inequalities for these groups.

In addition to these findings, the evaluations of the programme showed that there was high attrition after registration. Among those who did complete the programme, I found that there were improvements in diabetes management self-efficacy and diabetes-related distress.

Next, I have discussed the strengths and weaknesses of my research overall, before relating my findings to the relevant existing literature. Individual studies have already been discussed in each chapter.
11.4 Strengths and weaknesses

The strengths of the research include:

- The conduct of the research in routine NHS service delivery which allowed for greater external validity of the results.
- The use of theory and user-involvement in the development and evaluation of the HDSO programme;
- The use of mixed methods in the evaluations of the programme which allowed the qualitative findings to give the quantitative findings greater meaning;
- The iterative approach to intervention development.

Carrying out the research during implementation of the intervention in the NHS also led to several limitations and weaknesses. First, I have discussed the strengths and weaknesses of ‘real world’ research, then I have discussed the other strengths and weaknesses I identified.

11.4.1 The context: ‘real world’ research

I joined the HeLP team during the development of the first iteration of the programme. The aim was to implement it in the NHS and gain accreditation from the Quality Institute for Self-Management Education (QISMET). I developed the plan for my PhD in line with this agenda. I took the lead for the latter stages of development (as described in Chapter 3), and evaluated the programme when it was implemented in NHS primary care. I was therefore able to experience what it is like to research an intervention that is being implemented in the “real world”, rather than in a clinical trial. There were strengths to this but also limitations and challenges, which have been described in previous chapters, and which I have reflected on and summarised here.

Firstly, I have reflected on the strengths of carrying out the research in routine NHS practice. The greatest strength was the external validity of the results. As discussed in Chapter 7, an evaluation of an intervention in routine practice is more likely to include an accurate representation of the population at risk (354). RCTs are more limited in their external validity because of the
characteristics of patients who volunteer, and the inclusion and exclusion criteria in trial protocols (40, 355). For example, RCTs usually exclude patients with comorbidities, which means that eligible patients only represent a small proportion of the patients that are seen in normal practice (125, 355).

The participants of my studies accurately reflected the population of interest (people with T2DM treated in NHS primary care). I found evidence of this from my analysis of the usage data and exploration of the digital divide. One of the objectives of this study was to compare the demographic characteristics of people registered to use the programme or website with the target population (people with T2DM in inner London). I found that registered users were comparable with the target population. 51-60 year olds formed the highest proportion of registered users. This reflects Public Health England data showing that there is a higher proportion of people in the 41 to 60 year old age group living with T2DM than any other age group.

Another strength of the research is that I measured uptake in a clinical setting. It is important to measure uptake because population impact depends on reach (uptake) as well as effect (234). Uptake is particularly important for DHIs because their impact and cost-effectiveness are dependent on the number of users (63, 235). It is important to measure uptake of DHIs in community or clinical settings, because it may differ from uptake in clinical trials (448, 449). As discussed above, people using DHIs outside of trials may have more complex medical or social problems which affect their use of the intervention, or they may feel less obligation to use the intervention outside of a clinical trial context when they are not in contact with a researcher. A systematic review of real-world uptake and engagement with digital self-help interventions for anxiety and depression has been conducted to explore the differences in use (448). The review found that there were only 11 published studies which reported uptake and/or usage of self-help interventions for depression or anxiety which were available to the general public. The data were very inconsistent between studies, but overall they suggested that DHIs are used differently in clinical and research settings. Sustained use (for over 6 weeks) or completion of the online programmes varied from 1% to 28% in clinical
settings (448), compared to 43% to 99% in trials of online interventions for depression and anxiety, this suggests much lower use (258). My research was carried out in routine practice and my findings on uptake are more likely to mirror real life. Clinicians, commissioners and policy makers who are interested in the programme’s uptake in clinical settings may find these results useful when considering implementation.

Another strength of evaluations conducted in real world settings, is that they allow for recognition of factors other than patient characteristics, like the clinician-patient relationship. This is highly relevant for complex interventions like DSME, physiotherapy or community nursing, which depend on the relationship between the clinician and the patient for successful outcomes. The impact of the relationship between clinician and patient was incorporated into my studies, because patients were referred by clinicians, as well as being able to self-refer. One of the findings from my qualitative data highlighted the important of this relationship, and the influence GPs and Practice Nurses had on patient attitudes towards DMSE. One of the Diabetes Specialist Nurses I interviewed said that it was important for health professionals to “sell the benefits of education to patients” in order to improve engagement. In my discussion of possible reasons for high attrition below, I have listed lack of discussion on the benefits of the programme with health professionals as a possible contributor. This was disappointing in terms of usage and completion rates of the programme, but it has provided learning on the challenges of implementing an online structured education programme in primary care, and where improvements need to be made.

There were also challenges and limitations to carrying out the research in routine practice. I was unable to randomise participants in order to limit bias, as I would have been able to in a RCT. Findings from RCTs are considered to be closer to the true effect of the intervention due to the fact that participants are randomised and bias is limited. Whereas, studies like mine which are carried out in routine practice without randomisation, are highly susceptible to bias and regression to the mean and it is more difficult to be confident about the effectiveness of the intervention due to confounders. In the case of HDSO
I looked at the effect of the intervention on self-efficacy and emotional distress, and I looked at the effect of strategies to reduce attrition. I found that self-efficacy and distress did improve, but the people who completed the programme and provided these data also had high baseline self-efficacy and low emotional distress. It could be concluded that they were consequently more highly motivated to complete the programme, and more likely to experience and report improvements. If a RCT were carried out and patients were randomised, a more equal number of people with high self-efficacy and low distress would be seen in the intervention and control groups, and so any difference in effect between the intervention and control would be more likely due to the intervention rather than patient characteristics. When I evaluated the impact of telephone reminders and incentives on attrition from the programme, I found a small improvement in completion rate with the incentives. However, I suggested that there may have been other situational triggers which influenced activity and completion rates, and that I could not draw conclusions from the data without randomisation and comparison with a control group.

Another limitation was the heterogeneity in the way CCGs and practices adopted and implemented services. Some practices undertook electronic records searches to identify eligible patients and sent them invitation packs to register for the programme, whilst others did not and relied on patients noticing flyers in waiting rooms or clinicians remembering to invite patients to register for the programme in consultations. I had little control over how patients were recruited to the programme, as the CCGs who commissioned the programme each had their own priorities, plans and resources and did not have to follow a research protocol dictated by me. This meant that there was a lot of variation in the way patients were made aware of the programme and referred to the programme, which may in turn have affected engagement. This also meant that it was impossible to collect data on how many patients were offered the programme in total, and how many declined to register in comparison to how many did register. I could not collect data on which methods practices used to register patients for the programme, as they were offering a NHS service and were not part of a research study. So I was unable to quantify how many
practices used each method (e.g. text messages) or to use this data to determine which method was effective at achieving the highest number of patient registrations. It may also have been interesting to interview patients who were offered the programme but declined, but because I did not have their details I could not do this. There would also have been ethical limitations to this, as I would have had to ask them for consent to be contacted at the point at which they declined registration.

Another important limitation was that I was not able to collect data on clinical outcomes. The causal model I developed shows that weight loss and decreased HbA1c are distal outcomes for the intervention. I could therefore have measured weight, HbA1c and other markers of physical health like blood pressure and lipids to look for evidence of impact of the intervention. However, I could not ask practices to collect clinical data for the purposes of my research, and I could not access the electronic medical records to access clinical data. I have suggested that if I were to carry out a RCT I would build in visits to the practice during and at the end of the study to extract clinical data and ethical approval for this. Although the programme is supposed to be completed over four weeks, data could be extracted at 3 or 6 months to look for evidence of long-term sustained change.

There were many aspects to the research that I found interesting, despite the challenges. Firstly, I learnt about developing a complex intervention, evaluating it and implementing it in the health system. As a result of the implementation in the health system, I had to be more flexible and adaptable to the limitations imposed by the clinical setting. For example, when I noticed there was high attrition from the programme I made changes to the programme and its delivery package, and developed and tested strategies to try and reduce attrition in response. I was able to do some of these things concurrently. I carried out a user experience study to explore barriers to completing the programme during the evaluation of the first iteration of the programme. And I developed and tested strategies for reducing attrition during the evaluation of the second iteration of the programme. I would not have been able to take the decision to carry out these additional studies if I had conducted
a phase III RCT as I would have been following a much stricter protocol. I may have had to conduct these studies consecutively, which would have taken more time. It was useful to develop this flexibility and creativity, as these are important attributes for health researchers.

Next, I have listed other strengths and weaknesses of the methods I used which were not specific to the context of the research.

11.4.2 Other strengths and weaknesses of the methods

A strength of the research was the use of theory and user-involvement. As discussed in chapter 2, theory can be used to explain events by specifying relations among variables. Theory can help guide design of the intervention, and the methods and analysis used in the evaluation of the intervention. For my research, I used education theory, behaviour change theory and implementation theory to guide the development of the intervention and its evaluation. There was also user-involvement in the development of the intervention, including the user-testing of the initial intervention prior to its evaluation. Theory and user-involvement were central to the programme’s success in terms of acceptability, particularly with people from different demographic backgrounds. It was the careful design and development of the intervention that meant users of different age groups, education levels and ethnic backgrounds could use the intervention. Implementation theory like NPT can help to explain why the programme had poor uptake and high attrition, and the themes from the qualitative analysis were therefore mapped to NPT constructs in Chapter 6. Further consideration needs to be given to how the programme could be embedded and sustained in routine practice.

Another strength of the research was the use of mixed methods. I used quantitative methods to determine uptake, usage and effect and I used qualitative methods to determine programme acceptability. The findings from the qualitative study helped me to understand the quantitative findings, particularly factors affecting uptake like lack of time spent discussing the programme by health professionals. It also helped me to understand views on acceptability of the programme, and factors affecting engagement. People
described the features of the programme they liked such as videos and stories from others living with T2DM, and factors which may have affected user engagement with the programme such as non-prioritization, lack of personalization and lack of smartphone access.

A weakness of the research was the lack of consistent patient and public involvement throughout the four studies. I have reflected on PPI in each of the four studies (following the development of the first iteration which is described in Chapter 3), and how this could have been improved:

1. **Evaluation of the first iteration of the programme:** A protocol was written for the evaluation, and this was submitted for grant funding from the NIHR SPCR with PPI representatives as co-applicants. The PPI representatives provided advice on areas including the importance of the research question, the planned recruitment strategy and outcome measures (including questionnaires), and I updated the protocol accordingly. The grant application was successful and the evaluation was carried out (and is described in Chapter 4). During the study, the PPI representatives advised on recruitment packs sent to practices, which gave patients details of the programme and how to register. They gave comments on whether patients would find the information in the packs clear, and if they would help encourage patients to register. They also advised on patient information sheets and consent forms used in the qualitative research. Results were presented at steering group meetings every four months, and interpretation of the results was discussed with PPI representatives. I used their insight from these discussions to plan changes to the programme, and subsequent studies.

