

**Development of an online self-management
intervention for adults with type 2 diabetes
(HeLP-Diabetes)**

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PhD Thesis

Signed declaration

'I, Kingshuk Pal, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.'

Signature:

Date:

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This thesis is my own work but I could not have done this without the tremendous good fortune of being surrounded by some incredibly talented people whose work ethic and rigour have inspired and encouraged me over the past six years.

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Abstract

Background: The prevalence of type 2 diabetes is increasing and estimates suggest that by 2030 nearly 1 in 10 adults worldwide will be living with this condition. 10% of the NHS budget is spent on treating diabetes and related complications like heart attacks, strokes and blindness. Improving self-management in people living with type 2 diabetes is crucial in reducing the morbidity and mortality associated with this disease. Uptake of group-based self-management training is low and there is an urgent need for evidence based and effective alternatives. Computer-based interventions have the potential to provide cost-effective self-management training and improve outcomes for people with type 2 diabetes. The eHealth Unit was awarded a 5 year NIHR Programme grant for Applied Research to develop, evaluate and implement an online self-management intervention for adults with type 2 diabetes. This thesis describes my contribution towards developing the intervention.

Aims/objectives: To describe the development of an online self-management intervention for adults with type 2 diabetes.

Methods: The intervention development process was modelled on the MRC guidelines for developing complex interventions. This started with a systematic review of the literature on computer-based self-management interventions for adults with type 2 diabetes. Suitable theories to underpin the intervention were identified and used to construct a logic model to describe the potential mode of action. Qualitative work with people living with type 2 diabetes and health professionals was used to explore patient and professional defined wants and needs from such interventions. This data was then synthesized to inform the development of a theory-based online intervention called HeLP-Diabetes, designed to improve self-management in people living with type 2 diabetes.

Conclusions: The synthesis of previous evidence with new qualitative data from patients and health professionals has helped to create a unique online intervention that will hopefully help bridge current gaps in the delivery of self-management training and improve outcomes for people with type 2 diabetes.

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List of acronyms

| | |
|---------|--|
| ADA | American Diabetes Association |
| BCT | Behaviour Change Technique |
| BCW | Behaviour Change Wheel |
| CBT | Cognitive Behavioural Therapy |
| cCBT | computerised Cognitive Behavioural Therapy |
| CCG | Clinical Commissioning Group |
| DAFNE | Dose Adjustment For Normal Eating (diabetes self-management education programme) |
| DESMOND | Diabetes Education and Self Management for Ongoing and Newly Diagnosed (diabetes self-management education programme) |
| DM | Diabetes Mellitus |
| DSME | Diabetes Self-Management Education |
| DSMS | Diabetes Self-Management Support |
| EPP | Expert Patient Programme |
| NPT | Normalization Process Theory |
| OSMI | Online Self-Management Intervention |
| ROMEO | Rethink Organization to iMprove Education and Outcomes (diabetes self-management education programme) |
| SMI | Self-Management Intervention |
| SMS | Short Message Service |
| T2DM | Type 2 Diabetes Mellitus |

1. Introduction

1.1 Chapter outline

In this chapter I have presented the rationale for the research work done for this PhD thesis in developing a new digital self-management intervention for adults with type 2 diabetes. I have described the burden of diabetes on health services in England and worldwide and the role of diabetes self-management education in facing the challenges this presents. Following this, the evidence supporting the use of diabetes self-management education has been discussed, highlighting areas that have shown promise as targets for such interventions. The challenges faced by current programmes are summarised, and I have highlighted the ways in which digital programmes could help overcome some of these obstacles. In the final sections of this chapter I have provided an outline of the structure of the thesis and described the funding and context in which the research was done.

1.2 Objective for the research reported in this thesis

To describe the process of development of a new online self-management intervention for adults with type 2 diabetes.

1.3 Definition and diagnosis of type 2 diabetes mellitus

Diabetes mellitus describes a disorder of metabolism of multiple aetiology that is characterised by persistent raised blood glucose levels with associated disturbances of carbohydrate, fat and protein metabolism (WHO 1999). The majority of people with diabetes have type 2 diabetes which is caused by a combination of resistance to insulin action and a reduced insulin secretory response (ADA 2009). Raised blood glucose levels causes pathological and functional changes in various target tissues like eyes, kidneys, nerves and blood vessels and this may be present for some time before diabetes is detected – in the USA the mean age of diagnosis is 54 (National Center for Chronic Disease Prevention and Health Promotion 2015). The diagnosis and progression of diabetes is often done via a blood test for HbA1c – this measures the degree of glycosylation of haemoglobin and reflects average blood glucose levels over the preceding 2-3 months (International Expert

Committee 2009). HbA1c levels are normally below 42mmol/mol and a cut-off of 48mol/mol (6.5%) can be used to diagnose diabetes (WHO 2011).

1.4 The impact of diabetes on health services

Long-term conditions, like diabetes, that cannot at present be cured are at the heart of the biggest challenges facing many health services. In England, long-term conditions account for half of all GP appointments, 64 per cent of outpatient appointments and 70 per cent of inpatient bed days (Department of Health 2012). Around 30 percent of people in England are living with one or more long-term conditions, accounting for 70 percent of the total health and care spend (The King's fund 2015).

According to primary care registers, diabetes is the third most common long-term condition in England after hypertension and depression, and it affects around six percent of the population - while spending on diabetes and related complications accounts for 10 percent of the total NHS budget (Diabetes UK 2014a;Health & Social Care Information Centre 2014). Finding cost-effective solutions to improving outcomes in diabetes is an issue of significant importance to the NHS.

Diabetes is also an increasingly significant global challenge as well. Current estimates suggest that there are nearly 400 million people living with type 2 diabetes across the world with a prevalence of 8.3% in adults aged 20-79; numbers are rising and by 2035 there may be 600 million people living with this condition (Guariguata et al. 2014). The highest prevalence of diabetes is in the Pacific island nations with Tokelau having a prevalence of diabetes of 37.5%, while in Middle Eastern countries like Saudi Arabia, Kuwait and Qatar diabetes affects more than 20% of adults. In the USA, the prevalence of diabetes is estimated to be between 12-14% with a further 38% of the population at high risk of developing diabetes (Menke et al. 2015).

The health and economic implications of these figures are stark. Diabetes causes significant morbidity and mortality: it increases the risks of kidney damage, blindness and amputation and the higher risks of heart attacks, strokes and other fatal complications can shorten life expectancy by 8-10 years if diabetes is poorly controlled (National Collaborating Centre for Chronic

Conditions 2008). Around four million deaths worldwide are related to diabetes and direct healthcare costs range from 2.5 to 15% of annual health care budgets – around the world over 500 billion dollars is spent on treating diabetes, with the majority of costs spent on treating diabetes related complications (Diabetes UK 2014b;International Diabetes Federation 2013). Around 90 percent of patients have type 2 diabetes, and 95 percent of patients with diabetes in the UK are over 40 (Diabetes UK 2014a).

1.5 The role and definition of Diabetes Self-Management Education (DSME) and Online Self-Management Interventions (OSMIs)

Educating patients about their diabetes and helping them improve self-management skills can reduce the risks of developing diabetes related complications four-fold and improve glycaemic control, at least in the short term (Deakin et al. 2005;Ellis et al. 2004;Nicolucci et al. 1996;Norris et al. 2002;Powers et al. 2015). The importance of helping patients improve self-management means that providing access to structured education for people with diabetes is recommended in national standards for diabetes care in both the US and the UK (Diabetes Care 2013;National Institute for Health and Care Excellence 2015).

Diabetes UK list seven key self-management activities for living with diabetes: (i) managing the relationships between food, activity and medications; (ii) self-monitoring of blood glucose, blood pressure and having retinal screening carried out; (iii) targeting goals tailored to individual need, for example around foot-care, weight loss, injection technique and self-monitoring activities; (iv) applying sick day rules when ill, or what to do if going into hospital; (v) understanding diabetes, what care to expect and how to access services; (vi) managing acute complications – hypoglycaemia and hyperglycaemia; and (vii)understanding legislative issues such as those related to employment and driving (Diabetes UK 2009). The American Diabetes Association (ADA) defines diabetes self-management education (DSME) as the on-going process of facilitating the knowledge, skill, and ability necessary for diabetes self-care. This includes the needs, goals, and life experiences of the person with diabetes and is guided by evidence-based standards (Haas et al. 2014).

The ADA concept of DSME has a broader scope and is better aligned with the theoretical frameworks used for this programme of work (described in more detail in Chapter 2). Therefore the ADA definition was used as the basis for DSME used in this thesis.

According to the ADA definition, the overall objectives of DSME are to support informed decision making, self-care behaviours, problem solving, and active collaboration with the health care team to improve clinical outcomes, health status, and quality of life. These four key objectives are discussed in more detail below in section 1.6.

The ADA has also expanded the concept of DSME to include the concept of diabetes self-management support (DSMS) which extends beyond the initial education programmes and had been defined as activities that assist a person with diabetes in implementing and sustaining the behaviours needed to manage his or her condition on an ongoing basis beyond or outside of formal self-management training (Haas et al. 2013). The support provided can be behavioural, educational, psychosocial, or clinical. However diabetes is a progressive long-term condition and patient needs change over time in response to life events, escalating treatment or complications. As these needs change, the support required by patients also changes so interventions that can respond to evolving needs and provide ongoing DSMS are likely to be as important as DSME. Another important aspect of the definition of DSMS is the inclusion of a psychosocial element. The impact of psychological and social factors were also key components of one of the theoretical models underpinning the intervention described in Chapter 2 (Corbin et al. 1988) and there is evidence that negative emotional reactions to diabetes and low mood also affect outcomes (Aikens 2012; alexTsujii et al. 2012). Therefore the scope of the intervention described in this thesis (HeLP-Diabetes) included the provision of both DSME and DSMS (DMSE/S). However, most of the data in the literature are from studies of DSME rather than DSMS and this is reflected in the evidence presented in sections 1.5 and 1.6.

This thesis explores the development of a new digital intervention to support DSME/S. Desktop, laptop or handheld computers and mobile phones have the processing power and connectivity to allow remote access to information and

algorithms that have the potential to support most of the targets of DSME programmes discussed in section 1.6 (Griffiths et al. 2006; Jackson et al. 2006; Murray et al. 2005; Pereira et al. 2015). Digital interventions have the potential to be relatively cheap, easily distributable, delivered at multiple locations (clinical, community-based, at home or on the move) at times convenient for patients, offer patients as many interventions as they need or want and offer continuing support (DSMS), send out automatic reminders and present information in an attractive, tailored format to suit patients' needs (Murray 2012). The connectivity mentioned above also allows easy formation of social networking and peer support groups beyond traditional clinical settings.

The definition and scope of an online Self-Management Intervention (OSMI) is explored in more detail in the systematic review in Chapter 3. Digital self-management interventions have been defined as computer-based software applications that respond to user input and aim to generate tailored content to improve one or more of the following self-management domains through feedback, tailored advice, reinforcement and rewards, patient decision support, goal setting or reminders. The new digital SMI described in this thesis was called HeLP-Diabetes, which was an acronym for **H**ealthy **L**iving for **P**eople with type 2 **D**iabetes.

1.6 Evidence for DSME

Current guidelines recommend the use of group-based structured educational programmes to support diabetes self-management (National Collaborating Centre for Chronic Conditions 2008). Examples of these diabetes self-management education programmes include: the Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (DESMOND) programme for people with newly diagnosed type 2 diabetes (Davies et al. 2008), the 'Rethink Organization to iMprove Education and Outcomes' (ROMEO) for people with type 2 diabetes (Trento et al. 2010), the 'Diabetes X-PERT Programme' (Deakin et al. 2006) for people with type 2 diabetes and the Dose Adjustment For Normal Eating (DAFNE) for people with type 1 diabetes (Amiel et al. 2002). Examples of general patient self-management programmes include the Chronic Disease Self-Management Programme (CDSMP) (Lorig et al. 2001) and the Expert Patient Programme (EPP) (Kennedy et al. 2007a). Group-based training

for self-management in people with type 2 diabetes appears to improve diabetes control and knowledge of diabetes with weaker evidence to show effects on blood pressure, weight and health-related quality of life (Deakin et al. 2005). However, the benefits on blood glucose control appear to wane over time. In contrast, there does not currently appear to be much evidence to support the use of existing individual face-to-face patient education programmes as they have not shown significant improvements in glycaemic control, body mass index or blood pressure (Duke et al. 2009). As digital interventions are typically used by individual users in isolation, this could raise concerns about the potential impact of a digital SMI. Previous reviews of digital interventions found evidence of potential effectiveness but there were no meta-analyses that could quantify this (Costa et al. 2009; Jackson et al. 2006). Therefore there was a need for an up-to-date systematic review and meta-analysis of digital SMI and this has been described in Chapter 3.

1.7 Targets for DSME/S interventions

To understand how self-management interventions might act, sections 1.6.1 – 1.6.6 below highlight the evidence supporting six potential targets for the self-management intervention based on the key constructs of DSME/S described above: 1. informed decision making, 2. self-care behaviours, 3. problem solving, 4. active collaboration with the health care team 5. emotional management and 6. social support.