2. **Changes to the first iteration of the programme:** I developed the ideas for the changes to the first iteration of the programme using the results of the evaluation of the first iteration, and an addition user experience study (described in Chapter 5). I presented these ideas to the HeLP team (including the PPI representatives) at a steering group meeting, and all changes were agreed with the team before implementation. I could have ensured more significant PPI by asking PPI representatives to suggest their own ideas for changes to the programme after presenting the results of the evaluation of the first iteration, and the user experience study. However, I decided that user views had been explored in the user experience study itself. If I were to repeat the study I would ask for PPI at the stage of data interpretation and development of themes from the user experience study, to check my interpretations and themes with the PPI representatives and get a patient perspective.

3. **Evaluation of the second iteration of the programme:** The evaluation of the second iteration of the programme was not conducted as a research study, as the HDSO programme had been commissioned and was being offered as a NHS service. There was less opportunity, therefore, for PPI in this study. Recruitment was different in each CCG that the programme was offered in, so the PPI representatives could not advise on this. They had
already seen and commented on the recruitment packs, and patient information sheets and consent forms for the interviews. They had also advised on outcome measures, including questionnaires, as part of the evaluation of the first iteration and the meeting about the changes to the first iteration of the programme. Initial results of the quantitative and qualitative components of the study were shared with PPI representatives at a steering group meeting during the course of data collection. Again, more significant PPI could have been achieved if I had shared results with the representatives more frequently and involved them more in the qualitative analysis process. This would have been challenging as my PPI representatives would have needed training in thematic analysis, but I could have considered this in the timelines and costs of the SPCR grant for the evaluation of the first iteration of the programme. I could also have asked PPI representatives to help with dissemination of findings, to their local networks such as Diabetes UK groups, or local GP surgeries and hospitals. Another possibility would have been to present the findings of the research with the PPI representatives at events for healthcare professionals or the public. These are both options that could be revisited in the future, and the findings of the PhD as a whole could be disseminated with the assistance of PPI representatives to generate more impact.

There was less PPI in the second two studies of the PhD (Analysis of Usage Data and Reducing Attrition), and in developing the recommendations for the final intervention. This was, in part, due to lack of funding following the end of the SPCR grant during the evaluation of the second iteration of the programme. I was unable to ask the PPI representatives to continue giving their time and traveling to UCL without being able to offer them appropriate payment, as advised by INVOLVE (an organisation funded by the National Institute for Health Research, to support active public involvement in NHS, public health and social care research) (450).

I could have incorporated PPI in the usage data study by discussing with them and inviting their interpretation of the findings. I could also have incorporated PPI and gained patient insights into the development of strategies to reduce attrition, and in the development of recommendations for the final intervention. This could have led to the strategies to reduce attrition being more successful, the recommendations for the final intervention being more relevant to patients.

A further weakness was to combine the qualitative data from patients who used the first iteration of the programme and the second iteration of the programme. Had these findings been separated out, I may have been able to
learn more about patient perceptions of the changes to the intervention. However, only three people who used the first iteration of the programme agreed to be interviewed and this was not enough to draw any conclusions. Other weaknesses of the qualitative research are discussed in Chapter 6, and include some of the interviews being conducted by a user experience design expert.

11.5 Relationship to existing literature

Next, I have discussed the relationship of each of my main findings to the existing literature. These are: feasibility, acceptability and effect of the HDSO programme; and uptake and usage.

11.5.1 Feasibility, acceptability and effect of the HDSO programme

Systematic reviews of online self-management support for T2DM have shown evidence of effectiveness at improving health outcomes (72). However, there is substantial heterogeneity in the use of theory in development of interventions (75), in the outcomes that are measured in trials, and in the duration of follow-up (72, 451). All of the interventions included in the Pal review were evaluated in randomised controlled trials (72). Less is known about the feasibility, acceptability and effectiveness of online structured education for T2DM in routine NHS care. HeLP-Diabetes is one of the first web-based self-management support interventions to be implemented in the NHS. As discussed in Chapter 1, most of the structured education programmes currently commissioned in the NHS are face-to-face courses. A randomised controlled trial of the HeLP-Diabetes website published in 2017 found that HbA1c improved over 12 months for participants in the intervention group. This suggests that online self-management support for T2DM can improve glycaemic control. However, HDSO is a structured education programme that is accessed from the HeLP-Diabetes website and so evidence of its effectiveness is also needed.

The evidence for structured education that is available online for patients in the NHS is still emerging. In 2017, two interventions were invited to join the NHS Innovation Accelerator called My Diabetes My Way (MDMW), and Oviva
Diabetes Support. The NHS Innovation Accelerator supports innovation in the NHS by helping organizations who have developed high-impact, evidence-based interventions to grow to scale across the NHS (452). MDMW is an interactive educational resource implemented by NHS Scotland since 2008 for people with T1 and T2 diabetes, and their carers (453). In 2010 an electronic personal health record was launched in MDMW, to allow patients to access their shared health record as well as diabetes information (453). In 2013, the programme had 3,391 registered users (31% with T1DM), of these 2,015 had completed the enrolment process and 861 had logged in (453). Users reported that they found it helpful for monitoring results, discussing results with health professionals and prioritising areas to improve (453). The programme now has 200 multimedia education resources, data-driven personalised advice, communication tools for health professionals, links to social media and peer support, and 32,000 registered users (452). Unlike HDSO, MDMW doesn’t provide NICE-approved structured education and it is a personalised health record as well as an education resource. Until recently MDMW was only available in Scotland, but it now has also been launched in Somerset and North West London (452). Data from these areas is not yet available.

Oviva does offer, as one of its diet-related suite of programmes, NICE-aligned QISMET-accredited structured education for T2DM (454), in addition to coaching from a diabetes-specialist dietician. The programme runs for 8-12 weeks and is delivered by telephone or using the app. Oviva outcomes data have shown an average reduction in HbA1c of 13mmol/mol and weight loss of 4.5% (454). Again, this is unpublished data. Oviva Diabetes Support is delivered via the Digital Diabetes Coach project led by the West of England Academic Health Science Networks (AHSNs) (454), and in North West London in partnership with Imperial College Health Partners (452).

The available published literature on online DSME, and the outcome data from programmes being implemented in the NHS, have shown that it is feasible and acceptable to patients, and can improve health outcomes (72, 453, 454). My research on HDSO adds to this. I have not measured the effect of HDSO on
clinical outcomes, as has been done in previous studies of online DSME, and this is a priority for future research.

11.5.2 Uptake & usage

Another important consideration, in terms of the relationship of my research to the existing literature, is what is known about uptake and usage of other diabetes structured-education programmes, and other DHIs.

As discussed in Chapter 1, uptake of diabetes structured education in England is poor (440), with only 7.1% of referred patients recorded as attending. As discussed in Chapter 6, my data on the completion rate of HDSO therefore compare favourably at 9.4%. A systematic review examining reasons why people referred to structured education choose not to attend found similar results to my qualitative findings, that people perceived no benefit, felt they had sufficient knowledge already, and were influenced by healthcare professionals who lacked enthusiasm for education (56). These are barriers that are applicable to both online and face-to-face courses, and are not overcome by offering an online option alone.

It is also important to relate the attrition from HDSO to usage of other DHIs. “Nonusage attrition” is when participants stop using an intervention, and is a problem that has been recognised in the literature on DHIs, with attrition rates of up to 80% being recorded (240). As discussed in Chapter 8, nonusage attrition has been seen in studies of online interventions for psychological disorders, problem drinking, weight loss, smoking cessation, and TD2M self-management (84, 89, 91, 93, 94, 258, 364, 365). Structured programmes containing modules, like HDSO, have found similarly low completion rates. In a study of a web-based cognitive behavioural therapy (CBT) programme, only 1.03% of registered users completed the 12-week programme (367). In a study of an internet-based diabetes self-care intervention, use was greatest in the first few days and declined rapidly thereafter (84). However, improvements in self-reported self-care activities (such as diet, exercise and smoking) were still seen in participants using the intervention at the end of the study (84).
The reason for high attrition is likely to simply be that people lose interest over time (455), and strategies for overcoming this need to be developed to improve adherence. I have considered what may have caused the high attrition from HDSO in terms of intervention factors, patient factors, and health care system factors, and discussed this below.

11.5.2.1 Intervention and delivery package factors contributing to attrition

Systematic reviews of the factors influencing engagement with DHIs have identified that use of behaviour change techniques (BCTs) such as action plans, goal-setting and feedback result in higher engagement (241, 391). These features were included in the HDSO programme, but high attrition was still seen. It may have been the case that the BCTs were helpful for improving engagement with the intervention for some users and not others.

The use of rewards or incentives has also been hypothesised to be effective at improving engagement, but evidence from trials is scarce (241). Monetary incentives have been found to improve retention in RCTs and return of postal questionnaires (378, 379). Response also increased with non-monetary incentives (379). In keeping with this, I found that use of a non-monetary incentive was effective at improving the completion rate for the HDSO programme. There were, however, limitations to my study including small sample size and lack of randomisation. In contrast to my findings on the impact of telephone reminders on attrition, a review has shown that the use of telephone and text message reminders improve patient adherence (456).

I found that my findings were in agreement with some of the literature on engagement with DHIs but not others. In order to explore the reasons for attrition from the HDSO programme more deeply, I considered the features of the programme and reflected on how they may have affected user engagement. In particular I have focused on the structured nature of the programme, and the need to complete one session before moving on to the next.
In Chapter 6, I discussed the finding that 80.6% of people who started the programme, did not go further than week 1. 57.7% of people did not go further than the homepage. This made me consider whether some people prefer to dip in and out of an education programme, rather than completing each session in a specified order, and whether this was a factor which contributed to high attrition.

The rationale for HDSO being a structured programme with a spiral curriculum which people were asked to work through from start to finish, was to meet NICE requirements (15) and gain QISMET accreditation (145). The HeLP-Diabetes website was an unstructured self-management resource with information organised into sections which people could pick and choose from. HDSO was added to the HeLP-Diabetes website, to act as an additional incentive for commissioners, who are required to refer patients to DSME within 9 months of diagnosis (17). Both the HDSO programme and the HeLP-Diabetes website were accessed via a single registration. The HeLP-Diabetes website may therefore have acted as competition for the attention of people who did not want to complete the sessions in the HDSO programme from the HeLP-Diabetes, as it was available to them and much more flexible to use. I have evidence for this from my analysis of the usage data from HDSO and HeLP-Diabetes. I compared the number of page visits to the HeLP-Diabetes website with the number of page visits to the HDSO programme. I found that HDSO only received 13.3% of the visits received by the HeLP-Diabetes website. This finding suggests that there was preferential use of the HeLP-Diabetes website.

Some work has been done looking at whether people prefer structured or unstructured education. In the field of digital health, this has been considered in terms of 'user control'. The Perski review of engagement with digital behaviour change interventions suggests that when users have more control over how they use an intervention, they are more likely to engage with it (241). This is based on two studies comparing user engagement when intervention content is delivered either sequentially (as in the case of HDSO), or when all content is made available at once (as in the case of the HeLP-Diabetes
website) (91, 350). The first is a study of engagement with a tailored web-based smoking cessation programme. Participants were randomised to either being able to access all sections of the website at once, or sequentially receiving each section over 5 weeks. Participants who were given content sequentially were more likely to disengage (91). Comparisons were not made between sequential and non-sequential information in the same users.

The second of the two studies in the Perski review is a study of online education for hepatitis to determine whether and how user control (the ability to skip pages) increases both website use, and knowledge gained from the website (350). The authors found that having less user control and viewing the webpages in a pre-determined order (a tunnelled version of the website), resulted in less perceived efficiency but a greater number of pages visited, time on the website, and knowledge gained from the website. Efficiency was measured with a questionnaire containing questions such as: “I was able to access the information quickly on this website” and, “the website provided me with relevant information about...”. The measures had been previously validated. Interestingly, perceived efficiency was less with less user control but website use was greater. This may be because the idea of control and choice is more important than actually having it.

Research on consumer psychology has shown that consumers report wanting to have choices, and cannot imagine not preferring to have choices (457). Choice is important because it increases intrinsic motivation (268). Intrinsic motivation is a component of self-determination theory and has been described as one’s innate propensity to engage and exercise capacity to achieve challenges (268). Choice increases intrinsic motivation by prompting an internal locus of causality (458). An internal locus of causality is the attribution of outcomes to an internal factor, such as skill (458). It has been suggested that the nature of the choices presented to people is also important. Having options does not always increase motivation. If people are offered options they do not value, or find irrelevant, this may be depleting of their energy and motivation. Whereas options which have personal value may
increase energy and motivation (459), so tailoring may be effective for this reason.

Consumer preferences for choice can be so strong that choice is preferred even if the control is illusory (460). The illusion of free will results in a feeling of stability and control, and allows people to act with a sense of moral responsibility (461). This is essential in striving for achievement, autonomy and dignity (462).

The findings of the hepatitis website study suggest that a structured approach to online health education results in greater use than a more flexible approach. However, self-determination theory and theory on free will suggest that choice is important for increasing motivation and sense of achievement. My findings are also inconsistent with the hepatitis website study, as I found that people visited the structured HDSO programme less than the unstructured HeLP-Diabetes website.

I have also considered how greater flexibility and personal choice may conflict with the principles of structured education. The NICE guidance for T2DM management states that DSME should follow a structured curriculum. This is to ensure that core topics that are considered essential learning are included, and that learning starts with basic principles before moving on to more complex ideas. During the development and optimisation of HDSO, the HeLP team were very careful to make sure that these principles were maintained and core content from the HeLP-Diabetes website was retained even when the programme was shortened from four session to eight. Personalization and personal choice would result in less control over which pages are visited. It may result in people not accessing core information, or not starting with basic concepts first. This may subsequently result in less effective learning, and the learning objectives of the course not being met.

From a digital health perspective, it is worth considering how we measure effective use of a DHI, and why and whether completing all parts of a structured programme are important. The issue of ‘effective engagement’ has been discussed in the digital behaviour change literature. There is agreement
that engagement with health interventions is necessary for effectiveness (349). There is evidence that engagement with digital behaviour change interventions can be poor, and leads to high levels of non-usage attrition as discussed in Chapter 8 (240, 340). Engagement has been operationalised in the behavioural science literature as the degree to which people use the intervention as the developers of the intervention had intended, focusing on frequency and duration of use of specific content (348, 352, 463). In the case of HDSO, this would mean completing all four sessions of the programme. This pattern of use assumes a ‘dose-response’ relationship, and that the outcomes of the intervention can only be achieved if the intervention is used in this way. However, the evidence for whether usage is so closely related to outcome is mixed, and this has also been discussed in Chapter 8. To summarise, there is evidence from systematic reviews that adherence does result in better outcomes (88, 347). But the reviews attempt to synthesise different measures of adherence, and this makes it difficult to draw conclusions. It is also difficult to confirm the mediator of a dose-response relationship, and whether the improvement in outcomes results from other factors like patient motivation, which overlaps with or is obscured by patient engagement (348). Motivation is considered to have such an important role that it has been described in the literature as the “unmeasured third variable” with relation to engagement and outcomes (241). There is also the possibility that reverse causality is an attributing factor. Reverse causality is when the user experiences better outcomes, and so becomes more engaged with the intervention. As discussed in Chapter 8, it seems likely that on balance there is at least an association between adherence and outcomes. The question I have chosen to focus on here is what dose of the intervention is needed to give the intended outcomes (the effective dose).

The reason I think this is important, is that there are various ways to engage with an intervention. This fits more with the HCI definition of engagement, where it is seen more flexibly as a subjective experience of flow, characterised by attention and enjoyment (241). The intended outcomes of the HDSO pathway, as illustrated by the causal model in Chapter 3, include proximal outcomes like improved self-efficacy and reduced distress, and distal
outcomes like weight loss and physical activity. The intention is that engagement with the programme leads to improved self-efficacy and distress, which results in changes in behaviour like healthy eating, which subsequently leads to weight loss. The proximal outcomes were measured by the programme but the distal outcomes were not. Outcomes were only measured in those who completed all 4 parts of the programme, as users were asked to complete the follow-up questionnaires at the end of week 4. It is possible, however, that improvements may have occurred for people who did not complete all four parts of the programme, and did not complete the questionnaires on self-efficacy and distress. It is possible that some people displayed non-usage attrition, and used some parts of the HDSO programme and perhaps some parts of the HeLP-Diabetes website and still benefited from the intended outcomes. In this case cessation of engagement for these users, could mean sufficient engagement. However it is impossible to measure this without being able to follow up the non-adherent users. However, further research could be used to measure outcomes in people who did not complete the whole programme, and compare these outcomes with people who did complete the programme. This may help contribute to understanding what effective engagement is, rather than focus on sustained engagement and completion of the programme. It would also build evidence for what has been described the “optimal dose” for digital behaviour change interventions, or the pre-defined level of use at which these interventions are effective (241). However it has been hypothesised that this optimal dose will vary between users (464, 465), and this could mean tailoring of the intervention for individuals. Focusing on effective levels of engagement rather than adherence prioritises patient-centredness, as it focuses on how patients can gain benefit from the intervention, rather than the interests of the developer. It may be that focusing more on the time spent using the intervention, the quality of the use, or other aspects of engagement may be more useful (91, 348). Figure 12-1 illustrates the concept of sufficient engagement.
The figure shows a Phase 1 where users engage with the intervention only before engaging with behaviour change. It also illustrates a Phase 2 where users engage with behaviour change mediated by the intervention, and the two are occurring concurrently. The figure then demonstrates the possibility that engagement with behaviour change can continue after cessation of engagement with the intervention (Phase 3). Finally, the figure also demonstrates the possibility that users can re-engage with the intervention at a later date if needed (Phase 4). This is another possibility that I think may apply to the HDSO programme. The sessions are called “Weeks” to indicate that they should be completed once a week. In addition, users who completed Week 1 of the programme were recommended to do “one session a week” in the congratulations email they received. However, it is possible that a proportion of people who registered either planned to start it a later date, or started it and then planned to complete it a later date. These people would have contributed to the nonusage attrition I found in my evaluations. Perhaps one way of measuring this would be to ask people to complete a survey on registration to provide information on when they were planning to start or complete the programme, but this may be unreliable as intentions change over time, and may be prone to bias if respondents feel they need to answer that...
they will start the programme straight away. This leads on to a further discussion about patient factors which contributed to the attrition.

### 11.5.2.2 Patient factors contributing to attrition

There are several patient-centred factors which may have contributed to attrition. My data suggested that patient factors contributing to engagement may have included competing priorities, not being ready for information, perceived relevance and perceived need for structured education. As stated earlier in this chapter, my qualitative findings are in agreement with a systematic review of reasons why people referred to structured education choose not to attend. This review found that people perceived no benefit from attending structured education, did not see it as a priority, felt they had sufficient knowledge already, or felt they received inadequate information from health professionals (56). The review also found that some people were already satisfied with the care they received, felt there was no need to be educated as they did not perceive a problem, were unaware of available programmes, had negative feelings towards diabetes education, did not want to know about complications, were afraid of excessive demands, were in denial or had literacy, cultural or language problems (56). Lack of personal relevance has also been identified as a contributor to high attrition (241).

Dropout from attrition trials has been investigated with interviews and participants have described lack of personal relevance as a cause (466-469).

Patient demographic characteristics have also been found to influence engagement with DHIs (241). There is evidence for a trend towards greater engagement with younger age, female gender, higher educational attainment, and non-minority ethnic background. However no meta-analysis has been conducted so it is impossible to draw conclusions about effect size (359, 361). These findings are in contrast with my usage data discussed in Chapter 7, which showed that the characteristics of people who registered for the programme reflected those of people living in inner London with T2DM (older age, less education and BAME background). I found weak evidence of less use of the website or programme by the mixed ethnicity group, but no evidence of less use by Black or Asian people. I found weak evidence of differential use
of the programme by people with degrees and school leavers, and found both
groups were more likely to use the “Living and working with diabetes” (p=0.03)
and “Treating diabetes” (p=0.04) sections of the website. There was no
evidence of a difference in the way the more educated people (people with
degrees) used the website compared to people with less education (school
leavers).

User engagement is also influenced by social and cultural factors, like family,
cultural norms, and media and social cues (241, 349, 470). The physical
environment can also play a role including financial resources, location and
the health system (241). DSME is commissioned by local CCGs in England,
and there can therefore be geographical variations in the programmes that are
available. HDSO was only available to 5 CCGs, all of which were in inner
London, during my research. Waiting lists for places on face-to-face structured
education can be long in some areas, and affect patient attendance. Social,
cultural and physical factors need to be addressed for engagement with DHLs
and structured education to improve (349). For example, incorporating peer-
to-peer support and being available in different languages. HDSO is not yet
available in other languages, but does offer peer-to-peer support via the user
forum. But, it was not one of the more popular sections of the website. When
I looked at the number of visits to the different sections of the HeLP-Diabetes
website, I found that the forum and help sections (which includes the blog) had
the seventh highest number of visits out of twelve sections.

11.5.3 Healthcare system factors contributing to attrition

The programme was evaluated during implementation as a routine NHS
service. I therefore could not collect data on how many people self-referred
after seeing a flyer or message from the practice, and how many people were
referred by health professionals. The flyer (see Appendix G) gave details of
the HDSO programme, as a “four-part programme”. Health professionals may
not have highlighted this or encouraged people to complete the programme.
This may have resulted in people not understanding that the programme was
designed for all four sessions to be completed in order. Users may have
registered and looked at the homepage and realised that all four sessions
needed to be completed sequentially, and they may have contributed to the 57.7% of people who dropped out at the homepage. Or people may then have been more attracted by the unstructured nature of the HeLP-Diabetes website, from which they could pick and choose as little or as much information as they wanted. This may have resulted in the higher number of page visits that was seen to the HeLP-Diabetes website then the HDSO programme. This is both a healthcare system and intervention factor. Health professionals need to explain the nature of the programme, and the benefits of completing a structured programme, in order to encourage engagement form patients.

11.6 Implications

The findings of the research have implications for practice, policy and research. These are described below.

11.6.1 Implications for clinical practice

The HDSO programme was implemented in five inner London CCGs during the evaluation of the second iteration of the programme. 791 people registered to use the programme, suggesting that it is feasible to deliver online structured education for T2DM in NHS primary care. Only 74 of the people who registered for the programme completed it, suggesting that people need more support and encouragement to continue using the programme when they register and after registration.