1.7.1 Informed decision making

Providing patients with information and involving them in decisions about their care can help them take a more active role in managing their condition, make better choices and increase concordance with treatment plans (Epstein et al. 2004). Braddok et al describe seven elements of informed decision making – (i) Discussing the patient's role in decision making; (ii) Explaining the nature of the decision; (iii) Exploring alternative options; (iv) Discussing pros and cons of options; (v) Discussing uncertainties associated with the decision; (vi) Assessing understanding; and (vii) Exploring patient preferences (Braddock, III et al. 1999). The first five elements require patients to have access to relevant information in a way that they can understand and process. Therefore providing knowledge in a way that is accessible and easily understood by patients is the

foundation for supporting informed decision-making and enabling successful self-management.

The degree to which individuals can obtain, process, understand, and communicate about the health-related information needed to make informed health decisions is one definition of “health literacy” – a key concept in trying to describe the variability in the abilities and needs of individual patients to make informed decisions (Berkman et al. 2010). The skills required for health literacy can be divided into functional, interactive, critical and numeric skills (AI et al. 2013). Functional health literacy includes the ability to read and understand written text, locate and interpret information in documents and write or complete forms. Interactive literacy refers to the ability to speak and listen effectively and communicate health-related information. Critical skills for health literacy include the ability to navigate the health care system and make appropriate decisions. Numeric skills are needed for tasks like medication dosing, self-monitoring and understanding food and nutrition requirements. Printed educational materials and verbal instructions often require advanced health literacy skills and can create significant barriers to self-management education in people with low health literacy (White et al. 2010). While simple changes like avoiding long sentences or medical jargon can reduce the required reading age and help overcome barriers caused by low functional literacy; they may not be enough to compensate for low numeric, critical or interactive literacy (Weiss et al. 1997). Therefore making information in self-management programmes accessible requires more than just simplifying text and may benefit from the use of images or videos and this was an important consideration in the design of HeLP-Diabetes.

Low levels of health literacy appear, from cross-sectional studies, to be associated with poorer outcomes in patients with diabetes (Schillinger et al. 2002). However a systematic review of studies on health literacy in diabetes found that health literacy is strongly associated with diabetes knowledge, but there was no conclusive evidence of a link between increasing health literacy and better diabetes outcomes (AI et al. 2013). Therefore the priority for self-management interventions is not to increase the health literacy of participants but to make sure that content is accessible and matched with the capabilities of

the target audience. Half of the UK working population have reading age of 11 years old or younger and the UK Office of National Statistics style-guide advises that websites should aim for an average sentence length of 12 words and a Fleisch-Kincaid reading score of 60 and over (Office of National Statistics 2016). This was used as a reference when writing content for HeLP-Diabetes.

It should also be noted that although informed decision making is reasoned, it is not purely utilitarian and it is influenced by factors like emotional states, past experience and beliefs, which will influence the weight people attach to different options (Blanchette et al. 2009; Pfister et al. 2008). The process of decision making can also be influenced by decision features (e.g. framing of choice options, ordering of choices, choice justification), situational factors (e.g. time pressure, cognitive load and social context) and individual differences (e.g. risk attitudes, cognitive ability, motivation, personality, decision making styles) (Appelt et al. 2011). Concordance between patients and professionals defined goals and strategies for diabetes treatment can be quite low – for example avoiding medication, particularly insulin, can be a key patient priority not shared with health professionals (Heisler et al. 2003). It should, therefore, not be assumed that informed decision making will always lead to better clinical outcomes – informed decision making should be part of patient-centred care that reflects patient values and priorities (like quality of life) over other clinical outcomes like HbA1c that might be health professional priorities. This was an important consideration for the intervention – content needed to be written in a neutral way with information provided in the form of evidence based suggestions with a clear rationale, avoiding moral “right/wrong” implications or didactic advice.

1.7.2 *Self-care behaviours*

The main behaviours that are part of DSME/S that support self-management are physical activity, eating, taking medication and reducing complication risk and these are discussed below.

Physical activity: Physical activity is an important part of diabetes self-management and unless there are contra-indications, people should be looking to do a minimum of 150 minutes per week of moderate intensity exercise in bouts of at least 10 minutes and spread over at least 3 days (Colberg et al.

2010;Sigal et al. 2006). It can improve blood glucose control even in the absence of weight loss (Boule et al. 2001). Higher levels of aerobic fitness reduce the risk of cardiovascular and overall mortality in people with diabetes (Church et al. 2004;Wei et al. 2000). Exercise training has been shown to have modest effects on improving blood pressure and lipids in the general population (Leon et al. 2001;Whelton et al. 2002). The potential mechanisms for reduction of cardiovascular risks include decreased systemic inflammation, improved diastolic function, improved endothelial function and decreased visceral fat (Stewart 2002). Physical activity improves insulin sensitivity for up to 72 hours, and this effect is greater than the impact of equivalent calorie restriction through diet on insulin sensitivity (Ross et al. 2000). Exercise may also help to improve depression but the evidence for this is not conclusive (Chalder et al. 2012;Lawlor et al. 2001).

Only 67% of men and 55% of women in England meet physical activity guidance and this decreases with age (Townsend et al. 2015) – therefore providing users with support to improve their physical activity levels was a key priority for the new intervention. However this support needed to take into account the restrictions that might be placed on users from co-morbidities like cardiovascular disease, arthritis or obesity.

Eating healthily: Improving diet can reduce HbA1c and cardiovascular risks in people living with diabetes, but there is no “ideal” diet for people living with type 2 diabetes - examples of positive dietary changes include calorie restriction to facilitate weight loss in overweight patients and eating a Mediterranean style diet (Evert et al. 2013). A Mediterranean style diet has the strongest evidence for health benefits with evidence of improvements in blood glucose control, weight loss and reducing risks of heart disease, cancer and dementia (Ajala et al. 2013;Sofi et al. 2010). Dietary changes can improve HbA1c by 1-2% depending on duration of diabetes (Pastors et al. 2002;Pastors et al. 2003). Changes to eating habits have also been shown to reduce blood lipid levels in the general population with benefits seen within 3-6 months (Yu-Poth et al. 1999). Lifestyle changes like weight loss, reducing dietary sodium and increasing dietary potassium, increasing fresh fruit and vegetables in the diet

and moderating alcohol intake can reduce blood pressure by more than 10 mmHg (Whitworth 2003).

Providing dietary advice was something that was potentially relevant and important for all users, but needed to take into account the unique needs of each user as they would have different calorie requirements, cultural norms and dietary preferences. Social occasions where high-calorie foods are popular and religious festivals that included fasting or celebrations (e.g. Ramadan and Yom Kippur) were examples of the specific challenges that users might need support with.

Adherence to medication: Achieving good glycaemic control is an important aspect of managing diabetes, although the benefits are not quite as clear as might be expected. Intensive control of type 2 diabetes has significant benefits in reducing microvascular complications (retinopathy and nephropathy) and neuropathic complications (Ohkubo et al. 1995;UK Prospective Diabetes Study Group 1998a). The effects on macrovascular complications (heart attack, strokes and ischaemic limbs) are less clear – long term follow-up of UKPDS trial participants suggests intensive treatment around the time of diagnosis has significant reductions in rates of heart attacks and all-cause mortality (Holman et al. 2008). However intensive treatment in patients with more advanced diabetes or existing cardiovascular problems is less beneficial and may even increase mortality (Skyler et al. 2009). However, for patients with high blood pressure there are clear benefits of achieving good control of hypertension using medication, with a reduction in the risk of heart attacks, strokes and kidney damage (Adler et al. 2000;Cooper-DeHoff et al. 2010;Cushman et al. 2010;UK Prospective Diabetes Study Group 1998b). There are also clear benefits in both primary and secondary prevention of cardiovascular disease gained from providing cholesterol-lowering medication to people with diabetes on (Baigent et al. 2005;Mihaylova et al. 2012). There is also recent evidence to suggest that the risk of death in adults with type 2 diabetes over 65 is lower than the rest of the population – perhaps due to better control of cardiovascular risk factors like blood pressure and cholesterol (Tancredi et al. 2015). Therefore adherence to medication regimes for glucose control, blood pressure control and cholesterol are important for improving long-term outcomes in people with

diabetes. There is evidence that rates of adherence to medication are associated with glycaemic control and blood lipid levels in people with diabetes (Krapek et al. 2004; Pladenvall et al. 2004). Lack of adherence to blood pressure lowering medication is a major factor for sub-optimal blood pressure control and is estimated to be a problem for between 50-70% of patients treated for hypertension (Schroeder et al. 2004).

As stated above, low levels of adherence with treatment regimens adversely affects outcomes so HeLP-Diabetes needed to provide support to help patients with taking medication. But, as mentioned earlier in this chapter, avoiding medication and not starting on insulin are often patient priorities that are at odds with health professional priorities. Therefore the planned intervention needed to provide clear explanations for the benefits of medication and the rationale and evidence for their use so that patients could be better informed and help align patient and professional agendas where possible.

Reducing risks of complications: This requires a combination of lifestyle changes and taking medication as already dealt with above, and attending regular screening checks to pick up early signs of organ damage and take action to reduce the chances of complications progressing. The UK National Institute for Health and Care Excellence (NICE) advises nine checks to be done every year at an annual diabetes review (National Collaborating Centre for Chronic Conditions 2008). These are (i) measure body mass index (height and weight) (ii) blood pressure check (iii) a foot check (iv) review of smoking status (v) blood test for HbA1c (average blood glucose levels) (vi) blood test for cholesterol (vii) blood test for creatinine (viii) urine test for protein - microalbumin : creatinine ratio (ix) attend retinal (eye) screening. For someone with diabetes, this would involve attending appointments at least once a year for (i) a consultation with a health care professional (ii) a blood test and urine test (iii) an eye test (iv) referral to smoking cessation where appropriate. The UK national diabetes audit 2010-2011 showed that only 56.4% of patients with type 2 diabetes in England had all 9 checks done (Health and Social Care Information Centre 2012).

Supporting patients with attending their appointments was therefore another important function of the intervention. Similar to support for medication

adherence, this was felt to require a combination of information provision to explain the benefits of the checks (to help align patient and professional agendas) and tools to help prompt attendance like reminders.

1.7.3 Problem solving

Problem solving is a cognitive and behavioural process by which a person attempts to identify effective and adaptive solutions for specific problems encountered in everyday living (Fitzpatrick et al. 2013). A simpler description is a series of cognitive operations used to figure out what to do when the way to reach a goal is not apparent (Schumann et al. 2011). A model for understanding problem solving in the context of diabetes self-management has been proposed (Hill-Briggs 2003), highlighting four key components relevant to diabetes self-management : (i) problem-solving skill (ii) problem-solving orientation (iii) disease-specific knowledge (iv) transfer of past experience. Problem-solving skill refers to the approach an individual takes to solving problems (rational, impulsive/careless, avoidant), with a rational approach being most effective. Problem-solving orientation refers to individuals' attitudes and beliefs about their disease and the problems they encounter. Problem-solving orientation can be positive (e.g., problems viewed as a challenge) or negative (e.g., problems viewed as a threat). The third component of problem solving is disease-specific knowledge. To solve problems related to disease self-management effectively, individuals must have a working knowledge base about the disease and its management. The fourth component, transfer of past experience, refers to the use of previous experience in attempting to solve novel problems. This transfer of past experience can also be effective (e.g., using a solution that was effective in a similar situation in the past) or ineffective (e.g., trying an ineffective solution repeatedly in the same situation). Each component of problem solving operates within the problem environment, composed of the social and physical context and characteristics of the problem itself. The evidence about the effectiveness of problem solving interventions is mixed. A systematic review of problem solving interventions for diabetes self-management and control showed less than half of adult problem-solving interventions demonstrated significant improvement in HbA1c (Fitzpatrick et al. 2013).

However even if improving problem solving by itself does not lead to behaviour change and improving HbA1c, a positive approach to problem solving is likely to be important in reducing the impact of negative responses to the challenges of self-management like denial, avoidance, rumination or feeling overwhelmed; seeing problems as surmountable obstacles and feeling confident about tackling them are likely to be important parts of successfully living and managing a long-term condition. An online self-management intervention could facilitate positive problem solving components by helping participants take a reasoned and rational approach to problems (e.g. support structured goal setting), create a positive environment to boost self-confidence and prevent problems feeling overwhelming or threatening through the way tone and content are written, supply relevant information so participants had the knowledge required to generate solutions and provide an environment in which participants and discuss their past experiences and learn more effective solutions for recurring problems through tools like an online forum. Such support would also be important for making positive psychological adjustments and the importance of this is discussed in section 1.6.5.

1.7.4 Engaging with health professionals

While people living with diabetes can do many things for themselves to improve their health outcomes, the chronic and evolving nature of the condition requires a truly multi-disciplinary approach to supporting life-long management. Primary care physicians and nurses, podiatrists, dieticians, endocrinologists and opticians or ophthalmologists are routinely involved in treatment and monitoring. Complications may require further input from cardiologists, nephrologists or vascular surgeons if heart disease, kidney disease or limb ischaemia develop. For the person with diabetes, this requires organisational skills to manage appointments, motivation to see different professions in different settings and the skills to access and communicate with multiple health care providers. People with diabetes wanting to take an active role in managing their condition and improve their self-management need to do all of the above but also establish long-term relationships with their health-professionals and develop partnerships that facilitate lifelong learning and development (Lorig et al. 2003). Shared decision-making means that patients must be willing to engage in the

decision-making process – i.e. to take responsibility for disclosing preferences, asking questions, weighing and evaluating treatment alternatives and formulating a treatment preference (Charles et al. 1997).