My data showed that more people registered to use the programme in a CCG where there was a Change Manager employed to liaise with patients and practices about the use of HDSO. This suggests that having a dedicated Change Manager may be a helpful model for engaging patients with structured education. The findings from my qualitative interviews suggested that GPs and Nurses don’t have enough time to spend with patients discussing the benefits of structured education, and encouraging patients to engage with it. It was suggested that HCAs or administrators may be better placed to do this. There was also the suggestion that GPs do not have a good enough understanding of what structured education consists of, to be able to discuss it effectively with patients. One of the DSNs that I interviewed carries out training for GPs
and health professionals teaching them about diabetes structured education for their patients. If uptake of structured education is to improve, it may be necessary to involve HCAs, administrators and other allied health professionals in referring and supporting patients, and to educate GPs about diabetes structured education so that they are able to have more effective discussions with patients. My qualitative findings and the findings of other qualitative studies, also suggest that patient factors like patient perception of the value of structured education or the need for structured education, impair uptake of education courses. These are barriers that are common to both face-to-face and online learning, and more research is needed into how these barriers are to be overcome if the uptake of structured education is to improve.

I considered and evaluated different ways of reducing attrition from the programme. I found that telephone calls and offers of incentives were not effective at improving the proportion of people completing the HDSO programme, but there is growing evidence that more personalised support may be helpful in improving engagement (348, 352, 471). I therefore developed a protocol for personalised email support for HDSO users. If evidence is found that personalised email support is successful at reducing attrition from the programme, it could be added to the delivery package that is implemented in practice, as a cost and resource-effective way of improving usage of the programme without relying on GPs and nurses who are already under considerable pressure to increasing workload.

11.6.2 Implications for policy

It is NHS policy for people with T2DM to be offered structured education within nine months of their diagnosis (15, 17). When the first iteration of the HDSO programme was offered to people newly diagnosed with T2DM, 24 people registered to use it. But when the second iteration of the programme was offered to anyone with T2DM, 791 people registered to use it. There were other differences in the way the programme was offered which caused this disparity. These include the fact that HDSO was not yet commissioned in the CCGs participating in the evaluation, and fewer practices were approached by the HeLP team to participate in sending out registration packs.
556 people provided data on duration of T2DM. These data showed that 69.4% of people registered to use the programme had T2DM for more than one year. The qualitative data from the patient interviews suggested that some patients were not ready for structured education, did not perceive it as relevant at their stage of the illness or did not feel the need for it. These data support the argument that NHS policy should be updated to ensure that all people with T2DM are offered structured education, and given the opportunity to access it even if they are not newly diagnosed.

Currently, diabetes structured education is mainly offered as face-to-face courses. The All-Parliamentary Group for T2DM conducted a year-long investigation into the state of diabetes education and support in 2015, and concluded that people need more flexible options for support including online options (60). The strategy for the NHS outlined in the Five Year Forward View describes using digital technologies to support patients with self-management of long-term conditions (28). My findings show that it is feasible to respond to these recommendations and to deliver online diabetes structured education in the NHS.

**11.6.3 Implications for research**

My findings led to recommendations for further research on the HDSO programme. These recommendations were made in Chapter 10. More research is needed on how HDSO compares to face-to-face courses, in terms of clinical outcomes like HbA1c, and in terms of cost-effectiveness.

In Chapter 10 I have proposed to address these questions with a cluster-randomised controlled trial of HDSO to determine its relative effectiveness and cost-effectiveness, compared to face-to-face structured education courses. The rationale for carrying out a feasibility trial prior to a definitive trial is that important parameters can be estimated to improve the precision of the definitive trial (472). These parameters include a standard deviation of the outcome measure, which can be used to calculate a sample size for the definitive trial (472). Other parameters that could be estimated in a feasibility trial of HDSO compared to face-to-face courses are the willingness of
participants to be randomised, the willingness of clinicians to recruit participants, the feasibility of using routine clinical data to determine clinical outcomes, and the feasibility of collecting health economics data. If these conditions were determined to be feasible, then it is much more likely that a phase III definitive RCT will be successful.

In the broader field of digital health research, I have added to the evidence for the feasibility and acceptability of online structured education for T2DM. I have also added to the evidence for different demographic groups being able to use online structured education for T2DM. These successes have been due to a collaborative, iterative development and evaluation process, suggesting that further research in the field should follow a user-centred approach with a series of studies evaluating feasibility and acceptability prior to a full-scale trial as recommended by the MRC guidance (44).

11.7 Conclusion

This thesis consists of four empirical studies addressing the development, optimisation and formative evaluation of an online structured education programme for people newly diagnosed with type 2 diabetes (HeLP-Diabetes: Starting Out). I found that it was feasible to deliver online structured education in the NHS, and the programme was acceptable to patients with different demographic characteristics.

There were problems with attrition, and there was a high level of attrition between registration and starting the programme. Telephone reminders and offers of a telephone consultation with a dietician did not reduce attrition. Based on my findings, and the existing literature, I have made recommendations for a fully optimised intervention including the introduction of personalised email support.

Further research on the intervention is needed to determine relative effectiveness (including impact on clinical outcomes) and cost-effectiveness compared with established face-to-face courses. If relative effectiveness and cost-effectiveness can be determined, this will provide policy-makers and
clinicians more evidence for offering patients with T2DM online structured education.
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APPENDICES

Appendix A NHS Ethical Approval for Camden and Islington

Dr Shoba Peddacal
Department of Population Health and Primary Care
Ludlow Third Floor, UCL Medical School, Royal Free Campus
Moulton Hill Street
NW3 2FF

Dear Dr Peddacal,

This NHS Permission is based on the NTC favourable opinion given 28 April 2015.

I am pleased to confirm that the following study has now received R&D approval, and you may now start your research in the trust(s) indicated below.

<table>
<thead>
<tr>
<th>Name of the trust</th>
<th>Name of current PI/LOC</th>
<th>Date of permission issue(d)</th>
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<tr>
<td>NHS Camden CCG</td>
<td>Dr Shoba Peddacal</td>
<td>12 November 2016</td>
</tr>
<tr>
<td>NHS Islington CCG</td>
<td>Dr Shoba Peddacal</td>
<td>12 November 2016</td>
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Specific Conditions of Permission (if applicable)

If any information on this document is altered after the date of issue, this document will be deemed INVALID.

Yours sincerely,

Research Operations Manager
Appendix B NHS Ethical Approval of minor amendment for HCP interviews and inclusion of Haringey CCG

Dr Shoba Poduval  
Clinical Research Fellow  
University College London  
Department of Population Health and Primary Care  
Upper Third Floor, UCL Medical School, Royal Free Campus  
Rowland Hill Street  
NW3 2PF

24 June 2016

Dear Dr Poduval

Letter of HRA Approval for a study processed under pre-HRA Approval systems

Study title:  Pilot evaluation of an online structured education programme for Type 2 Diabetes called “Starting Out”.
IRAS project ID:  159488
REC reference:  15/SS/0078
Sponsor:  University College London
Amendment Reference:  15/SS/0078/AM03
Amendment Date:  31/5/16

Thank you for your request to bring the above referenced study under HRA Approval.

I am pleased to confirm that the study has been given HRA Approval, on the basis of the document set provided, any clarifications noted in this letter and taking account of reviews and approvals previously conducted and issued.

The extension of HRA Approval to this study on this basis allows the sponsor and NHS organisations to set-up the study in accordance with HRA Approval processes, with decisions on study set-up being taken on the basis of capacity and capability alone.

Participation of NHS Organisations in England
The sponsor should now provide a copy of this letter to participating NHS organisations in England which are being set up in accordance with HRA Approval Processes.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. Please read Appendix B carefully, in particular the following sections:
Appendix C NHS Ethical Approval for South London (Lambeth and Lewisham)

National Institute for Health Research
Clinical Research Network
South London
16th Floor, Tower Wing
Guy’s Hospital
Great Maze Pond
London, SE1 9RT
Tel: 020 7188 9404
Email: crn@nhr.ac.uk
Web: www.crn.nhr.ac.uk/london

Dr. Shoba Puduvai
NIHR GP Research Fellow
e-Health Unit
UCL Department of Primary Care and Population Health
Royal Free Campus, Rowland Street
London
NW3 2PF

05 January 2016

Dear Shoba,

Study title: Pilot evaluation of an online education programme for Type 2 diabetes
REC Ref: 15/S5/0078
CSF/R&D Ref: 159488

The study team must get written agreement from each participating site confirming their decision to take part in this study. Please give a copy of this letter to each participating site.

Please note that one of the DI/NIHR objectives for UKCRC portfolio projects is for the first patient to be recruited within 30 days of the date of this letter. A CRN South London Research Officer will be working closely with the study team to enable this objective to be achieved. If you have any queries about this please contact Simon Davies at Simon.Davies@gtr.nhs.uk.
PARTICIPANT INFORMATION SHEET
Evaluation of an online education programme for people with type 2 diabetes

You are being invited to take part in our research study. Before you make a decision, it may help to understand why the research is being done and what it would involve for you.

What is the study about?
Research has shown that diabetes education can improve people’s health and wellbeing. We have developed an online education programme to help support people who have recently been diagnosed with diabetes called HeLP-Diabetes: Starting out. The course has eight sessions, each of which takes about 60-90 minutes to work through. Each session has three or four modules in it, and a whole session can be done at once, or if the participant prefers they can dip in and out, taking one module at a time. It is suggested that participants do one session a fortnight (every two weeks), and an email is sent to introduce a new session.

Each session combines learning in knowledge, skills and attitudes, as well as addressing medication, emotions and taking control. Over the course of the 8 sessions, participants are encouraged to undertake self-assessment quizzes and provided with feedback. These self-assessment exercises will help participants understand their baseline knowledge, emotional state, self-efficacy in managing their diabetes, and assess which health behaviours need modifying. Participants will be encouraged to reflect on these exercises through provision of written feedback which will encourage them to focus on particular areas of need, whilst encouraging and praising areas of strength. As participants progress through the sessions, participants will be reminded of earlier self-assessment exercises, and asked to link goals and action plans with the results of these exercises.
At the end of the course we would like to interview participants to get your feedback on the programme including what you liked about it and what you think could be changed. We are also interviewing healthcare professionals to get their views on whether patients need help completing the programme.

**Why have I been invited?**
You have been invited to take part in the research because you have been using HeLP-Diabetes: Starting out or you are a healthcare professional working with patients using the program, and we would like to hear what you think so that we can make the programme better.

**Do I have to take part?**
No. It is up to you whether to take part in the study. If you do decide to, you can let us know by: emailing us on this address: educators@help-diabetes.org.uk; or calling us on this number: 020 7794 0500 (Ext: 36323).

If you do not want to take part you do not need to do anything. Whether or not you choose to take part will not affect your healthcare in any way.

**What will happen to me if I take part and what do I have to do?**

- A research GP from the HeLP-Diabetes team will contact you to check that you still want to take part and to answer any questions you might have about the study.
- If you are still happy to take part, the research GP will arrange to meet you at your surgery or other convenient public place at a time that is convenient for you to interview you and discuss what you think of the programme.
- Telephone interviews with 5 participants will also be carried out a web designer as a usability-testing exercise. Audio recordings of the interviews will be analysed by the researcher.

**What are the possible disadvantages of taking part?**
The main disadvantage of taking part is the time it takes to meet with us and talk about the programme. It is very unlikely that you will come to harm as a result of taking part in the study. Some people may be upset by talking about information about their health and potential future
problems. If so, we encourage you to talk about any worries or anxieties you have with your doctor or nurse.