This was an important theme for the new intervention - with an emphasis on patient empowerment, support for patient-centred care and tools to help attend appointments. Providing high quality and accessible information to support informed decision making, helping patients with their care-plans and reminders for appointments were features that were planned as parts of the intervention.

1.7.5 Emotional management: psychological adjustment and low mood

A systematic review of psychological adjustment to chronic disease identified four elements of successful adjustment by patients: (i) remain as active as is reasonably possible; (ii) acknowledge and express their emotions in a way that allows them to take control of their lives; (iii) engage in self-management; and (iv) try to focus on potential positive outcomes of their illness (de Ridder et al. 2008). These are described in more detail below.

The direct metabolic benefits of physical activity were discussed in section 1.6.2. However levels of physical activity are also linked to how people adjust to living with a chronic illness. Many chronic diseases are characterised by sickness behaviour that includes weakness, malaise, inability to concentrate, depressed mood, lethargy, anhedonia, and anorexia and this is thought to be mediated by chemical mediators called cytokines (Dantzer 2001). In acute illness, such behaviour might be beneficial by promoting rest and conserving energy to help healing. This process stimulates adjustment similar to the desire for food in response to hunger, pain in response to injury, and the fight-or-flight response to threat. However, in chronic conditions these responses can become maladaptive e.g. in diabetes, hunger can make adjustment to a healthy diet difficult and lethargy and reduced physical activity will increase insulin resistance and blood glucose levels. Graded physical activity has been shown to be helpful in a range of chronic conditions (Smidt et al. 2005); because of the direct metabolic improvements in blood glucose levels with physical activity, the benefits are likely to be even greater in diabetes. Therefore encouraging physical activity through a self-management intervention as discussed previously would be important for both physical and psychological health.

Emotion regulation is a term encompassing several conscious or unconscious styles of experiencing, processing, and modulating emotions (de Ridder et al. 2008). Two main categories of emotion regulation have been distinguished: (i) avoidance and inhibition of emotions, which is associated with maladaptive outcomes such as an increase in disease occurrence and risk of disease progression; and (ii) expression and acknowledgment of emotions, which has been shown to promote good adjustment (Austenfeld et al. 2004). However, there are cultural differences in how adaptive emotional responses are. Prospective studies of emotion regulation suggest that in North American and western European cultures, the regular use of avoidant non-expressive styles of emotion regulation correlate with poorer psychological adjustment and survival. In the context of the less emotionally expressive Japanese culture, non-expressive emotion regulation styles appear to have better outcomes (Hirokawa et al. 2004).

Denial and non-expression of emotions may be a useful short-term strategy to cope with the stress surrounding the diagnosis of a chronic illness (Wiebe et al. 2003). However in the longer term, unresolved emotions could have negative effects through chronic raised sympathetic arousal (stress), delayed help seeking, rumination and poor communication with health-care providers. There are several potential benefits if emotions are expressed and processed. Thinking, talking or writing about negative emotions can make the experience less intensive and invasive (habituation), increase insight into why emotions are experienced and how their impact can be reduced (cognitive reappraisal), decrease emotional distress and create opportunities for social support and enhanced closeness with others and improve self-regulation (de Ridder et al. 2008). Such activities can be facilitated through digital interventions by providing tools for patients to record their feelings and through online forums where users can share their experiences and provide support for each other.

Patients living with severe chronic illnesses like HIV/AIDS and cancer have reported some positive outcomes from looking beyond negative outcomes and focusing on some positive aspects of living with the condition, such as an improved appreciation of life, enhanced sense of purpose, changes in life priorities, and improved personal relationships. At least one positive change as

a result of their illness has been reported in 60-85% of patients with breast cancer, 83% of HIV positive women and 58% of people after a heart attack (Petrie et al. 1999; Sears et al. 2003; Siegel et al. 2000).

Finding benefit or growth could be one of the cognitive strategies used to offset the negative effects of illness, referred to as a 'response shift process' (Sprangers et al. 1999). After diagnosis with a chronic illness, patients may re-evaluate their health or quality of life to maintain an acceptable quality of life in the face of declining health. This has been found to take several forms: (i) change their internal standards of what constitutes health or other aspects of quality of life (recalibration) (ii) adjust their values and priorities (reprioritisation) (iii) redefine what they think is important (reconceptualisation). A digital SMI could help with this process by helping inform patients about appropriate targets for parameters like blood glucose control and accepting higher than "normal" ranges where appropriate. An example of reprioritisation could be educating patients to place more importance on good blood pressure control and less importance on self-blood-glucose monitoring as there is strong evidence of benefit for the former but no evidence for the latter (Cooper-DeHoff et al. 2010; Farmer et al. 2012). It would also be important for the SMI to help users understand that diabetes is inherently progressive and define "good health" as slowed progression of the disease.

Benefit finding and growth have also been related to personality characteristics such as trait optimism, dispositional hope and extraversion (Affleck et al. 1996; Sears et al. 2003; Siegel et al. 2000; Sprangers et al. 1999). Early benefit finding might be a form of denial and may be different to benefit finding later on in an illness; in patients with breast cancer, benefit finding within 4 months of diagnosis predicted increased negative affect and worsened mental function after 3 months (Tomich et al. 2004). However benefit finding at 1 year post diagnosis predicted lower distress and depression scores 4-7 years later (Carver et al. 2004). Encouraging patients to engage with benefit finding or using a cognitive-behavioural stress management intervention shortly after diagnosis can lead to positive outcomes, including positive effects on physical adjustment (Antoni et al. 2001; Stanton et al. 2002).

Therefore if the self-management intervention could promote constructive social support (e.g. from peers) by providing forums for expressing and processing emotions and benefit finding - this could provide an important mechanism for psychological adjustment; it could also facilitate a positive approach to problem solving, the importance of which has been described earlier.

There is evidence that poor emotional outcomes are associated with poor physical outcomes. The literature draws a distinction between diabetes-related distress and depression (Cockburn 2014). Diabetes-related distress can be defined as significant negative emotional reactions to the diagnosis of diabetes, threat of complications, self-management demands, unresponsive providers, and/or unsupportive interpersonal relationships and are distinct from depressive symptoms (Gonzalez et al. 2011). Depression has been correlated with prognostic and diagnostic implications in diabetes: it has been associated with poor glycaemic control and increased rates of complications (de Groot et al. 2001; Lustman et al. 2000); while in prospective studies, depression has been found to double the likelihood of being diagnosed with diabetes (Eaton et al. 1996; Kawakami et al. 1999). However the evidence linking depression and blood glucose control has been mixed (Georgiades et al. 2007); treating depression does not result in improvements in HbA1c (Katon 2004). In contrast, cross-sectional and prospective evidence suggests that changes in diabetes-related distress correlate with changes in glycaemic control, possibly through changes in adherence with medication, while depressive symptoms are better correlated with self-management behaviours (Aikens 2012; Tsujii et al. 2012).

Therefore an online SMI that reduced diabetes-related distress and promoted positive psychological adjustment and emotional well-being as described previously could improve both physical and mental health in participants, even if they were suffering from depression. If the intervention included strategies for tackling depression like computerized CBT, it could help to improve self-management in people suffering from persistent low mood.

1.7.6 Social support

Positive social support can have a beneficial effect on self-care behaviours (Tang et al. 2008) and self-help groups can improve knowledge and glycaemic control (Simmons 1992). However a systematic review of 14 RCTs of peer

support interventions found mixed evidence of benefits on biological outcomes, but both trials that looked at perceived social support showed evidence of improvements (Dale et al. 2012). The impact of social support is likely to be a complex phenomenon that depends on sharing of knowledge and experience within the community, access to resources and the awareness of and ability to deal with relationships within social networks (Vassilev et al. 2014). Using peer support networks to share information is particularly effective for deprived populations, so patients with the most need have the potential to benefit the most (Koetsenruijter et al. 2016). A potential concern about the limitations of such benefits could be the “digital divide” and the accessibility of digital interventions for deprived patients and this is discussed in section 1.8.

The way that individuals construct their social identities and manage their roles within family and social networks is discussed in Chapter 2.

1.7.7 *Barriers to self-management*

Targeting known barriers to self-management behaviours in people with type 2 diabetes could also help improve outcomes. Common barriers to adherence in people with diabetes in one study included regimen complexity of more than one diabetes mellitus drug or more than one dose daily, depression, and remembering doses and refills (Odegard et al. 2007). In another study, the main barriers were reported as lack of knowledge of a specific diet plan, lack of understanding of the plan of care, helplessness and frustration from lack of glycaemic control and continued disease progression despite adherence (Nagelkerk et al. 2006).

By providing tools and reminders, good quality accessible information and promoting acceptance and good psychological adjustment, an online SMI could help people with type 2 diabetes improve self-management behaviours.

1.8 Limitations of current DSME programmes and potential for OSIMIs

The previous sections have discussed the need for good diabetes self-management, the evidence of effectiveness and the main targets to improve outcomes in type 2 diabetes. However, there are a number of challenges faced by existing self-management programmes that limit their effectiveness.

Lack of appropriate theoretical basis: Similar to findings from reviews of other complex interventions, a meta-analysis of diabetes education programmes concluded that the quality of reporting of important design issues was mostly poor and that very few programmes had been informed by psychological research (Loveman et al. 2008). The importance of theory and using findings from behaviour change research in designing interventions will be explored in Chapter 2. Learning from these experiences, HeLP-Diabetes was developed as a theoretically informed intervention (see Chapter 2) with input from a multi-disciplinary team as described in section 1.10.

Setting and convenience: Most education programmes are delivered in the clinical setting and there is little evidence on the use of DSME programmes in other locations. However a review of this area did find evidence to support their use in community gathering places for adults with Type 2 diabetes and at home for adolescents with Type 1 diabetes so there appears to be potential for self-management interventions outside traditional clinical settings (Norris et al. 2002). As mentioned earlier in this chapter, group-based education appears to be more effective than individual education, so it would not appear cost-effective offer individual training at home. However the challenge with group education is the low uptake rate. The ability to offer patient education at any time the patient desires might be important for increasing uptake – a qualitative study into reasons for non-attendance for DSME found that inconvenience was a major factor for low uptake (Winkley et al. 2015a). A digital SMI could be accessed by participants from any location convenient to patients that had internet access at a time of their choosing and therefore has the potential to overcome this barrier.

Duration of effect: Another issue appears to be that many of the benefits of DSME programmes diminish rapidly after the interventions have ended with the duration of an intervention being a predictor of a programme's success (Clark 2008; Pillay et al. 2015). And as described earlier, the American Diabetes Association guidelines specify the need for continuing diabetes self-management support (DSMS). An online intervention could be accessed multiple times at no extra cost and therefore provide repeated exposure to the intervention as needed. This could allow yearly or more frequent “doses” that

could ensure that patients continued to benefit over the course of their illness journeys.

Uptake: The ADA guidelines on self-management education advise that DSME is a critical element of the care for all people with diabetes and it is necessary in order to improve patient outcomes (Haas et al. 2014). However, uptake of diabetes education is low - only 3.6% of newly diagnosed people with type 2 diabetes in England were recorded as having attended structured education in the National Diabetes Audit published in 2014 (Health and Social Care Information Centre 2014). This is in spite of the availability of multiple local and national DSME programmes like DESMOND, DAFNE, X-PERT and the EPP as described earlier in section 1.5. In America, previous surveys have shown that only 35-45 % of patients received DSME (Coonrod et al. 1994). The advantages of convenience and anonymous use give digital SMIs the potential to increase the uptake of DSME/S.

Cost: The economic data for these interventions are not well documented, but a review for the National Institute for Clinical Excellence found estimates of cost ranged from £66 per person attending a diabetes centre-based teaching programme for three afternoons, to £545 for the DAFNE programme (National Collaborating Centre for Chronic Conditions 2008). This review also highlighted cost-effectiveness data from 3 studies:

- A behavioural intervention addressing diet plus exercise was more cost effective than a general educational intervention in adults with type 2 diabetes, with significant improvements in quality of life at a cost of \$10,870 per well year (calculated at 1986 prices).
- Dietary self-management improved intermediate health outcomes (dietary fat consumption, saturated fat consumption, serum cholesterol) compared with usual care in adults with both type 1 and type 2 diabetes at a cost of \$137 per participant
- After reviewing the figures from the DAFNE programme with more conservative assumptions, the net benefits were calculated to be 0.063 Quality Adjusted Life Years (QALYs) with a net cost saving of £536 and a mean incremental cost-effectiveness ratio of £14,400 per QALY

However if we take into account the need for on-going diabetes self-management support, and if the benefits were not maintained as suggested by the evidence discussed in section 1.5, the cost-effectiveness would significantly decrease. The running costs of digital interventions tend to be low (Bailey et al. 2010; Murray 2012). Therefore if they are effective, the potential cost-effectiveness of such interventions could be significantly better than face-to-face, especially if they could provide ongoing DSMS or repeated courses of DSME for no extra cost.