**What are the possible benefits of taking part?**

You will have the opportunity to tell us what you think about HeLP-Diabetes: Starting out and make it more useful for others.

**What will happen if I don’t want to carry on with the study?**

You are free to change your mind about taking part at any time without giving a reason. However, any information that you have already provided will be kept in the study.

**Will my taking part in this study be kept confidential?**

Yes. All information collected about you during the course of the study will be kept strictly confidential. Your conversation with the research GP will be recorded and transcribed so that we have a record of your views, but your personal details will be kept separately from the recording and transcript which will be given a unique participant identification number.

**Will my GP and health care team know I am in the study? (programme participants only, not applicable to healthcare professionals)**

Yes. We will inform your GP that you are in the study. This will not affect the care they give you in any way.

**What personal data do I have to provide and what will it be used for?**

Your views on the programme will be asked for because it will help the researchers to understand if the programme is useful and how it can be improved. Your contact details will only be used to contact you while the study is running and to send you a summary of the research findings (if
you want one). Nobody outside the research team will see information about you.

**What happens when the study ends?**

We hope that the results of this and future studies will help make the programme more widely available, so everyone with diabetes in England can have access to it.

**What will happen to the results of the research study?**

At the end of the study we will write a report of our results to be published in medical journals and presented at conferences. We would be happy to send you a summary of the results if you wish to see this.

**Who is organising and funding the research?**

This study is organised by researchers from the Departments of Primary Care and Population Health at University College London. The National Institute of Health Research has funded this project. For more information about the research team, please see [http://www.ucl.ac.uk/pcph/research-groups-themes/e-health](http://www.ucl.ac.uk/pcph/research-groups-themes/e-health)

**Who has reviewed the study?**

This study will be reviewed by the UCL Ethics Committee and Camden & Islington Research & Ethics Committee.

**What if there is a problem?**

If you wish to complain, or have concerns about any part of this study please contact Dr Shoba Poduval (Phone: 020 7794 0500 ext 36232, email: educators@help-diabetes.org.ac.uk) who will do her best to answer your questions. If you are still unhappy and wish to complain formally, you can do this through the NHS Complaints procedure. Details
can be obtained from the Patient Advice and Liaison Service (PALS - www.pals.nhs.uk).

Is there an independent contact point where I can get general advice about taking part in research?

Yes. INVOLVE is a national advisory group that provides advice on public involvement in research. You can find out more from their website: www.invo.org.uk

You can contact them at: INVOLVE, Wessex House, Upper Market Street, Eastleigh, Hampshire, SO50 9FD or Telephone: 023 8065 1088

Further information and contact details

If you have any questions at all about the study or would like further information, please contact the Principal Investigator Dr Shoba Poduval, or Chief Investigator Professor Elizabeth Murray using the contact details below.

<table>
<thead>
<tr>
<th>Name</th>
<th>Email</th>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Shoba Poduval</td>
<td><a href="mailto:educators@help-diabetes.org.uk">educators@help-diabetes.org.uk</a></td>
<td>eHealth Unit, UCL Research Department of Primary Care &amp; Population Health Upper 3rd Floor, Royal Free Hospital, Rowland Hill Street</td>
</tr>
<tr>
<td>Professor Elizabeth Murray</td>
<td><a href="mailto:Elizabeth.murray@ucl.ac.uk">Elizabeth.murray@ucl.ac.uk</a></td>
<td>eHealth Unit, UCL Research Department of Primary Care &amp; Population Health Upper 3rd Floor, Royal Free Hospital, Rowland Hill Street</td>
</tr>
</tbody>
</table>
What do I do if I wish to take part?

If you are interested in taking part in the study please email educators@help-diabetes.org.uk.

The small print

We will keep your personal identification data (your name, address) separate from the information you give us about the programme, which will only be identified by a unique participant identification number. The data will be stored online on a secure server which has been approved for clinical research. Only authorised persons (the research team and the regulatory bodies that monitor researchers in the UK) will have access to your personal data. We will handle, process, store and destroy data following procedures in keeping with the Data Protection Act 1998.

THANK YOU FOR YOUR TIME IN READING THIS INFORMATION SHEET
Appendix E Patient Consent Form: Evaluation of an online education programme for people with type 2 diabetes

Study Number: 
Patient Identification Number for this trial: 

CONSENT FORM (Patients)

Title of Project: **HeLP-Diabetes: Starting out**

Please initial the boxes

1. **I confirm that I have read and understand** the information sheet dated 19.2.16 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. **I understand** that I am volunteering to participate in a research study evaluating an online education programme for Type 2 Diabetics.

3. **I understand** that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

4. **I understand** that the regulatory authorities who ensure that researchers follow good practice may wish to look at the information I provide as part of the study. **I agree to this**.

5. **I agree** to my GP being informed of my participation in the study

6. **I understand** that the interview with the researcher will be anonymously audio-recorded and destroyed after the close of the study. All the information I provide will be confidential and I will remain anonymous.

7. **I agree** to take part in a face to face interview with the researcher and, if necessary, a follow-up telephone interview with a member of the HeLP-Diabetes team.

Name of Participant ........................................
Signature ........................................

Date ........................................
If you would like us to send you a summary of the results once the study has been completed, please tick here

Please provide your email address and/or postal address below

Email address: …………………………………………………………

Postal address:

House/Building number:

Street name:

City:

County:

Post code:

This piece of paper will be stored apart from your consent form, and will not be linked to the data you provide in any way.
Appendix F Health Professional Consent Form: Evaluation of an online education programme for people with type 2 diabetes

Title of Project: HeLP-Diabetes: Starting out

Please initial boxes

8. I confirm that I have read and understand the information sheet dated 19.2.16 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

9. I understand that I am volunteering to participate in a research study evaluating an online education programme for Type 2 Diabetics.

10. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

11. I understand that the regulatory authorities who ensure that researchers follow good practice may wish to look at the information I provide as part of the study. I agree to this.

12. I understand that interviews will be audio-recorded anonymously and recordings will be destroyed at the close of the study. All the information I provide will be confidential and I will remain anonymous.

13. I agree to take part in the above study.

Name of Participant  Date  Signature

Name of Person taking Consent  Date  Signature
If you would like us to send you a summary of the results once the study has been completed, please tick here

Please provide your email address and/or postal address below

Email address: ……………………………………………………………..

Postal address:

House/Building number:

Street name:

City:

County:

Post code:

This piece of paper will be stored apart from your consent form, and will not be linked to the data you provide in any way.
DO YOU HAVE TYPE-2 DIABETES?
WE’RE HERE TO HeLP!

Sign up today for HeLP Diabetes: Starting Out – a free new online service to help you:
- Eat well
- Take control of your diabetes
- Lower your risk of complications
- Live healthier and happier

HeLP Diabetes: Starting Out is a four-part programme designed to help you make simple but effective changes to manage your diabetes.

Register over the phone now by calling 020 7431 9114

Or email us at: admin@help-diabetes.org.uk if you have any questions
Appendix H Topic guide (patients)

**Topic Guide**

**Background:**

- How long have you had Diabetes?
- How did you feel when you were diagnosed?
- How do you feel about having diabetes now?
- How important is it to you to understand how to manage your diabetes?
- How important is learning about self-managing diabetes to you? Why?
- What would make you feel motivated to learn more about your diabetes?
- What has your experience of learning about your Diabetes been like?
- Have you taken part in any other education programmes? If so what was your experience of this like?
- What do you use the internet for?
- What would you say your computer skills are like?
- What do you do if you need help with using the internet?

**Reasons for taking part in programme:**

- How did you hear about HeLP-Diabetes: Starting Out?
- What motivated you to take part?
- What appealed to you about the programme?
- Do you think you needed structured education?
- Do you feel different now?

**Starting the programme:**

- How did you find communication with the team about login details?
- Did you have any problems logging on?
- Were you able to access it on your chosen device?
- How did you find the questionnaires?

**Working through the programme:**

- At what time of day/setting did you work through the programme?
- How long did it take you to complete a session?
- What did you find difficult about completing each session?

**Likes/dislikes:**

- What did you like about the structure/content?
- What did you dislike about the structure/content?
- Is there anything you would like us to change?
- What was the most valuable thing you learnt?
- What did you wish you learnt?
- Would you recommend the programme to a friend? If not why not?

Recommendations:

- Who do you think the programme would be most useful for?
- How do you think we should be recruiting new users?
- How do you think we could recruit more PPI reps?
- Are you interested in becoming a PPI rep?
Appendix I Topic guide (Health professionals)

**HCP Topic Guide**

**Role:**

- Your role – GP/PN/DSN/CCG
- How long have you been in your role?
- What does your role involve?
- Do you work directly with patients?
- Do you work at one practice or multiple practices?

**HeLP-Diabetes: Starting Out**

- How did you hear about HeLP-Diabetes: Starting Out?
- Have you received any training, or accessed the programme yourself?
- How long have you been aware of it?
- What is your role in telling patients about the programme?

**Patient referral process:**

- How does your Practice/CCG inform patients about the programme - mail out/text message/email?
- How many patients have responded?

**Patient acceptability:**

- Have you referred anyone in a consultation?
- What was your experience of talking to patients about the programme in a consultation?
- How have patients responded to you talking to them about the programme?
- What do you think the barriers/facilitators to using the programme might be for patients?
- Any other thoughts about engagement – with online or face to face structured education?
Appendix J Total number of visits to each section of the HeLP-Diabetes website by female and male users

<table>
<thead>
<tr>
<th>Website section</th>
<th>Total number of visits by female users</th>
<th>Total number of visits by male users</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forum and help</td>
<td>157</td>
<td>343</td>
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</tr>
<tr>
<td>Homepage</td>
<td>417</td>
<td>536</td>
<td>0.29</td>
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<tr>
<td>Living and working with diabetes</td>
<td>118</td>
<td>306</td>
<td>0.48</td>
</tr>
<tr>
<td>Managing my feelings</td>
<td>104</td>
<td>132</td>
<td>0.89</td>
</tr>
<tr>
<td>Miscellaneous articles</td>
<td>83</td>
<td>110</td>
<td>0.33</td>
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<tr>
<td>My health records</td>
<td>505</td>
<td>767</td>
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<tr>
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<td>93</td>
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<td>0.20</td>
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<tr>
<td>HeLP-Diabetes: Starting Out</td>
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<td>525</td>
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</tr>
<tr>
<td>Staying Healthy</td>
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<td>610</td>
<td>0.56</td>
</tr>
<tr>
<td>Treating Diabetes</td>
<td>104</td>
<td>239</td>
<td>0.07</td>
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<tr>
<td>Understanding Diabetes</td>
<td>370</td>
<td>434</td>
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</tr>
</tbody>
</table>
Appendix K Total number of visits to each section of the HeLP-Diabetes website by users of different education levels