Equity: In American patients with type 2 diabetes, exposure to diabetes education has been shown to be associated with younger age, black race, residence in the midwest region of the U.S., higher level of education, presence of diabetes complications and higher income (Coonrod et al. 1994). Existing interventions do not appear to effectively target the whole spectrum of diabetic patients. Similarly, early implementation studies of the UK based (generic) Expert Patient Programme courses tended to draw in people who were already committed to self-managing and who tended to be white, middle class and well educated (Greenhalgh 2009). If the concerns around the digital divide discussed in section 1.8 can be addressed, interventions targeted at ethnic minorities or targeted at those with low health literacy could potentially reduce health inequalities. Alternatively, if digital SMIs are more acceptable for those who are good at self-management and could be provided at lower costs to meet their needs, this could free resources for more intensive interventions for those who need it. Use of peer support networks through digital SMIs might also provide a conduit to connect those good at self-management with those struggling and use peer support to reduce inequalities through sharing knowledge as discussed previously in this chapter.

Tailoring to needs: Tailored interventions where programmes are individualised by patient characteristics and adapt to patient needs are potentially more effective at behaviour change (Collins et al. 2004). Group based DSME interventions have limited flexibility in how much the programme can be adapted to suit the individual needs of different patients. Any changes to the intervention are potentially complicated and expensive to implement and disseminate – it may involve reprinting large volumes of written information,

retraining staff or needing to employ new staff who can speak a different language. Interactive digital SMIs could be programmed to offer tailored content to individual users or updated for all users at much lower costs.

Barriers to implementation: A national survey of DSME programmes in America highlighted a number of barriers to access identified by educators, physicians and patients (Peyrot et al. 2009). Diabetic educators felt that some barriers were related to referring doctors: physicians did not educate patients about the importance of DSME, did not recognise programme quality, did not want to lose control of patients, did not know how to refer or did not believe that DSME interventions were effective. Physician held beliefs that were barriers included feeling that patients were told things they did not agree with, patients were not interested in DSME, there were not enough referral sources or the referral process was not easy. Patient beliefs that hampered access to DSME included ideas that their doctor told them everything they needed to know, they already knew what they needed to know, they felt that their doctor did not think DSME was important or they did not need it because they did not have any problems. Both educators and physicians believed that some of the barriers to DSME were that patients did not think they needed DSME, they would not be able to fit it into their schedules, it would not be covered by insurance or it was too expensive. While not all of the opinions described above would affect every patient or health system, it is important to consider the relevant ones that resonate with prevalent attitudes that might hinder uptake of education programmes. Qualitative data from patients in the UK suggests that patient reasons for non-attendance include fear of stigma, inconvenience and a lack of understanding of the importance of DSME while survey data showed that low attendance was associated with male gender, smoking, poor blood glucose control and a primary care provider not achieving glucose control targets (Winkley et al. 2015a;Winkley et al. 2015b). A convenient and anonymously accessed digital SMI could overcome some of the barriers that patients face regarding inconvenience and stigma, but the challenge of promoting DSME and health professionals encouraging use would apply to digital SMIs as much as face-to-face DSME. This is explored in more detail in Chapter 5.

1.9 Potential limitations of OSMIs

There are a number of potential pitfalls of using new technology. The lack of face-to-face contact may be an issue for some users and reviews have suggested that contact with health professionals is a factor in the effectiveness in current interventions (Ellis et al. 2004; Pillay et al. 2015). The efficacy, cost-effectiveness and active components of digital interventions are still relatively unknown (Costa et al. 2009); and the pace of evolution in the digital landscape means that such evaluations of their impact require frequent reassessment. Stand-alone internet interventions often have high levels of attrition and engagement needs to be actively addressed in all such programmes (Wangberg et al. 2008). There can be significant difficulty with quality control and enabling professionals and patients to choose evidence-based and effective applications can be challenging (Armstrong 2015). Reports of adverse effects from digital interventions are rare in the literature and the main limitations appear to be a lack of engagement or engagement with poor quality interventions as highlighted above.

One of the biggest concerns with new technology surrounds equity and access – often referred to as the digital divide. The digital divide can be defined as the gap between those who have and do not have access to computers – and it has been noted that use of the internet and access can be highly correlated with income, age, education and occupation (Dutton et al. 2013; van Dijk 2006). However access is improving rapidly and online interventions now have the potential to reach the majority of the adult UK population (Office for National Statistics 2015). Digital interventions increasingly have the potential to be a crucial channel to improve access to self-management training and improve health outcomes across society and help to reach those with the greatest need and the most potential to benefit. When the work described in this thesis was started, there were no digital self-management interventions being used in England.

There are also questions around the uptake and usage of digital health interventions. Active users are most likely to be female, highly educated, white, and living in high-income countries (Kohl et al. 2013). Adherence to online interventions varies widely, with small RCTs reporting adherence of up to 93%

but larger online observational studies reporting adherence as low as 1 % (Eysenbach 2005;Kelders et al. 2011). Therefore strategies for engaging and retaining users needs to be an important consideration in designing digital health interventions and this was explored in the qualitative work described in Chapters 4 and 5.

The final challenge to the potential for OSMIs is the problem of integrating a new service into routine clinical practice. Such interventions are often developed in systems suited to academic use and not be compatible with information technology used in routine clinical settings and the intervention may not have the required infrastructure require for ongoing delivery once research grant funding has ended (Glasgow et al. 2014). The challenges to implementation also extend beyond technical specifications and encompass social and organisational issues as well (Cresswell et al. 2013). The introduction of new technology into complex organizations is not a straightforward linear process but it is dynamic and iterative requiring alignment of technological, social and organisational domains (Cresswell et al. 2011). Examples of important factors required for such change include early and on-going input from users, early demonstrable benefits and long-term advantages of the intervention, a close fit with organizational priorities, appropriate training and support and effective leadership and change management. Chapter 4 has described the qualitative study done to understand user perspectives and the process of participatory design for ongoing user input has been described in section 6.4.5. The use of Normalization Process Theory (NPT) as a model to understand the organisational challenges of implementation has been described in section 2.5.

1.10 Outline of thesis

The aim of this thesis is to describe the work done in developing a new online self-management intervention to support adults with type 2 diabetes (HeLP-Diabetes). In the next six chapters I have described the theory, evidence and methods used to understand the context and scope of the intervention, and guide the development process. Chapter 2 explores the main theoretical frameworks used for this work which included the Medical Research Council (MRC) complex interventions framework, Corbin and Strauss' model of living

with a chronic condition, Normalization Process Theory and the COM-B model of behaviour change. In Chapter 3 I have written about a systematic review of the literature on digital self-management interventions for adults with type 2 diabetes. Chapter 4 has described qualitative work to explore the wants and needs of patients, while Chapter 5 deals with similar work done with health professionals to explore their views. The sixth chapter has covered the process of synthesising the data from chapters 2-5 to create the HeLP-Diabetes intervention. Chapter 7 summarises the main findings of the thesis and puts them into the wider context of the literature, highlighting the main lessons learnt from this body of work. There is a brief reflection on my personal development and learning in putting together this thesis in Chapter 8.

1.11 Funding and my role in the research activity described in this thesis

The research work described in this thesis was funded by a five year National Institute for Health Research (NIHR) programme grant for applied research to develop, evaluate and implement an online self-management intervention for adults with type 2 diabetes. I was second author on the successful programme grant application and contributed to writing and editing the application for the grant. I also wrote the first draft for the application for ethical approval for the qualitative and development work for the programme grant and did the initial drafts for the consent forms and written study material. The core research team for the programme grant included:

- EM, Director of the eHealth Unit, GP
- FS, Lecturer in medical sociology
- KP, Clinical Research Associate, GP
- CD, Research Associate, Health psychology training
- JR, Research Associate, Health psychology training
- EG, Academic GP trainee

Co-applicants mentioned in this thesis were:

- SM, Professor of Health Psychology

- CM, Professor of Healthcare Innovation

The text of Chapter 3 is based on a Cochrane systematic review for which I was the first author. It may bear similarities to this publication as this research work was done for my PhD. All of the remaining chapters are based on original material written for this thesis, although the studies described in Chapters 4 and 5 are due to be submitted for publication and I plan to disseminate my analysis in Chapter 6 at international conferences.

As first author of the systematic review described in Chapter 3, I was responsible for drafting the protocol, abstract screening (with another colleague), data extraction (with another colleague), analysing data, organising steering group meetings, re-writing manuscripts and submissions for publication.

For the qualitative work described in Chapters 4 and 5, I drafted the initial application forms for ethics as described above but subsequent revisions and submission were done together with CD. I shared the responsibility of facilitating focus groups and doing interviews with CD. A preliminary functional analysis to create a project specification for the final intervention was done in data clinics where all the core team members were present and contributed to the initial coding and thematic analysis. However subsequent re-coding and in-depth analysis were done by me and checked by EM and FS.

CD, JR, EG and I contributed to developing the intervention. CD led on designing the behaviour change tools for the intervention, JR on the design and content while I led on the technical development and project managing the software company. All members contributed to writing content for the intervention. However the analysis in Chapter 6 represents my own work – specifically, the application of the COM-B model, Taxonomy of Behaviour Change Techniques and Behaviour Change Wheel to the description of the intervention was done by me for this thesis.

1.12 Timeline for the research

A timeline for the research described in this thesis is provided below with a summary of important dates and milestones.

| Date | Milestone |
|------------|--|
| 01/02/2009 | Start of my role as Clinical Associate UCL |
| 24/07/2009 | First draft of my protocol for the Cochrane systematic review of computer-based self-management interventions for adults with type 2 diabetes. |
| 07/12/2009 | I received ethical approval for a qualitative study of patient preferences for online self-management interventions |
| 29/03/2010 | Submission of application for NIHR Programme grant for applied research (KP 2 nd applicant) |
| 07/06/2010 | I receive NIHR SPCR grant for the Cochrane review |
| 20/07/2010 | Provisional award of NIHR programme grant for applied research (PGfAR) |
| 06/10/2010 | Publication of protocol for Cochrane review |
| 10/01/2011 | Ethical approval for development work for NIHR PGfAR |
| 01/03/2011 | Start of 5 year NIHR PGfAR |
| 19/04/2011 | Data collection started for health professionals preferences for HeLP-Diabetes (completed August 2011) |
| 13/06/2011 | Data collection started for patient preferences for HeLP-Diabetes (completed August 2011) |
| 01/09/2011 | Start of development of HeLP-Diabetes website with SoftForge |
| 01/03/2013 | Start of Randomized controlled trial (RCT) of HeLP-Diabetes |
| 28/03/2013 | Publication of systematic review |
| 15/02/2016 | End of RCT |
| 29/08/2016 | End of NIHR PGfAR |
| 07/10/2016 | Submission of thesis |

2. Developing a theory base for an online diabetes self-management intervention

2.1 Chapter outline

In this short chapter I have described the main theoretical principles that informed our understanding of the challenges at the start of the development process and guided plans for the development of the intervention. The main overarching framework for the development process was the MRC complex interventions guidance, while the scope of the intervention was defined by Corbin and Straus' model of living with a chronic condition. To inform our exploration of issues surrounding implementation into clinical practice, we used Normalization Process Theory. The final part of the chapter focuses on behaviour change. I start with a summary of the possible targets of diabetes self-management interventions described in Chapter 1. I then highlight the main behaviours that are proposed drivers for improvements in biological outcomes. I have briefly summarised the range of behaviour change theories and explain how we used the COM-B system to help analyse the relevant behaviours. This helped to identify the theories well placed to underpin the behaviour change elements of the intervention. This work is summarised in a logic model that proposes a mechanism of action for the digital diabetes self-management intervention (HeLP-Diabetes) that is the focus of this thesis.

2.2 MRC complex intervention framework

An online self-management intervention for people living with type 2 diabetes needs to have a number of different interacting components targeting multiple behaviours for people with a wide range of co-morbidities at different stages of their chronic illness trajectory. It also needs to be implemented in the context of multi-disciplinary care delivered by many different health professionals that includes nurses, GPs, endocrinologists, dieticians and podiatrists. It is therefore a complex intervention with potential for complexity in multiple dimensions that include:

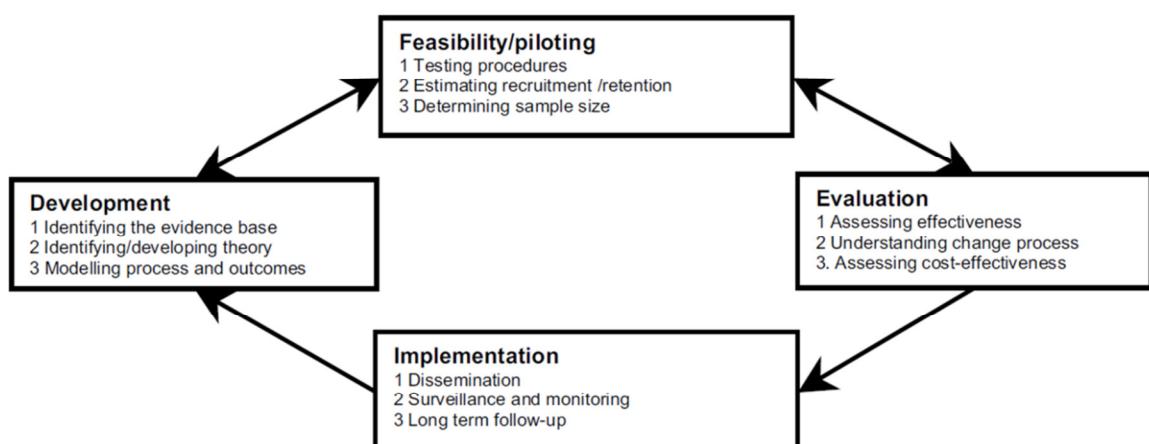
- i. intervention design and components that might include text based information provision, videos and tools

- ii. multiple behavioural and emotional targets for action e.g. eating, physical activity, concordance with medication or mood
- iii. outcomes that could be biological, behavioural, emotional or related to quality of life
- iv. meeting perceived needs defined by patients with different socio-economic, technical and ethnic backgrounds and a range of health professionals as described above.

While there are a number of frameworks for developing and evaluating complex interventions, one of the highest profile and most cited ones is the Medical Research Council (MRC) framework (Corry et al. 2013; Craig et al. 2013). This is a widely used guideline used to judge research proposals and develop interventions and it was the basis of the application for the research grant that funded this study and helped to structure the work.

The Medical Research Council (MRC) framework for the development and evaluation of complex interventions was originally published in 2000 and updated in 2008 (Craig et al. 2008). The updated framework provides a flexible and non-linear approach that emphasises the importance of the development and implementation phases of such work. An overview of the stages defined in this framework can be found in Figure 2-1.

Figure 2-1 Key elements of the MRC complex intervention framework (2008)



A significant advantage of the MRC framework is flexibility and the broad definitions of the elements allow it to be tailored to the needs of particular

interventions using other theories or models for specific implementation or development requirements. Two broad theoretical models were used to help understand the context of the intervention – one from a patient perspective (Corbin and Strauss' model of living with a chronic condition), the other focusing on implementation within the health service environment (Normalization Process theory). These are described in more detail below.

Reported limitations of the MRC framework have included:

- (i) a lack of emphasis on the **contextual variability** underlying the complex health care systems within which such interventions are delivered (Anderson 2008; Shiell et al. 2008) and
- (ii) insufficient attention paid to the difficulties with **defining such interventions** and the difficulties of using standard evaluation methodology when interventions need to evolve over time or adapt to local circumstances (Mackenzie et al. 2010).

One advantage of an online intervention is that the intervention is less dependent on local health services which removes some of the contextual variability normally associated with complex interventions, as the effective components of the intervention are delivered by the intervention directly to users. However, since engagement with the intervention and usage can be influenced by recommendations and conversations with health professionals, the context of the intervention can influence the effects of the intervention and so the health-care setting within which online interventions are deployed will need to be described and understood.

Heterogeneity in terms of usage of the intervention reflects the behaviour of the participants as well as encouragement from health professionals. Intervention use can be measured and recorded as part of the intervention and can be accounted for when analysing outcomes.

The challenge of defining the intervention and active ingredients was addressed using defined techniques based on the taxonomy of behaviour change techniques described later in this chapter and computerized cognitive behavioural therapy (cCBT).

The three main tasks of the development stage outlined by the MRC framework are:

- Identifying/developing theory – as described in this chapter
- Identifying the evidence base – this was done through the studies described in Chapters 3, 4 and 5.
- Modelling mechanisms of action – a description of the proposed mechanism of action of the intervention and the logic model used for this can also be found at the end of this chapter in figure 2.4.

The MRC framework provided a structure for the whole of the NIHR Programme Grant for Applied Research that funded this work as stated in Chapter 1. This work included the development work described in this thesis but also the evaluation of the intervention and implementation in two Clinical Commissioning Groups (CCGs) in London that were not part of my thesis.

2.3 The use of theory in the development stage of the MRC framework

Identifying/developing theory is a key element of the development stage of the MRC complex interventions framework. Theory can be defined as a coherent description of a process that is arrived at by a process of inference, provides an explanation for observed phenomena and generates predictions (West et al. 2013). Interventions based on theory have the advantages of a generalisable framework, the possibility of understanding why the interventions might work, and facilitating the accumulation of knowledge (Michie et al. 2008). Theory may also encourage a comprehensive review of a full range of possible antecedents of a behaviour and therefore illuminate more levers of change (Hardeman et al. 2005). The explicit use of theory does not necessarily lead to effective behaviour change and reviews have reported a spectrum of results with some finding a positive association between effectiveness and use of theory (Taylor et al. 2012; Webb et al. 2010), some finding no association (Gardner et al. 2011) and some finding a mixed association (Bhattarai et al. 2013). Possible reasons for the ineffective use of theory may include challenges with selecting the most appropriate theory matched to the specific needs of the target behaviours (e.g. using theories of reflective behaviour where habitual or emotional factors are important drivers of behaviour) or the use of theory as a general guide to intervention development rather than a systematic approach to analysis and content design and delivery (Prestwich et al. 2014). However the use of theory

remains an important principle as when it is done well it has the ability to advance science and lead to more effective intervention design (Michie et al. 2014b).

Theoretical frameworks were used to help guide three key tasks:

1. defining the scope of the intervention
2. understanding the context and challenges of implementing the intervention into clinical practice
3. developing the theory base to support effective behaviour change

2.4 Defining the scope of the intervention: Corbin and Strauss' model of living with a chronic illness

While the MRC guidance provided a framework to help define the main stages of the research project, other theories were needed to help model the tasks of self-management and possible mechanism of action of the intervention. To help define the scope of the intervention, a model was required that promoted understanding of the work of self-management. One of the most cited pieces of work in the literature on living with a chronic illness is the work done by Corbin and Strauss on managing chronic illness (Corbin et al. 1988). This work has informed much of the subsequent literature on self-management (Lorig et al. 2003). Corbin and Strauss described three types of work when living with a chronic illness – illness work, everyday life work and biographical work. These tasks have also been described as medical management, emotional management and role management (Schulman-Green et al. 2012). Illness related work consists of the tasks of managing treatment regimens, preventing and managing crises, symptom management and diagnosis related work. Everyday work describes the essential regular work of running the household and includes the sentimental work of managing emotions and relationships. Biographical work describes the work done in extracting meaning from life experiences and creating a personal socially constituted identity that encompasses the roles that people play in their lives as patients, parents, spouses, partners, professionals or friends. Being diagnosed with a chronic illness can have a significantly disruptive impact on a person's biographical narrative and sense of identity (Broom et al. 2004; Bury 1982).

There were a number of reasons for using the Corbin and Strauss model. Firstly, it provided a holistic overview of self-management that included the medical management tasks that were part of the definition of DSME discussed in section 1.4 and the emotional work that affects adjustment and diabetes related distress discussed in section 1.6.5. It also explicitly addressed the work of role management and encouraged efforts to understand how patients interpret their experience and construct meaning and roles for themselves. The constructs of the Corbin and Strauss model are inherently patient-centred as they focus on the work done by patients rather than starting with a health professional defined list of tasks that tends to assign medical management the highest priority.

Corbin and Strauss' model defined the aim of the intervention – to help people living with type 2 diabetes manage their illness, the impact it has on their lives and the disruption to their biographical narratives. These aims are linked to the DSME/S targets discussed in Chapter 1 and with specific tasks that patients would need to be supported with in Table 2-1 below.

Table 2-1 Table linking Corbin and Strauss, DSME/S and patient tasks

| Patient work | DSME targets | Specific tasks |
|-------------------|--|-----------------------------------|
| Illness work | Informed decision making | Acquire relevant knowledge |
| | Self-care behaviours | Physical activity |
| | | Healthy eating |
| | | Taking medication |
| | | Reducing risks of complications |
| | Problem solving | Use rational problem solving |
| | | Maintain positive orientation |
| Life work | Engaging with health professionals | Attend appointments |
| | | Share decision making |
| | Emotional management | Psychological adjustment |
| | | Manage diabetes related distress |
| Biographical work | Role management | Treating depression |
| | | Share experiences |
| | | Manage relationships |
| | Constructing identity as a patient and beliefs about illness | Communicate values and priorities |

2.5 Analysing implementation challenges: Normalization Process Theory (NPT)

As mentioned in section 2.2, understanding the context within which a complex intervention is used is crucial. Physician communication has been shown to be a significant facilitator for improving patient engagement with treatment advice (Roter et al. 2009;Zolnierk et al. 2009). Therefore implementing the intervention into routine clinical practice and getting health professionals engaged and recommending the intervention was a key priority. Normalization Process Theory was used as a theoretical model to understand this process for reasons described in section 2.5.3.

2.5.1 *The main constructs of NPT*

NPT has been applied to a number of different interventions and also used in systematic reviews to understand the process of implementation (Elwyn et al. 2008;Lloyd et al. 2013;Mair et al. 2012). These studies have used the four main constructs of the theory to analyse the work involved: Coherence, Cognitive participation, Collective action and Reflexive monitoring.

Coherence is the “sense-making” work that users do individually and collectively to develop their understanding of the problems they face when operationalizing a set of practices. Implementation would be less likely if health professionals did not understand and support the aims of the OSMI, and appreciate the OSMI would be a useful novel addition to existing practice.

Cognitive Participation is the relational work that people do to engage with or get “buy-in” to the innovation and build and sustain a community of practice around a new technology or complex intervention. If health professionals cannot be motivated and engaged with the work required to promote the OSMI and explain its benefits to patients, it is unlikely that it would be widely used.

Collective Action is the operational work that people do to implement a set of practices and explores the relationships between new and existing work. If implementing the new OSMI required health professionals to do administrative work that they felt was not appropriate for their perceived status or skill set or it made their existing work more difficult (e.g. longer consultations with patients with type 2 diabetes) it would be unlikely to be widely adopted.

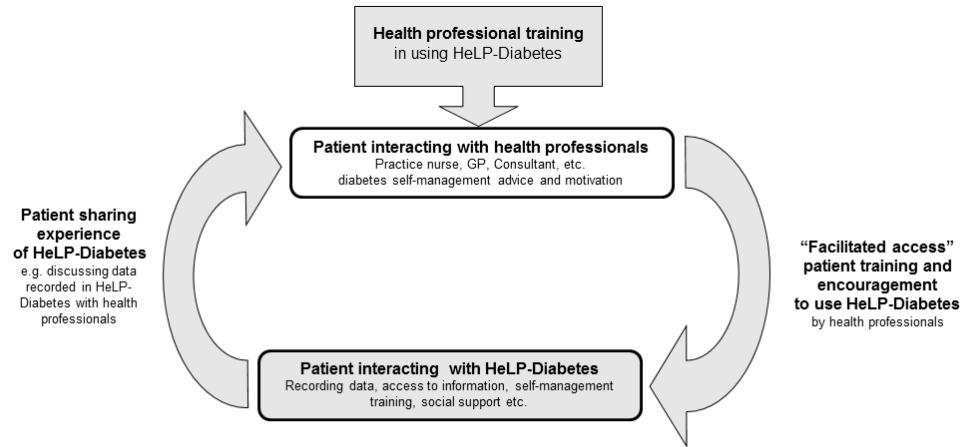
Reflexive Monitoring is the appraisal work that people do to assess and understand the ways that a new set of practices affect them and others around them. If the new OSMI was popular with patients and had evidence of improvements in health outcomes, it is more likely that the work done to adopt the intervention would be perceived as worthwhile and it would positively reinforce the work required for implementation.

These constructs have been used to analyse the challenges of implementation when analysing the data from the qualitative work with health professionals described in Chapter 5.

2.5.2 *The role of health professionals in implementing a OSMI*

Patient-centred clinician communication does not just improve medication adherence, but it has also been shown to improve other diabetes self-management behaviours (Heisler et al. 2002;Heisler et al. 2007). Educational and self-help programmes that are actively supported by clinicians can improve health outcomes for patients with long-term conditions (Coulter et al. 2007) and in patients with low health literacy the impact of written material is increased by verbal recommendations from professionals (Coulter 2012). Therefore the interaction between patients and their health professionals around the intervention was seen to be a key element of the intervention and this is illustrated in Figure 2-2. We judged that the intervention was more likely to be used consistently over time by patients and therefore more likely to be effective if clinicians prompted regular use and expressed appreciation for the self-management effort made by patients.

Figure 2-2 Model illustrating the interactions to be targeted by the intervention



The process of implementation of complex interventions into practice faces a number of challenges (Murray et al. 2010). There is often difficulty in crossing the translational gap “from clinical studies into everyday clinical practice and health decision making” (Woolf 2008), and it has been suggested that it can take 17 years to implement just 14% of research evidence (Balas 1998; Brownson et al. 2006). The particular challenges that might face a OSMI for type 2 diabetes being used in primary care settings in England were highlighted in section 2.5.1 and this is explored in more detail in Chapter 5.