<table>
<thead>
<tr>
<th>Website section</th>
<th>School leaver</th>
<th>A-level</th>
<th>Degree or NVQ4</th>
<th>Post Grad or NVQ5</th>
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<tbody>
<tr>
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<td>188</td>
<td>283</td>
<td>144</td>
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<tr>
<td>Living and working with diabetes</td>
<td>193</td>
<td>92</td>
<td>106</td>
<td>27</td>
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<td>Managing my feelings</td>
<td>61</td>
<td>45</td>
<td>82</td>
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<td>47</td>
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<td>341</td>
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<td>Staying Healthy</td>
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<td>201</td>
<td>297</td>
<td>154</td>
<td>0.32</td>
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<tr>
<td>Treating Diabetes</td>
<td>115</td>
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<td>129</td>
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<tr>
<td>Understanding Diabetes</td>
<td>251</td>
<td>225</td>
<td>234</td>
<td>67</td>
<td>0.93</td>
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</table>
Appendix L  Total number of visits to each section of the HeLP-Diabetes website by users of different age groups

<table>
<thead>
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<th>50-60</th>
<th>60-70</th>
<th>70-80</th>
<th>80-90</th>
<th>90 and over</th>
<th>P</th>
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<tbody>
<tr>
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<td>27</td>
<td>94</td>
<td>202</td>
<td>94</td>
<td>61</td>
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<td>347</td>
<td>249</td>
<td>125</td>
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<td>9</td>
<td>0.21</td>
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<tr>
<td>Living and working with diabetes</td>
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<td>49</td>
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<td>My health records</td>
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<tr>
<td>Staying Healthy</td>
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Appendix M Total number of visits to each section of the HeLP-Diabetes website by users of different ethnic groups

<table>
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<th>Black</th>
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<tr>
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<td>0.22</td>
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<tr>
<td>Understanding Diabetes</td>
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<td>18</td>
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</table>
Appendix N Participant Information Sheet: Pilot randomised trial of the effect of personalised email support on engagement with an online education programme for type 2 diabetes

You are being invited to take part in our research study. Before you decide whether to take part it is important that you understand why the research is being done and what this study will involve. Please take time to read the following information carefully and discuss it with relatives, friends, and GP if you wish. Ask us if anything is not clear or you would like more information.

What is the study about?
You have registered to use HeLP-Diabetes, an online education programme to help support people who have been diagnosed with diabetes. HeLP-Diabetes includes an interactive guide called HeLP-Diabetes: Starting Out, which you can access via the HeLP-Diabetes homepage (as illustrated in the screenshot below).
HeLP-Diabetes: Starting Out has four sessions, and each session combines learning in knowledge, skills and attitudes, as well as addressing medication, emotions and taking control. Each of the four sessions takes 60-90 minutes to complete and can be done at one sitting, or bit by bit. It is suggested that participants do one session a week. Participants are encouraged to undertake self-assessment quizzes to help them understand their baseline knowledge, emotional state, self-confidence in managing their diabetes, and assess which health behaviours need modifying. As participants progress through the sessions, they will be reminded of earlier self-assessment exercises, and asked to link goals and action plans with the results of these exercises. Research has shown that diabetes education can improve people’s health and wellbeing, and reduce long term complications.

At the moment emails are sent to introduce each new session, and to provide feedback on the self-assessment quizzes. We would like to know if providing weekly personalised emails helps more people to complete the four sessions. The personalised emails will be sent by a member of the HeLP-Diabetes team who will introduce themselves, encourage participants for making progress, ask about barriers to progress, and provide individualised feedback taking into account personal factors, priorities and goals. Emails will be sent at weekly intervals for four weeks. We collect anonymous data on how many people complete the programme, and will use this to decide if the personalised emails are helpful or not.

**Why have I been invited?**
You have been invited to take part in the research because you have registered to use HeLP-Diabetes, and we would like to know whether providing personalised emails for people who use HeLP-Diabetes: Starting Out will make it better.

**Do I have to take part?**
No. It is up to you whether to take part in the study. The service you are currently provided by HeLP-Diabetes will not be affected if you decide not to participate.
What do I do if I wish to take part?

If you **would** like to take part, you should click on the following link (link) to the HeLP-Diabetes website and read the consent form. If you agree, then you can tick the necessary boxes and press submit.

If you **do not want** to take part, you do not need to do anything. Whether or not you choose to take part will not affect your healthcare in any way.

**What will happen to me if I take part and what do I have to do?**

- You will be randomly assigned to one of two groups. The groups will be randomly selected by a computer (a bit like tossing a coin), so you cannot choose which group you are in. You will not know which group you are in before consenting to take part in the study.
- Group 1 (the control group) will receive the emails to introduce each new session of HeLP-Diabetes: Starting Out, and quiz feedback. Group 2 will receive the weekly personalised emails. Regardless of which group you are in, we will collect anonymised data on the number of people completing the four sessions and use this to decide if personalised emails are helpful.

**What are the possible disadvantages of taking part?**

There is no predicted disadvantage of taking part.

**What are the possible benefits of taking part?**

There is no direct benefit but you will have the opportunity to make HeLP-Diabetes: Starting Out more useful for others.

**What will happen if I don’t want to carry on with the study?**

You are free to change your mind about taking part at any time without giving a reason. You can do this by emailing s.poduval@ucl.ac.uk or calling 020 7794 0500 ext 38380 However, any information that you have already provided will be kept in the study.
Will my taking part in this study be kept confidential?

Yes. All information collected about you during the course of the study will be kept strictly confidential. We will keep your personal identification data (your name, address) separate from the information you give us about the programme, which will only be identified by a unique participant identification number. The data will be stored online on a secure server which has been approved for clinical research. Only authorised persons (the research team and the regulatory bodies that monitor researchers in the UK) will have access to your personal data. We will handle, process, store and destroy data following procedures in keeping with the Data Protection Act 1998.

Will my GP and health care team know I am in the study?

No. We will not inform your GP that you are in the study.

What personal data do I have to provide and what will it be used for?

Your contact details will only be used to contact you while the study is running and to send you a summary of the research findings (if you want one). Nobody outside the research team will see information about you.

What happens when the study ends?

We hope that the results of this and future studies will help make the programme more widely available, so everyone with diabetes in England can have access to it.

What will happen to the results of the research study?

At the end of the study we will write a report of our results to be published in medical journals and presented at conferences. We would be happy to send you a summary of the results if you wish to see this, and you can let us know if you would like a summary of the results on the online consent page.
Who is organising and funding the research?

This study is organised by researchers from the Departments of Primary Care and Population Health at University College London. For more information about the research team, please see http://www.ucl.ac.uk/pcph/research-groups-themes/e-health

University College London is the study sponsor.

Who has reviewed the study?

All proposals for research using human subjects are reviewed by an Ethics Committee before they can proceed. This proposal was reviewed by South East Scotland Research Ethics Committee.

What if there is a problem?

If you wish to complain, or have concerns about any part of this study please contact Dr Shoba Poduval (Phone: 020 7794 0500 ext 38380, email: s.poduval@ucl.ac.uk) who will do her best to answer your questions. If you are still unhappy and wish to complain formally, you can do this through the NHS Complaints procedure. Details can be obtained from the Patient Advice and Liaison Service (PALS - www.pals.nhs.uk).

Is there an independent contact point where I can get general advice about taking part in research?

Yes. INVOLVE is a national advisory group that provides advice on public involvement in research. You can find out more from their website: www.invo.org.uk

You can contact them at: INVOLVE, Wessex House, Upper Market Street, Eastleigh, Hampshire, SO50 9FD or Telephone: 023 8065 1088
Further information and contact details

If you have any questions at all about the study or would like further information, please contact the Chief Investigator Dr Shoba Poduval.

<table>
<thead>
<tr>
<th>Name</th>
<th>Dr Shoba Poduval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Role</td>
<td>Principal Investigator</td>
</tr>
<tr>
<td>Tel</td>
<td>020 7794 055 ext 38380</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:s.poduval@ucl.ac.uk">s.poduval@ucl.ac.uk</a></td>
</tr>
<tr>
<td>Address</td>
<td>eHealth Unit, UCL Research Department of Primary Care &amp; Population Health, Upper 3rd Floor, Royal Free Hospital, Rowland Hill Street, London NW3 2PF</td>
</tr>
<tr>
<td>Fax</td>
<td>020 7794 1224</td>
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<tr>
<td>Web</td>
<td><a href="https://www.ucl.ac.uk/pcph/research-groups-themes/e-health">https://www.ucl.ac.uk/pcph/research-groups-themes/e-health</a></td>
</tr>
</tbody>
</table>

THANK YOU FOR YOUR TIME IN READING THIS INFORMATION SHEET
Appendix O Patient Consent Form: Pilot randomised trial of the effect of personalised email support on engagement with an online education programme for type 2 diabetes

[UC department headed paper]

Study Number: R&D: 15/0202 Substantial amendment project ID 159488
Patient Identification Number for this trial:

CONSENT FORM (Patients)

Title of Project:
Pilot randomised trial of the effect of personalised email support on engagement with an online education programme for type 2 diabetes.

Please initial boxes

14. I confirm that I have read and understand the information sheet dated 19.1.18 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

15. I understand that I am volunteering to participate in a research study evaluating an online education programme for Type 2 Diabetics.

16. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

17. I understand that the regulatory authorities who ensure that researchers follow good practice may wish to look at the information I provide as part of the study. I agree to this.

Name of Participant ____________________________ Date ____________________________ Signature ____________________________

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If you would like us to send you a summary of the results once the study has been completed, please tick here

Please provide your email address and/or postal address below

Email address: .................................................................

Postal address:

House/Building number:

Street name:

City:

County:

Post code:

When you have completed this form please click on ‘Submit’
APPENDIX P Recommendations for further research

Introduction

The MRC guidance for developing and evaluating complex interventions recommends moving on to a full-scale evaluation once key uncertainties have been explored with a series of pilot studies (104). Similar recommendations are made for digital health interventions (63). Guidance suggests that progressing to a full-scale evaluation is appropriate once there is evidence that the intervention and its delivery package have sufficient acceptability and feasibility to ensure it will be used by enough people to make it cost-effective. The intervention should have been optimised to the point where it will remain stable and unchanged over the medium term (63). In Chapter 10 I described the final intervention, for which I have initial evidence of acceptability and feasibility in the NHS. However I have encountered challenges with reach and uptake. 791 people registered to use the programme, but only 74 people (9.4%) completed it. This is favourable when compared with the uptake of face-to-face structured education courses which is only 7.1% (440), and therefore may be cost-effective relative to courses that are currently being offered. I have made recommendations for further optimisation of the intervention to ensure sufficient uptake, and to be able to proceed to a phase III RCT where the programme could be compared to face-to-face education.

Evidence of relative effectiveness and cost-effectiveness of HDSO and face-to-face education is needed because HDSO has significant potential reach, as compared to face-to-face education. It is an online programme with low marginal cost per additional user, it can be offered to everyone with T2DM, and it can be accessed on a number of devices, bypassing the barriers of face-to-face education which requires people to attend at a location and time which may not be convenient for them. The relative effectiveness of HDSO compared to face-to-face education needs to be determined in a randomised trial, and the relative cost-effectiveness of HDSO compared to face-to-face programme needs to be determined in a health economics evaluation. A protocol with recommendations for a randomised trial and health economics evaluation are discussed below. Before describing my recommendations for the design of a
RCT, I have discussed feasibility and pilot randomised trials. This is in order to understand which phase of trial is the most appropriate next step.

Feasibility and pilot trials

Historically there has been a lack of clarity about the definition of feasibility and pilot trials. There is agreement that both are studies conducted in advance of a larger and more comprehensive trial (473). Thabane et al searched for definitions of pilot studies on the internet and did not draw distinctions, but concluded that a pilot study is “synonymous with a feasibility study intended to guide the planning of a large-scale intervention” (473). The NIHR has drawn distinctions between pilot and feasibility trials, by suggesting that feasibility studies occur earlier than pilot studies to answer the question “Can this study be done?” (472). The NIHR suggests that feasibility studies are used to estimate important parameters that are needed to improve the precision of the main study, and give it more chance of being successful (472). Such parameters include the following:

- Standard deviation of the outcome measure, needed in some cases to estimate sample size;
- Number of eligible patients, carers or other appropriate participants;
- Willingness of clinicians to recruit participants;
- Willingness of participants to be randomised;
- Characteristics of the proposed outcome measure;
- Follow-up rates, adherence or compliance rates;
- Availability of data needed;
- Time needed to collect and analyse data.

Feasibility studies do not need to be randomised, and do not evaluate the outcome measures which would be of interest in a full trial (472). The NIHR states that pilot studies are miniature versions of the main study, used to determine if all the components of the main study work together (472). They differ from feasibility studies in that they assess the primary outcome, and can provide data for the final analysis (in an internal pilot), or analysed separately (in an external pilot) (472).
A review by Arain et al was conducted to see if the NIHR recommendations had improved the reporting of pilot studies in the United Kingdom Clinical Research Network (UKCRN) Portfolio Database (423). They found that the majority of pilot studies identified in the database, were run as full studies with smaller sample sizes to test a number of methodological uncertainties. In comparison, the feasibility studies identified in the database tested fewer methodological components. However both were run as complete randomised trials, and there was still uncertainty about the distinction between the two terms (423).

In 2010 guidance on the reporting of pilot randomised trials was developed, in the form of an extension to the Consolidated Standard of Reporting Trials (CONSORT) guidelines for reporting parallel group randomised trials (474, 475). The CONSORT statement was developed in 1996 to improve the reporting of randomised controlled trials, and has been used worldwide since then (474). It includes a 25-point checklist of information to include when reporting a randomised controlled trial (474). In the guideline extension, the items that have been added to the checklist include how to proceed with a future RCT, and implications for progressing to a definitive RCT, including any amendments (475). An example of the checklist amendment for pilot trials is given below:

**CONSORT checklist of information to include when reporting a pilot trial**

<table>
<thead>
<tr>
<th>Section/topic and item number</th>
<th>Standard checklist item</th>
<th>Extension for pilot trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Background and objectives</td>
<td>Scientific background and explanation of rationale</td>
<td>Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial</td>
</tr>
<tr>
<td>Specific objectives or hypotheses</td>
<td>Specific objectives or research questions for pilot trial</td>
<td></td>
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<td>----------------------------------</td>
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</table>

The development work for the extension to the CONSORT guideline was used in conjunction with a large Delphi study, to develop a conceptual framework to help researchers design and report feasibility and pilot trials, and make clearer distinctions between the two (421). Figure 11-1 shows the final framework.

**Conceptual framework for feasibility, pilot and main trials (395)**

![Conceptual framework for feasibility, pilot and main trials](image)

Feasibility studies are situated as an overarching concept, to be considered when there is uncertainty about future RCT feasibility. Three other study types are distinguished within this: randomised pilot studies; non-randomised pilot studies and other feasibility studies. Randomised pilot studies are studies in which the main trial, or parts of it, are conducted on a smaller scale (piloted). Non-randomised pilot studies are those in which the future trial is piloted but without randomisation. Feasibility studies that are not pilot studies aim to address whether an element of a future trial can be carried out, but they do not implement the processes of the future trial (421). There is no linearity to the order in which these studies can be conducted.

Is a feasibility trial of HDSO needed?

I have done early phase work to evaluate HDSO and make recommendations for the design of the definitive trial. However, because of poor completion rates of the programme, questions remain as to the design of a trial which will achieve adequate recruitment and data collection. It could therefore be argued that a feasibility trial should be carried out first. The advantage of carrying out a feasibility study is the increased chance of success of the main trial. Feasibility studies are used to estimate important parameters that are needed to improve the precision of the main study, as previously discussed (472), including estimating the standard deviation of the proposed primary outcome measure, which can be used to calculate a sample size for the definitive trial (472). A sample size calculation is used to determine the number of participants needed to detect a clinically significant treatment effect (420). Other parameters that can be estimated in a feasibility trial are the willingness of participants to be recruited and randomised, and the willingness of clinicians to recruit participants, and examine recruitment to the study (472). It is crucial to identify issues with recruitment and randomisation before a definitive trial in order to ensure it is successful. Funders like the National Institute for Health Research (NIHR) therefore deem feasibility trials good value for money, as they improve the chances of success of more expensive full-scale definitive trials by demonstrating that key elements like recruitment of participants is feasible (476).
The arguments against conducting a feasibility study would be as follows. Feasibility trials themselves are expensive. The NIHR Research for Patient Benefit Programme (RfPB) funds feasibility trials of up to £250,000. Feasibility trials can also be lengthy (lasting a year or more), and cause delay in carrying out a definitive trial. This is particularly pertinent in the world of eHealth where technology is rapidly developing, and interventions can become out of date very quickly.

The aim of a feasibility trial of HDSO would be to determine if a phase III randomised controlled trial to determine relative effectiveness and cost-effectiveness of an online structured education programme for type 2 diabetes compared with group-based education is feasible, and what the parameters of such a trial should be. The objectives would address each of the parameters in question, for example:

1. Recruitment rate of practices and participants;
2. Feasibility of delivering the intervention and control;
3. Feasibility of using routine clinical data to determine clinical outcomes;
4. Observed changes in HbA1c (mean and standard deviation) to enable calculation of the sample size and intra-cluster correlation;
5. Observed uptake rates of the intervention and comparator;
6. Resources needed to support recruitment, data collection and analysis;
7. Feasibility of collecting health economics data, including healthcare resource use, other costs and utilities.

Cluster or individually randomised design?

Randomisation can occur at different levels. In individually randomised trials, individuals are randomly allocated to receive either the intervention or the comparator (44). In cluster randomised trials, individuals are grouped into units called “clusters” and randomly allocated to receive either the intervention or the comparator. Everyone within a cluster receives the same treatment (121). Cluster randomisation is used when the intervention is delivered at the level of the cluster (e.g. primary care mental health workers working at general practices (477), family-based dietary interventions, or educational activities aimed at the health practitioner (478)), or if there is risk of contamination. Contamination is when people in the comparator group are exposed to the intervention, and people in the intervention group are exposed to the
comparator. For example, children at a school sharing health promotion leaflets with children in the no leaflet group of a trial. The disadvantage of cluster randomised trials is the need for larger sample sizes due to individuals within clusters sharing characteristics, and being more likely to respond to an intervention in a similar way (121, 478). This leads to less statistical power than individually randomised trials and the need for a measure of the intracluster dependence, known as the intracluster correlation coefficient (ICC). The ICC is used to inflate a standard sample size calculation so that it gives the equivalent power as a individually randomised trial (478). The analysis of cluster randomised trials must also take into account the clustering, or it will produce artificially extreme p-values. The two main approaches are analysis at the cluster level or analysis at the patient level (478).

The argument for designing a trial of HDSO with cluster randomisation is that randomisation would occur at the level of the GP practice (cluster), and so consent could be taken from GPs for the participation of the whole practice, and not from every patient. There is evidence that people who consent to participate in individually randomised trials are a highly selected, poorly representative group (356). Consenting at the level of the cluster would improve the representativeness of the participants, and the external validity of estimates of uptake and effect of the intervention.

The disadvantage of carrying out a cluster randomised trial would be the larger sample size needed to give equivalent power as an individually randomised study. The analysis methods used would need to take into account clustering or an inaccurate effect size would be calculated. Another disadvantage is the lack of patient consent to access their records to extract data, so data extraction would need to be done by practice staff, anonymised and passed to the research team. This has been successfully done in a cluster randomised trial of a complex intervention for multimorbidity, called the 3D study (479), in which data were collected from GP practice records. Testing this data collection method is key for the feasibility and design of a definitive trial.
Determining relative cost-effectiveness

The aim of a randomised trial of HDSO would be to determine relative cost-effectiveness as well as effectiveness, when compared to face-to-face courses. A cost-effectiveness analysis (CEA) is a type of economic evaluation which could be used to determine cost-effectiveness of HDSO. Economic evaluations compare two treatment options in terms of cost and differences in consequences. CEA compares the cost of an intervention with its health outcomes, and is expressed as a ratio of costs divided by health outcomes or cost-effectiveness ratio (CER). Incremental cost-effectiveness ratios (ICERs) are the ratio of the difference in cost between two different treatments to the difference in effectiveness of the treatments (480).

For a cost-effectiveness analysis of HDSO compared with face-to-face courses to be conducted, data on costs and health outcomes would need to be collected. The cost of HDSO includes hosting and maintenance of the website and is recorded by the HeLP business team. Face-to-face structured education is commissioned by CCGs as part of a bundle of services. The feasibility of collecting this data needs to be explored. I would explore different methods, including asking commissioners and providers for the information, or, if necessary, estimating staff time involved in delivery. Costs relating to out-of-pocket expenditure by patients (e.g. for travel to courses) would also be needed. This could be requested from patients directly.

Health outcome data would include healthcare resource utilisation (consultations in primary and secondary care, prescriptions and secondary care referrals) and quality of life. The feasibility of collecting healthcare resource utilisation data from patient records would need to be tested. The quality of life measure used in economic evaluations is Quality Adjusted Life Years (QALYs). QALYs are a health outcome measure of the amount of years lived, taking into account that some of those years are lived in less than perfect health (480). Measures of health status are used to calculate QALYs. The EuroQoL-5D is a classification system with dimensions for mobility, self-care, usual activities, pain or discomfort, and anxiety or depression (480). It has
been developed into a questionnaire which can be given to participants to complete in a few minutes (481).

In the proposed feasibility study of HDSO, participants would need to be asked to complete EQ-5D questionnaires at baseline and follow-up to generate data for calculating QALYs in each arm. Again, the distribution and response rate of the questionnaires would be feasibility issues.

Having considered feasibility and pilot trials, and how cost-effectiveness would be determined, I will now describe a protocol for a randomised feasibility trial of HDSO. My recommendations are based on the findings from my research, guidance on evaluating digital health interventions, and my review of the literature on trial design.

Background to a feasibility trial

An evaluation of the second iteration of the HDSO programme showed evidence of feasibility and acceptability in primary care and some evidence of improvement in self-efficacy (self-confidence in self-management) and diabetes-related distress. A phase III randomised controlled trial is needed to compare HDSO with NICE-approved structured education delivered face-to-face, as this has not yet been done. The HeLP-Diabetes RCT compared the unstructured information on the HeLP-Diabetes website (excluding HDSO which had not yet been developed), with a simple information website based on Diabetes UK or NHS Choices, and not with face-to-face structured education. The focus of a trial of HDSO compared with face-to-face structured education would be on effectiveness (reduction in HbA1c), and uptake and cost-effectiveness would also be measured. This is because these are factors which are necessary for the successful commissioning and implementation of new services, and because combined uptake and effectiveness can be used to demonstrate population impact of an intervention (482, 483).