2.5.3 Rationale for using NPT

There is a great diversity of approaches to implementation. A review of 1024 sources of implementation literature identified more than 10 different academic disciplines that contributed to the uptake of innovations in health services (Greenhalgh et al. 2005). There are more than 60 theories and frameworks that have been developed to guide the process of implementation (Tabak et al. 2012). For this study we needed a theory that provided flexible constructs that could be adapted to implementing a new type of intervention (online) in a healthcare setting. It needed to be applicable at a micro level to look at patients and health professionals and at a meso-level within healthcare commissioning and provider organisations. NPT satisfied these criteria and members of the research team were familiar with its use. It also has been successfully used to analyse a variety of implementation processes and it was developed while

trying to implement a telehealth intervention, so the theory applies well to digital interventions (May et al. 2009b;McEvoy et al. 2014). Therefore it was used to inform our understanding of the challenges we might face when implementing a new intervention and it was used in the application for funding for the research work described in this thesis. It has also been used in the design and analysis of the qualitative work with health professionals described in Chapter 5.

2.6 Behavioural targets for diabetes self-management interventions

As listed in Table 2-1, the core behaviours underpinning the medical aspects of self-management considered for this study were: physical activity, healthy eating, taking medication and reducing complication risk (adopting health behaviours as listed above, engaging with health professionals and attending appointments). The evidence for supporting behaviour change in these domains was discussed in Chapter 1 and the remainder of this chapter will look at the theories chosen to inform the development of the behaviour change elements of HeLP-Diabetes.

In addition to the core diabetes self-management behaviours described above, two other behaviours were considered important for patient health – smoking and alcohol intake. People living with type 2 diabetes are three times more likely to die from cardiovascular disease, and this risk is significantly higher if they smoke (Stamler et al. 1993). Excess alcohol causes significant health problems and has been listed as one of the three primary causes of poor health by the WHO (Pettigrew et al. 2016). However behaviours associated with addiction like excessive alcohol intake and smoking are characterised by a failure of self-regulation and harm from maladaptive behaviour and the theories accounting for these behaviours have a different emphasis to the other diabetes self-management behaviours discussed above (Webb et al. 2010;West et al. 2013). Therefore evidence-based online tools specifically designed for managing alcohol intake and smoking cessation designed with those theories in mind were sought and used in HeLP-Diabetes and this has been covered in Chapter 6.

2.7 Overview of theories of behaviour

The explicit use of theory to develop or plan behaviour change interventions has been recommended by the UK's Medical Research Council (MRC) and National Institute of Health and Care Excellence (NICE) (Craig et al. 2008;National Institute for Health and Care Excellence 2007;National Institute for Health and Care Excellence 2014). The evidence for the associations between the use of theory and intervention effectiveness is quite mixed (Bhattarai et al. 2013;Gardner et al. 2011;Noar 2008;Taylor et al. 2012). The reasons for this mixed picture might include the use of theory as a stepping point for development rather than as a systematic framework for guiding development and the inappropriate or inadequate selection of theory to target the relevant antecedents of behaviour (Michie et al. 2014b). Even with a mixed evidence base, there were important reasons to consider the use of theory in intervention development. The appropriate use of theory has been stated to provide at least three major benefits for the process of intervention design: (i) providing a framework to consider the full range of antecedents (Hardeman et al. 2005;Michie et al. 2011b) (ii) supporting theorising about mechanisms of action for assessment of appropriate mediators and speeding up progress in the refinement of interventions (Rothman 2004) (iii) testing the theories used in development to provide evidence of effectiveness or support improvements of the relevant theories (Michie et al. 2008).

2.7.1 *Selecting theories to guide the development of the OSMI: the evidence for Control Theory*

The core self-management behaviours to support medical management were physical activity, healthy eating, taking medication and reducing complication risk. To identify evidence-based components that could be used to support healthy changes to these behaviours, relevant behaviour change techniques (BCTs) were identified from the literature. BCTs are standardized definitions of the techniques used in complex behaviour change interventions that are postulated to be the active ingredients of the intervention (Abraham et al. 2008). They can allow effective components to be identified in reports of individual interventions or literature reviews, provide a taxonomy of definitions that can be used to describe interventions in detail, help improve understanding of how

interventions might work and facilitate reliable implementation of interventions outside research settings (Michie et al 2011).

A cluster of BCTs associated with positive outcomes has been identified in meta-regression analyses of interventions to increase physical activity and healthy eating (Dombrowski et al. 2012; Michie et al. 2011). The cluster of techniques was consistent with Control Theory (Carver et al. 1982). Carver postulated that there was a synergistic association between receiving information about one's behaviour (via 'self-monitoring' or 'feedback') and having a strategy for acting on this information ('action planning' or 'information on where and when to perform the behaviour'). The former provides a cue and/or motivation for the latter. There was also some evidence consistent with this in the findings of my systematic review described in Chapter 3. Where goal setting was used alone, it was not associated with improvements in HbA1c. However prompting self-monitoring of behavioural outcomes and providing feedback on performance were the most commonly used techniques in interventions that had a statistically significant impact on HbA1c. Control theory would predict that goal setting would be less effective if presented without feedback. Based on this evidence, Control Theory was used as the basic mechanism for supporting behaviour change for the core behaviours of healthy eating and improving physical activity. Part of the implementation of the self-monitoring and feedback elements of Control Theory were envisioned to be done through providing users with access to relevant clinical data. By giving patients access to clinical data like HbA1c, weight or blood pressure readings we hoped that users would get feedback on the impact of their behaviour which would facilitate self-regulation.

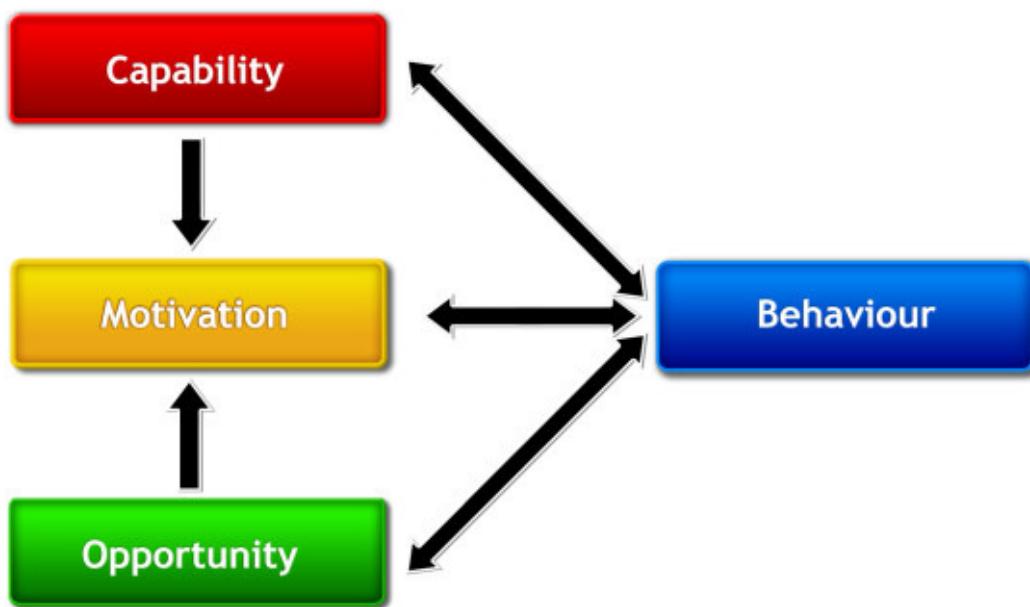
As described above Control Theory is an integrative theory that has a more inclusive range of determinants for behaviour than many other theories. However no single theory of behaviour can address all the possible antecedents of behaviour (Michie et al. 2014b). Therefore a more systematic approach was needed to consider if other theories could be used to consider a wider range of levers to influence behaviour and make the intervention more effective.

2.7.2 The COM-B system

There were a number of models and frameworks that supported a comprehensive approach to behaviour change but for the purpose of this intervention design the model used was the COM-B system (Michie et al. 2011b). This model had a number of potential benefits. It was designed as a model of behaviour and to provide a basis for designing an intervention to change behaviour. It provided a comprehensive framework to consider all the possible antecedents of behaviour, including both volitional and automatic motivators of behaviour. The system also had the advantage of being middle range theory that could be applied at an individual, group or environmental level.

Capability, opportunity and motivation are the key influences on behaviour and form the basis of analysis in the COM-B system and the key interactions between the components are shown in Figure 2-3.

Figure 2-3 The COM-B system for understanding behaviour [reproduced from (Michie et al. 2011b)]



Capability refers to the physical or psychological capacity to engage in the behaviour in question. This capacity resides within the individual. It includes knowledge and understanding as well as physical and mental skills and facilities. It also includes the capability to resist impulses to engage in an action as well as the ability to engage in an action.

Opportunity refers to the environmental factors that permit a behaviour to occur or that promote it. This may involve the physical environment, including for example availability of a given drug or cues that prompt people to eat or be physically active. It may also involve the social environment including social mores which encourage those behaviours.

Motivation refers to mental processes that energise and direct behaviour. It includes both self-conscious, reflective reasoning and choice and processes that have been labelled 'automatic', including emotions, habits, impulses and desires.

2.7.3 Expanding on COM-B constructs: Theoretical Domains Framework

The basic constructs of the COM-B system were broad categories that were easily comprehensible even for the health professionals who did not have a health psychology background. However to facilitate the process of behaviour analysis and selection of appropriate theories, it was helpful to look at the key theoretical domains covered by each element (Michie et al. 2005). This was done using the Theoretical Domains Framework (TDF) which has been used to understand many different behaviours in a variety of contexts (Francis et al. 2012). The links between the components of the COM-B system and the corresponding theoretical domains are shown in Table 2-2 below.

Table 2-2 Links between COM-B system and the Theoretical Domains Framework (Michie et al. 2014a)

| Component | Sub-component | Theoretical domains |
|------------------|--------------------------|--|
| Capability | Psychological capability | Knowledge Skills (cognitive and interpersonal) Memory attention and decision process Behavioural regulation |
| | Physical capability | Skills (physical) |
| Motivation | Reflective motivation | Social/professional role and identity Beliefs about capabilities Optimism Beliefs about consequences Goals Intentions |
| | Automatic motivation | Reinforcement Emotion |
| Opportunity | Physical environment | Environmental context and resources |
| | Social environment | Social influences |

The use of the TDF allows for a theory based assessment of behaviour change and identification of a range of potential targets for interventions (Huijg et al.

2014; Michie et al. 2005; Webster et al. 2015). Domains can be targeted by using the standardised behaviour change techniques (BCTs) defined in section 2.7.1. Possible links between DSME/S targets, theoretical domains and potentially relevant BCTs can be found in Table 2-3.

Table 2-3 Patient self-management targets, Theoretical Domains and examples of relevant Behaviour Change Techniques

| Patient DSME/S requirement | Theoretical Domain | Behaviour Change Techniques |
|--|---|--|
| Information to support informed decision making | Knowledge | Information about emotional consequences Information about health consequences |
| Shared decision making and care planning | Cognitive and interpersonal skills Goals | Goal setting (behaviour), prompts/cues |
| Self-management behaviours | Behavioural regulation | Goal setting (behaviour) Action planning Prompts/cues Monitoring of outcome(s) of behaviour without feedback Review behaviour goal Self-monitoring of behaviour Self-monitoring of outcome(s) of behaviour |
| Diabetes related distress, psychological adjustments and treating depression | Memory, attention and decision process Emotion | Reduce negative emotions, information about emotional consequences |
| Identity as a patient, impact on roles at work and at home | Social/professional role and identity | Reduce negative emotions, information about social and environmental consequences |
| Rational problem solving, positive problem solving orientation, self-care behaviours | Beliefs about capabilities | Problem solving, reduce negative emotions |
| Understanding risks of complications | Beliefs about consequences | Information about health consequences |
| Problem solving | Optimism | Reduce negative emotions, problem solving |
| Patient values and priorities | Intentions | Goal setting (behaviour), prompts/cues |
| Attending appointments and health service use | Environmental context and resources | Prompts/cues |
| Social and cultural influences on behaviour, sharing experiences with peers | Social influences | Social support (unspecified) |

2.7.4 Social Cognitive Theory, Operant Learning Theory and emotional management

This analysis also revealed three areas that were felt to be important by the team that were not being directly targeted by simply using Control Theory. Firstly, self-efficacy has been widely targeted by behavioural programmes and improved self-efficacy has been associated with improvements in diabetes self-management, physical activity and medication adherence (Kahwati et al. 2016;Olander et al. 2013;Wangberg 2008). Self-efficacy is concerned with people's beliefs in their ability to influence events that affect their lives and it is seen as a core belief that drives reflective motivation (Bandura 2010). Therefore Social Cognitive Theory was also used to help design the intervention as it included the constructs of self-efficacy and outcome expectations which are important elements of beliefs about capabilities and consequences (Bandura 1977). Questions about self-confidence and outcome expectations were incorporated into the behaviour change tools described in chapter 6.

Secondly, the team expected automatic behaviours driven by impulses, habits and emotions to be important drivers of the self-management behaviours underpinning diabetes self-management. More than 25 of the 93 BCTs mentioned previously are derived from learning theory and past (habitual) behaviour is one of the strongest predictors of future behaviours (Johnston 2016). To understand automatic motivation, Operant Learning Theory was selected as a general framework that has a very strong theoretical basis in motivational psychology (West 2013). Operant learning theory stresses the links between antecedents, behaviours and consequences and that behaviours can be influenced by changing antecedents and behaviours. This was a consideration when thinking about environmental cues for behaviour e.g. for healthy eating, encouraging users to change their environments to change behaviour by not keeping high calorie snacks in the house.

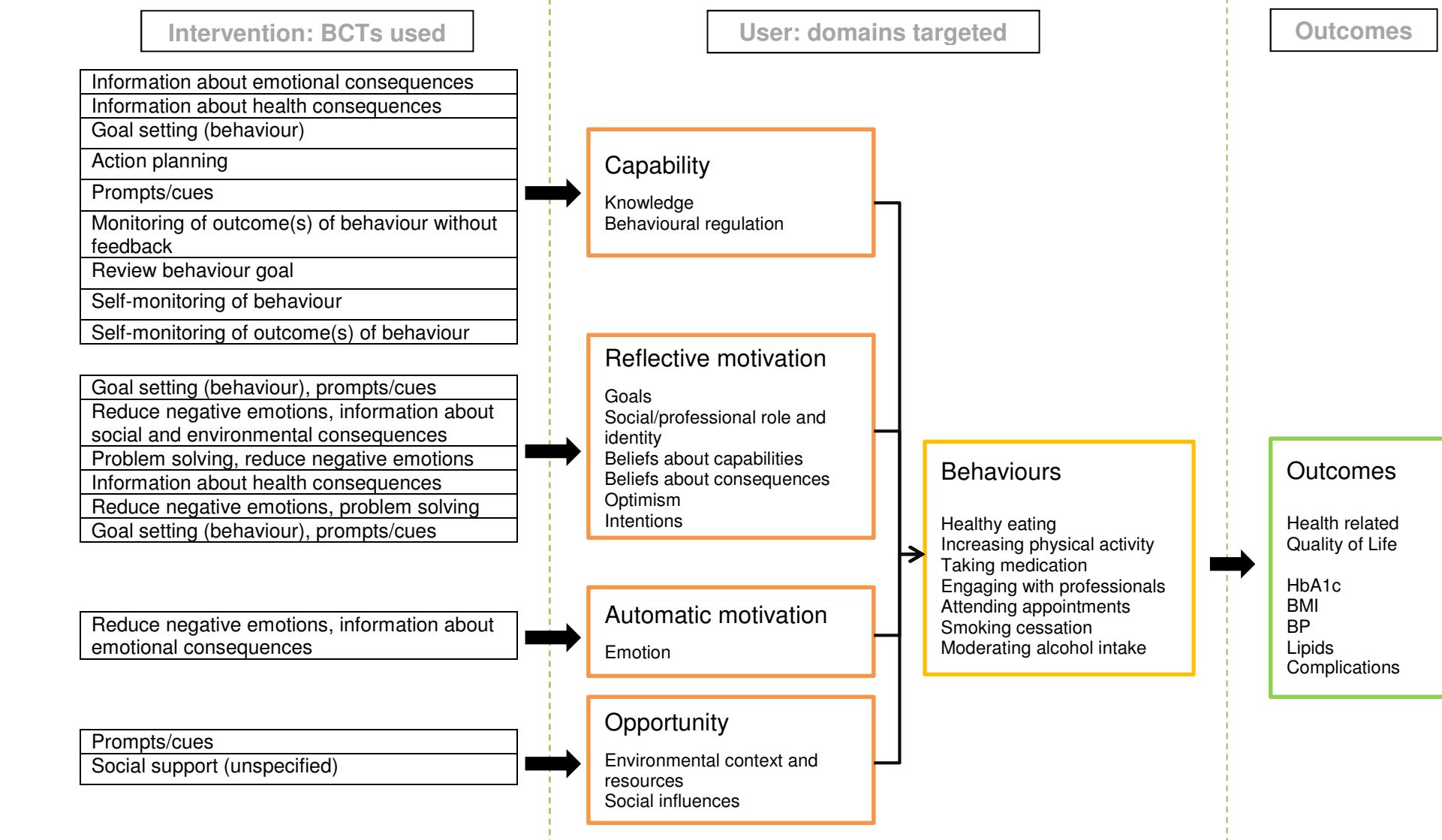
Finally a specific theory for emotional management was not used but a range of content and tools for emotional support were planned based on needs identified by the qualitative work with patients and healthcare professionals described in Chapters 4 and 5, and previous eHealth unit work of developing online

interventions. Planned components included information about emotional wellbeing, videos of people discussing their experience and a forum. In view of the associations between diabetes and depression described in the previous chapter, computerised cognitive behavioural therapy was chosen as an evidence-based intervention option to manage depression and anxiety (Kaltenthaler et al. 2004).

2.8 Proposed model of action

The ideas discussed above were combined into a proposed model of action which has been summarised as a logic model in Figure 2-4. The translation of the logic model into an intervention combining data from a systematic review and qualitative work with patients and professionals has been described in Chapter 6.

Figure 2-4 Proposed logic model for the intervention



Theories of behaviour change used:

Control Theory
Social Cognitive Theory
Operant Learning Theory

Intervention context:

Patient interacting with intervention at home
Patient discussing intervention use with health professionals

2.9 Conclusions

In this chapter I described the theoretical basis for developing a digital diabetes self-management intervention. The MRC framework for complex interventions helped to define the strategic plan for the programme of research work. Corbin and Strauss' seminal work on living with a chronic illness facilitated a holistic perspective on the tasks facing patients when self-managing their diabetes. Normalization Process Theory was used as a tool to plan for the likely challenges facing the use of the intervention in clinical settings. The COM-B system helped to break down the broad tasks of self-management defined by Corbin and Strauss into more specific targets. The components of the COM-B system were used to analyse the main self-management behaviours. The theories chosen to support this were Control Theory, Social Cognitive Theory and Operant Learning Theory. The theory base and logic model described in this chapter were combined with evidence provided by the systematic review in Chapter 3 and qualitative data on patient and health-professional wants and needs described in the next two chapters to develop the online diabetes self-management intervention described in Chapter 6.

3. A systematic review of digital diabetes self-management interventions for adults with type 2 diabetes

3.1 Chapter outline

In this chapter I have described my Cochrane systematic review of digital self-management interventions for adults with type 2 diabetes. The review and findings have been summarised in the abstract below.

Background: As described in Chapter 1, diabetes is one of the most common chronic medical conditions, affecting nearly 400 million people worldwide. Structured patient education programmes reduce the risk of diabetes-related complications four-fold. Internet-based self-management programmes have been shown to be effective for a number of long-term conditions. Digital self-management interventions could potentially provide a cost-effective option for reducing the burdens placed on patients and healthcare systems by this long-term condition.

Objectives: To assess the effects on health status and health-related quality of life of digital diabetes self-management interventions for adults with type 2 diabetes mellitus and determine what the essential or effective components of such programmes might be.

Methods: Six electronic bibliographic databases were searched for published articles and conference proceedings and three online databases for theses (all up to November 2011). Reference lists of relevant reports and reviews were also screened. Studies were included if they were randomised controlled trials of digital software applications that responded to user input and aimed to generate tailored content to improve one or more self-management domains through feedback, tailored advice, reinforcement and rewards, patient decision support, goal setting or reminders.

Data collection and analysis: Two review authors independently screened the abstracts and extracted data into standardised templates. The analysis was done in accordance with the analysis plan specified in the protocol for the review.

Results: 16 randomised controlled trials with 3578 participants fit the inclusion criteria. These studies included a wide spectrum of interventions covering clinic-

based brief interventions, internet-based interventions that could be used from home and mobile phone-based interventions. The mean age of participants was between 46 to 67 years old and mean time since diagnosis was 6 to 13 years. The duration of the interventions varied between 1 to 12 months. There were three reported deaths out of 3578 participants. Overall, digital diabetes self-management interventions showed evidence of limited effectiveness. They appeared to have small benefits on glycaemic control (pooled effect on glycosylated haemoglobin A1c (HbA1c): -2.3 mmol/mol or -0.2% (95% confidence interval (CI) -0.4 to -0.1; $P = 0.009$; 2637 participants; 11 trials). The effect size on HbA1c was larger in the mobile phone subgroup (subgroup analysis: mean difference in HbA1c -5.5 mmol/mol or -0.5% (95% CI -0.7 to -0.3); $P < 0.00001$; 280 participants; three trials). Interventions did not show adequate evidence for improving depression, health-related quality of life or weight. Four (out of 10) interventions showed beneficial effects on lipid profile. One participant withdrew because of anxiety but there were no other documented adverse effects. Two studies provided limited cost-effectiveness data - one study suggested costs per patient of less than \$140 (in 1997) or 105 Euros and another study showed no change in health behaviour and resource utilisation.

Conclusions: Digital diabetes self-management interventions to manage type 2 diabetes appeared to have a small beneficial effect on blood glucose control and the effect was larger in the mobile phone subgroup. There was no evidence to show benefits in other biological outcomes or any cognitive, behavioural or emotional outcomes. Based on these findings, the design of the intervention included support for mobile-phone based reminders and incorporated modules from specific evidence-based interventions for treating depression and supporting weight loss.

3.2 Background

Chapter 1 highlighted the growing challenges posed by the rising prevalence of type 2 diabetes and the implications for patients and health services around the world. Existing self-management interventions have low levels of uptake in spite of the evidence that they can improve outcomes, so alternative options to provide self-management education and support to people living with type 2

diabetes are a pressing need. The significant potential of online interventions to meet this need was also discussed in Chapter 1, but there were a number of unanswered questions that prompted the need for a systematic review of the literature which have been discussed below.

3.2.1 Why it was important to do this review

There has been growing evidence of potential benefits from digital interventions in the literature across a wide variety of conditions (Murray et al. 2005). There was evidence that low-intensity brief interventions for simple behaviour change (e.g. smoking cessation) were effective even when delivered by digital applications (Portnoy et al. 2008a), while higher-intensity face-to-face interventions (group or one-to-one) set the standard for diabetes self-management training (National Institute for Health and Care Excellence 2015). However there remained an important question about whether there was a cost-effective niche for digital ‘intermediate’ interventions (i.e. interventions that are more costly and time consuming than the brief intervention model but cheaper to implement than face-to-face contact) for the more complex (multiple) behaviour change required in chronic disease self-management, in this particular case, type 2 diabetes mellitus.

Previous reviews in this area

There were some important questions about digital self-management interventions for diabetes that needed answering and had not been fully answered by previous reviews in the area. One systematic review looked at 26 studies of interactive computer-assisted technology in diabetes care (Jackson et al. 2006). The reviewers felt the data were too heterogeneous for a meta-analysis and provided a narrative report. It identified 14 studies that looked at HbA1c levels and found that 6 of 14 studies demonstrated significant declines in HbA1c. Studies that looked at changes in body weight, blood pressure, micro-albuminuria and renal function found no significant differences post-intervention, while effects on lipids and depression were mixed. The interventions also appeared to improve healthcare utilisation with more foot examinations and HbA1c monitoring but had no effect on hospital admissions.

On the other hand, the meta-analysis looking at computer-based brief interventions for health promotion mentioned earlier found seven RCTs with elements of diabetes self-management and found no evidence to support their use (Portnoy et al. 2008b). It found that in general, computer-delivered interventions could lead to immediate post-intervention improvements in cognitive elements such as knowledge, attitudes and intentions and help modify behaviours such as dietary intake, tobacco use, safer sex and general health behaviours, but found no evidence to support computer interventions for more complex behaviour change such as diabetes self-management. However, the outcome measures and data analysis used to come to this conclusion about diabetes self-management were not described in any detail and it acknowledged the relative paucity of evidence in the field.

A final review of the effectiveness of information (IT)-based diabetes management interventions looked at 15 studies of which nine were RCTs (Costa et al. 2009). The authors felt that due to the limitations of the studies reviewed, the effectiveness of existing IT-based interventions was unclear and difficult to attribute solely to the interventions. The review concluded that future research efforts needed to focus on methodological issues to produce valid, reliable and generalisable findings.

Therefore a number of key questions about digital self-management interventions to support adults with type 2 diabetes remained unanswered.

1. Unknown efficacy - do they really work?
2. What is the clinical significance of any reported benefits of these interventions?
3. Uncertainty about active components - how do they work?
4. Are they cost effective?
5. What harm can come from digital interventions?

The MRC complex interventions framework described in Chapter 2 advises that a systematic review is a key part of gathering such information to inform the development process. It recommends that an up-to-date systematic evaluation of the best evidence should always inform intervention development and this should be maintained over the duration of the development process. The purpose of a systematic review is to collate the empirical evidence that fits pre-

specified eligibility criteria in order to answer a specific research question (Cochrane Collaboration 2011). Systematic reviews provide the best evidence for a number of reasons (Mulrow 1994). Systematic reviews allow researchers to:

- Efficiently and systematically integrate existing information from a wide data pool and provide high quality data for decision making
- Establish whether findings are consistent and can be generalised across populations and settings, or whether findings vary in different sub-sets
- Increase power and precision of estimates of treatment effects and exposure risks through meta-analysis
- Use explicit methods to limit bias and improve reliability and accuracy of conclusions drawn from the literature.

This systematic review was done to review the rapidly evolving literature in this area and to provide a high quality evidence base to inform the intervention development.

However, systematic reviews of complex interventions present certain challenges:

- Deciding the optimum methodology for the process of gathering and synthesising data for systematic reviews (Petticrew 2003)
- Synthesising across different study designs and outcomes measures (Caldwell et al. 2005)
- Synthesising heterogeneous interventions in a meaningful or statistically robust way (Herbert et al. 2005).