Before conducting a large, costly phase III randomised controlled trial, I need to make sure that such a trial is possible. In order to do this I would conduct a feasibility trial to answer the question, “Is a phase III randomised controlled trial possible?”.
The hypothesis in an eventual phase III randomised controlled trial would be that HDSO is more effective than face-to-face education with regards to the combined reach and effectiveness (reduction in HbA1c), and significantly lower cost than face-to-face education.

Preliminary data is needed to power such a trial, and a feasibility trial is needed to establish the parameters of such a trial.

Aims

The aim of the feasibility trial is to determine whether a phase III RCT is feasible, and if so, what the design features should include.

Objectives are to:

1. Determine the recruitment rate of practices
2. Determine the number of eligible patients (people with type 2 diabetes diagnosed within the last 9 months) per practice per 1,000 patients registered
3. Determine adherence rates
4. Identify the availability of data and limitations of clinical records
5. Determine a standard deviation of the outcome measure, in order to determine the sample size needed for a phase III trial
6. Determine time needed to collect and analyse outcome data
7. Determine availability and feasibility of collecting health economics data, including healthcare resource use and other costs.

I would compare the baseline basic demographic characteristics of participants in both arms of the study, comparing those in the intervention and control group.

Methods

Study design

Cluster randomised feasibility trial, conducted in GP Practices.

Setting
The study would be conducted in GP practices in London, and a less urban area outside of London in order to involve participants with different demographic characteristics.

I would conduct the study in CCGs that have not commissioned the programme (in contrast to my previous studies), in order for the aims of the research rather than commissioning to be the main driver for recruitment and procedures. This would allow me to be able to randomise participants and collect clinical and health economics data.

Recruitment

I would enlist the help of the local clinical research networks (CRNs) to identify research-active practices in each region. Practices would be invited to return an expression of interest in the study by post or email. Interested practices would be contacted by telephone to discuss the study further and answer any questions. Those that confirm interest would be visited to discuss what is required and timescales in more detail. Recruited practices would take part in research governance training. I would aim to recruit four practices in each of the two regions (a flowchart of trial procedures is illustrated in Figure 11-2).

As this would be a cluster randomised feasibility trial, a GP at each practice would be asked to provide consent on behalf of their patients. Eligible patients would be identified during routine practice and offered referral to a structured education programme. Patients in practices in the intervention arm would be offered HeLP-Diabetes: Starting Out, and patients in practices in the control arm would be offered NICE-compliant structured education that is delivered face-to-face (usual care). Both HeLP-Diabetes: Starting Out and the face-to-face programme adhere to NICE guidance, and are entirely compatible with current NHS guidance.

Processes for referral to the intervention or comparator would be kept as similar as possible in both arms in order to limit bias. This would include promoting attendance at structured education by outlining the benefits to patients; providing patients with a printout to encourage attendance at structured education (tailored according to intervention or comparator); and
completing a referral form and uploading it to the electronic medical record (with an attached referral code) for onward forwarding to the relevant provider.

I would undertake monthly searches of the clinical records to identify eligible patients not yet referred (i.e. without a referral code), in order to boost recruitment. Eligible patients from this search would be sent the printout encouraging attendance described above, and a letter from their GP advising referral and saying that they will be referred unless they let the GP know they do not want to be.

Randomisation

Practices will be stratified according to area (London, or outside London), and then randomly allocated to offer HeLP-Diabetes: Starting Out or face-to-face education at a ratio of 1:1 by a UCL Clinical Trials Unit statistician not involved in the trial, using a computer-generated list. A cluster randomised design was chosen after I considered an individually randomised design. I decided that an individually randomised design is not appropriate, because participants consenting to being randomised are unlikely to reflect the general population and give the study external validity. A further reason for not choosing individual randomisation is the lack of individual equipoise. From my previous research and other studies such as the Healthlines study of telehealth for individuals at high risk of cardiovascular disease (484), I know that people have a preference for either online or face-to-face interventions. For this reason it may be difficult to recruit patients to being randomised to online or face-to-face education. Patients who are not randomised to the intervention of their choice may drop out of the study, or may refuse to be randomised at all.

A cluster randomised design would make recruitment and randomisation more efficient, and any results more generalizable. The intervention is HeLP-Diabetes: Starting Out, an online structured education programme for patients newly diagnosed with Type 2 Diabetes (and the control is usual care which is NICE-compliant structured education delivered face-to-face), and can be delivered at cluster level.
Flowchart of trial procedures

Offer study to practices in London, and one other area

8 practices consented

Practices undergo research governance training and training in HDSO

Practices randomised

4 practices allocated to HeLP-Diabetes: identify eligible patients in routine practice and offer referral to HeLP-Diabetes: Starting Out

4 practices allocated to face-to-face education: identify eligible patients in routine practice and offer referral to face-to-face course

Patient accepts/declines referral

Patient accepts/declines referral

Patients who accept are referred to HeLP-Diabetes: Starting Out

Patients who accept are referred to face-to-face education

Patient completes/does not complete 4 session HeLP-Diabetes: Starting Out programme

Patient attends/does not attend face-to-face education

Outcomes for everyone offered referral extracted from clinical records (HbA1C, BP, weight, smoking, uptake, attendance, prescriptions, secondary care referrals, and diabetes-relevant attendances at secondary care)

Outcomes for everyone offered referral extracted from clinical records (HbA1C, BP, weight, smoking, uptake, attendance, prescriptions, secondary care referrals, and diabetes-relevant attendances at secondary care)
Intervention

The intervention is offer of referral to HeLP-Diabetes: Starting Out. HeLP-Diabetes: Starting Out is an online structured education programme for type 2 diabetes. Those patients who accept, would be referred to the researcher by the GP or Practice Nurse. Patients would be registered with HeLP-Diabetes: Starting Out by the researcher and sent login information.

HeLP-Diabetes: Starting out consists of 4 one hour-long sessions, and a fifth bonus session, which users are encouraged to complete weekly. Each session consists of 4 or 5 modules, each taking 15-20 minutes to complete. The programme follows a spiral curriculum and users build on the knowledge and skills acquired from previous sessions. When a user completes one session the next session is opened to them and they receive an email notifying them of this. Users who do not start the next session within a week are sent an email reminder. There are sessions with goal-setting tasks and users receive individualised feedback from diabetes specialist nurses. Once users complete the four sessions, they have access to the HeLP-Diabetes website containing further information and support on diabetes self-management, peer-support via a discussion forum, monthly news and research updates and a monthly email newsletter.

Comparator

The comparator is offer of referral to NICE-compliant structured education that is delivered face-to-face(485). This may be DESMOND (Diabetes Education and Self-Management for Ongoing and Diagnosed patients), X-PERT Diabetes or a locally developed programme, all of which are face-to-face courses. DESMOND consists of six hours of self-management group education over one day or two half-days. XPERT is a 6 week programme consisting of weekly two and a half hour group sessions with a trained diabetes educator.
Details of patients who accept a referral to a face-to-face course would be sent to the organisers of the course, and patients would be sent information on when and where to attend.

Outcome measures

Outcome measures reflect the objectives of the study, that is, to inform the design of a phase III randomised controlled trial (see Table 11-2).

**Outcome measures of the feasibility study**

<table>
<thead>
<tr>
<th>Objective</th>
<th>Outcome measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Determine the recruitment rate of practices</td>
<td>Number of practices invited to take part, number of practices agreeing to take part</td>
</tr>
<tr>
<td>Determine the number of eligible patients per practice per 1,000 patients registered (people with type 2 diabetes diagnosed within the last 9 months)</td>
<td>Number of people with type 2 diabetes diagnosed within the last 9 months per 1000 patients registered,</td>
</tr>
<tr>
<td>Determine adherence rates</td>
<td>Number of patients referred to structured education who complete the HeLP-Diabetes: Starting Out/attend face-to-face education</td>
</tr>
<tr>
<td>Identify the availability of data and limitations of clinical records</td>
<td>Completeness of data in clinical records (including demographic data, clinical data, referral/uptake/attendance at structured education data)</td>
</tr>
<tr>
<td>Task</td>
<td>Description</td>
</tr>
<tr>
<td>---------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Determine sample size needed for a phase III trial</td>
<td>HbA1c and uptake at baseline and 6 months.</td>
</tr>
<tr>
<td>Determine time needed to collect and analyse outcome data</td>
<td>Self-reported time needed to collect data using a diary</td>
</tr>
</tbody>
</table>
| Determine availability and feasibility of collecting health economics data | Costs of the intervention (including hosting & maintenance costs) and the control;  
Health and social care resource utilisation during the study period, including prescriptions and secondary care referrals |

Data collection

I would extract data from the clinical records by running a pre-defined search strategy in the clinical records system, supervised by a member of the practice staff. Data would be exported from the clinical records to an Excel file and anonymised with an identification number. The Excel file would be used for the analysis. I would visit practices to extract baseline data for all eligible patients monthly from months 7 to 18 (during the patient recruitment period). This is to ensure that I capture all eligible patients. I would return to practices at month 24 (6 months after patient recruitment ends) to collect outcome data on all eligible patients, using the same procedure of supervised extraction and anonymization of data to an Excel file. It is possible that the outcome data I require would not be available at 6 months, but I would consider this part of my assessment of the availability of data and the limitations of the clinical records. If necessary I would return at 9 months to repeat the data extraction procedure. I would use a window of 3-9 months for the follow-up data (+/- 3 months from
6 month time point) and use this as a proxy for 6 months, adjusting for time point in the analysis.

The search strategy would reflect the outcome measures and would include the following:

- Demographics: age, gender, ethnicity, postcode
- Clinical data: HbA1c, smoking, blood pressure, weight and lipids
- Data on structured education: referral offered, referral sent, acceptance/decline of referral, and attendance at face-to-face education (data on completion of HeLP-Diabetes: Starting Out programme would be collected online)

Health economics data:

I would assess the feasibility of calculating the overall cost-effectiveness of offering referral to HeLP-Diabetes: Starting Out compared to offering referral to the usual (face-to-face) diabetes education course. This would include feasibility of collecting costs of the intervention, including hosting and maintenance of the website, and costs of the control, including use of health services as well as any costs associated with the usual diabetes management interventions.

Adherence and loss to follow-up

I would aim to achieve follow-up rates of over 90%. For the clinical data this would depend on availability, completion and accuracy of the clinical records.

Concealment of allocation, blinding and protection against bias

Randomisation is occurring at the practice level. Practices cannot be blinded to their allocated intervention. Only objective data would be collected in the feasibility trial so this would not be affected by lack of blinding.

Statistical analysis

As this is a feasibility trial I am mainly looking at process outcomes including recruitment, eligibility, and adherence rates, so statistical analyses would not be needed.
I would use data collected on change in HbA1c to help calculate sample size needed for a phase III randomised controlled superiority trial.

Conclusion

In this chapter I have proposed a protocol for a cluster randomised feasibility trial, comparing HeLP-Diabetes: Starting Out with face-to-face education courses. The aim of the trial would be to determine if a more costly and time-consuming phase III randomised controlled trial to determine the relative effectiveness and cost-effectiveness of HeLP-Diabetes: Starting Out compared to face-to-face courses could be carried out. This is the next step for the research on HeLP-Diabetes: Starting Out according to guidance on evaluating complex and digital interventions, following the early phase work I have completed for this thesis.