These challenges were anticipated and mitigated by plans to describe the interventions in terms of components, mode of delivery and intensity to make sense of variability in outcomes. This required a theoretically informed understanding of the mechanisms of change underlying the interventions and the BCTs described in Chapter 2 were used to facilitate this process. However this was only possible where there was sufficient detail in the intervention description to analyse the intervention or control conditions.

3.3 Objectives

Primary aim: To assess the effects on health status and health-related quality of life of digital diabetes self-management interventions for adults with type 2 diabetes mellitus.

Secondary aims: To determine the effective components, cost-effectiveness and possible harm from such interventions.

3.4 Methods

3.4.1 Criteria for considering studies for this review

Types of participants: Adult patients with type 2 diabetes mellitus. Adult patients were defined as patients aged 18 and over.

Diagnostic criteria: To be consistent with changes in classification and diagnostic criteria of diabetes mellitus through the years, the diagnosis should have been established using the standard criteria valid at the time of the beginning of the trial (for example ADA 1999; ADA 2008; WHO 1998). Ideally, diagnostic criteria should have been described. Where necessary, authors' definition of diabetes mellitus were used.

Types of interventions: Computer-based software applications that respond to user input and aim to generate tailored content to improve one or more of the following self-management domains through feedback, tailored advice, reinforcement and rewards, patient decision support, goal setting or reminders.

Possible targets for the interventions could include:

Cognitions

- Knowledge about the diabetes disease process, complications and treatment options.
- Goal setting to promote health.
- Self-efficacy and confidence in own ability to manage diabetes.

Behaviours and skills

- Incorporating appropriate nutritional management.
- Incorporating physical activity into lifestyle.
- Utilising medications (if applicable) for therapeutic effectiveness.
- Monitoring blood glucose, urine ketones (when appropriate), and using the results to improve control.
- Accessing services and preventing, detecting and treating acute complications.
- Preventing (through risk reduction behaviour), detecting, and treating chronic complications.

Emotions

- Integrating psychosocial adjustment to daily life.
- Managing anxiety, depression and stress.
- Providing social support for patients.

Types of comparators: Possible comparators could be

- Standard diabetes care.
- Educational material.
- Delayed start/waiting list.
- Face-to-face diabetes self-management education.
- Non-interactive digital programme.

There was no equivalent of a placebo-controlled trial as all of the controls have patients with a chronic illness who will have ongoing clinical input that could have an effect on the target population. It could be argued that any effect of standard care is desirable as it counteracts the effect of the selection bias inherent in choosing volunteers for trials who are more likely to be motivated and concerned about their health and it may provide a more realistic estimate of any advantage of the treatment over existing clinical care. However, in the case of behavioural interventions, 'standard care' may involve a number of the behavioural techniques that are being tested and their presence in the control group could make the results difficult to interpret. We therefore tried to analyse any 'standard care' provided to comparison groups and implicit intervention or technique that might be part of the comparison group (de Bruin 2009).

Types of outcome measures: Integrating all the factors contributing to diabetes self-management into a unified model to describe how they might affect outcomes is challenging. A detailed exploration of possible mechanisms of action and a proposed logic model have been developed in Chapter 2. As many of the complications of diabetes and health outcomes like heart attack or stroke take years to develop, it is not practical to use them as primary outcome measures for this review as follow-up in the studies would not be long enough to demonstrate differences in these. However, more proximal variables such as glycosylated haemoglobin A1c (HbA1c, representing an average measure of blood sugars), body mass index (BMI), depression or anxiety may show changes over suitable time scales.

Setting: There were no restrictions based on setting or technology used to deliver the intervention.

Types of studies: Randomised controlled clinical trials.

3.4.2 Exclusions

Studies were excluded on the following criteria:

Participants:

- Targeted only at patients with type 1 diabetes
- Involving participants aged under the age of 18 (including studies on mixed populations of adults and children)

Studies carried out on mixed populations of patients with type 1 and type 2 diabetes were included in the review as long as more than 50% of the patients had type 2 diabetes. Where possible, data for patients with type 2 diabetes were extracted and the data for patients with type 1 diabetes discarded. When that was not possible, data for the mixed population were used. A subgroup analysis was undertaken to examine the impact of removing studies on mixed populations.

Interventions:

- Used only for communication between patients and professionals

Outcomes:

Not targeting any of the primary outcomes measures of this review, i.e.:

- Health-related quality of life
- Death from any cause
- HbA1c

3.4.3 Data extracted from included studies.

The following data were extracted from studies included in the systematic review.

Primary outcomes

- Health-related quality of life
- Death from any cause
- HbA1c

Secondary outcomes

Cognitions

- Change in knowledge and understanding
- Self-efficacy

Behaviours

- Physical activity

Social support

- Change in social support

Biological markers

- Cardiovascular risk factors, which include blood pressure, BMI and lipids

Anxiety or depression

Adverse events

- Hypoglycaemia
- Hospital admissions or emergency unit attendances

Cost-effectiveness and economic data

3.4.4 *Timing of outcome measurement*

At the end of the intervention and for as long as follow-up was carried out. Short-term follow-up was defined as that measured within 30 days of the end of the intervention period to measure the immediate effects of the intervention; medium-term follow-up as between one to six months after the intervention to see if the effects continue; long-term follow-up data as six months and later from the end of the intervention to see how effects change over time. For the overall meta-analysis the data at the longest follow-up date available were used.

3.4.5 *Search methods for identification of studies*

Electronic searches

We used the following sources for the identification of trials.

- The Cochrane Library (2011, issue 10).
- MEDLINE (from inception until week 1 November 2011).
- EMBASE (from inception until 14/11/2011).
- PsycINFO (from inception until week 2 November 2011) (for studies and dissertation abstracts).
- Web of Science (from inception until 14/11/2011) (for studies and conference proceedings).
- CINAHL (from inception until 17/11/2011).

For detailed search strategies please see Appendix 1.

Studies published in any language were included and the final included studies were published in English (15) and Chinese (1).

Searching other resources

Reference lists from relevant published studies were screened and authors contacted for further information when required.

The following resources were searched for unpublished literature.

- ASLIB Index to Theses.
- Australasian Digital Theses programme.
- UMI ProQuest Digital Dissertations and Theses.

3.4.6 Data collection and analysis

Selection of studies

To determine the studies to be assessed further, two review authors (SE and me) independently scanned the abstract, title or both sections of every record retrieved. All potentially relevant articles were investigated as full text. Where differences in opinion existed, they were resolved by a third party (EM) and the rationale justified in a steering group meeting. An adapted PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) flow-chart of study selection can be found below in Figure 3-1.

Data extraction and management

For studies that fulfilled inclusion criteria, two review authors (SE and me) independently extracted relevant population and intervention characteristics using standard data extraction templates with any disagreements resolved by discussion or, if required, by a third party (EM). Any relevant missing information on the trial was sought from the original author(s) of the article, when required. Given the heterogenous nature of the interventions, we analysed the theoretical basis for the interventions and tried to define in as much detail as possible the active components. We had planned to pool the results where there was evidence that the interventions being grouped shared approaches that draw on a similar theoretical basis, but there were not enough studies to do this.

Dealing with duplicate publications

In the case of duplicate publications and companion papers of a primary study, we tried to maximise yield of information by simultaneous evaluation of all available data. In cases of doubt, the original publication (usually the oldest version) took priority.

Assessment of risk of bias in included studies

Two review authors (SE and me) assessed each trial independently. Possible disagreements were resolved by consensus, or with consultation of a third party (E.M.) and discussed in a steering group meeting where the final decision was made.

Risk of bias was assessed using the Cochrane Collaboration's tool (Higgins 2011). The following criteria were used:

- Was the allocation sequence adequately generated?
- Was the allocation adequately concealed?
- Was knowledge of the allocated intervention adequately prevented during the study?
- Were incomplete outcome data adequately addressed?
- Are reports of the study free of suggestion of selective outcome reporting?
- Was the study apparently free of other problems that could put it at a high risk of bias?

Studies were judged on risk of bias criteria as 'low risk', 'high risk' or 'unclear risk' and evaluated individual bias items as described in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011). A 'Risk of bias' graph can be seen in Figure 3-2 and a 'Risk of bias' summary can be seen in Figure 3-3.

Unit of analysis issues

We took into account the level at which randomisation occurred, such as cross-over trials, cluster-randomised trials and multiple observations for the same outcome.

Dealing with missing data

Relevant missing data were requested from trial authors. Evaluation of important numerical data such as numbers of screened, randomised patients as well as intention-to-treat (ITT), as-treated and per-protocol (PP) population were

carefully performed. Attrition rates, for example dropouts, losses to follow-up and withdrawals were recorded. Issues of missing data and imputation methods (for example, last observation carried forward (LOCF)) were critically appraised.

Assessment of heterogeneity

Heterogeneity was identified by visual inspection of the forest plots, by using a standard Chi² test and a significance level of $\alpha = 0.1$, in view of the low power of this test. Heterogeneity was to be specifically examined with the I^2 statistic quantifying inconsistency across studies to assess the impact of heterogeneity on the meta-analysis, where an I^2 statistic of 50% to 90% may represent substantial heterogeneity and 30% to 60% may represent moderate heterogeneity (Higgins 2011).

When heterogeneity was found, we attempted to determine potential reasons for it by examining individual study and subgroup characteristics.

Assessment of reporting biases

A funnel plot was planned to assess for the potential existence of small study bias. However, there were too few studies to allow a meaningful assessment and therefore this has not been included in the review.

3.4.7 Data synthesis

The self-management interventions were heterogenous in their aims and design. All data were summarised narratively. In addition, data were analysed statistically and meta-analyses done when data were available, sufficiently similar and of sufficient quality. Two common outcomes that we thought would be shared by the majority of studies were HbA1c and health-related quality of life (QoL) measures (both are continuous outcomes). Where studies provided sufficient data, we were able to look at the difference between means for HbA1c. We planned to use standardised mean differences for QoL measures that used different scales, however, we were unable to do this due to insufficient data. The effects on QoL measures were therefore described narratively. Statistical analysis was performed according to the statistical guidelines referenced in version 5 of the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011).

3.4.8 Applying the taxonomy of behaviour change techniques

Two independent raters (SE and me) piloted the taxonomy of behaviour change techniques (Michie et al. 2011a) on two studies. They underwent two cycles of an iterative process of independent coding, comparing results and discussion of differences and further refinement of the application of the taxonomy descriptions. Once good agreement was reached, SE and I coded the intervention and control groups of the remaining studies, followed by re-coding of the pilot studies.

The published reports of studies involving complex interventions are seldom reported in enough detail to replicate them (Michie et al. 2009b). This was true of the studies included in this review, limiting the possibility of specifying interventions in terms of their component behaviour change techniques or identifying their likely mechanisms of action. Since there were not enough studies to conduct a meta-regression to investigate which techniques were effective, an exploratory exercise was conducted by considering the techniques that featured most commonly in effective, compared with ineffective interventions and inspecting patterns of association between techniques and the effective with effective interventions.

3.4.9 Subgroup analysis and investigation of heterogeneity

Where performed, subgroup analysis has been clearly marked as a hypothesis-generating exercise.

A previous meta-analysis of diabetes self-management interventions (18/20 were face-to-face) showed a greater effect from shorter studies with short-term follow-up (Minet et al. 2010). Therefore we performed a subgroup analysis to see if there was any suggestion this hypothesis might also be true for digital self-management interventions. A recent meta-analysis of the effect of mobile phone intervention for diabetes on glycaemic control (Liang et al. 2011) suggested that mobile phone-based interventions led to statistically significant improvements in glycaemic control and self-management in diabetes care, especially for patients with type 2 diabetes.

The following subgroup analyses were planned.

- Age.
- Gender.
- Behaviour change techniques used (based on proposed model for behaviour change).
- Education techniques used (to determine the most effective components of education).
- Duration of intervention (previous reviews have noted correlations between effect and duration of interventions).
- Duration of diabetes below or over five years (patients who have had diabetes for longer are likely to have more advanced disease and increased insulin resistance, more complications and are more likely to be on insulin therapy; any treatment modality may have smaller effects in more advanced disease).
- Different modes of delivery (primary care, outpatient or community settings, mobile-phone) (likely to affect attrition: interventions that are more convenient for patients are likely to be better accepted and used but there may be some attraction for group interactions as well).
- Studies with participants with type 2 diabetes only (type 1 and type 2 diabetes tend to be more prevalent in very different age groups and have differences in aetiology and therefore may not respond the same way to the interventions).

3.4.10 Sensitivity analysis

We also planned to perform sensitivity analyses in order to explore the influence of the following factors on effect size.

- Restricting the analysis to published studies.
- Restricting the analysis taking into account risk of bias, as specified above.
- Restricting the analysis to very long or large studies to establish how much they dominate the results.
- Restricting the analysis to studies using the following filters: diagnostic criteria, language of publication, source of funding (industry versus other) and country.

However, there were not sufficient data to perform these analyses. The robustness of the results was tested by repeating the analysis using different statistical models (fixed-effect model and random-effects model).

3.4.11 Differences between protocol and review

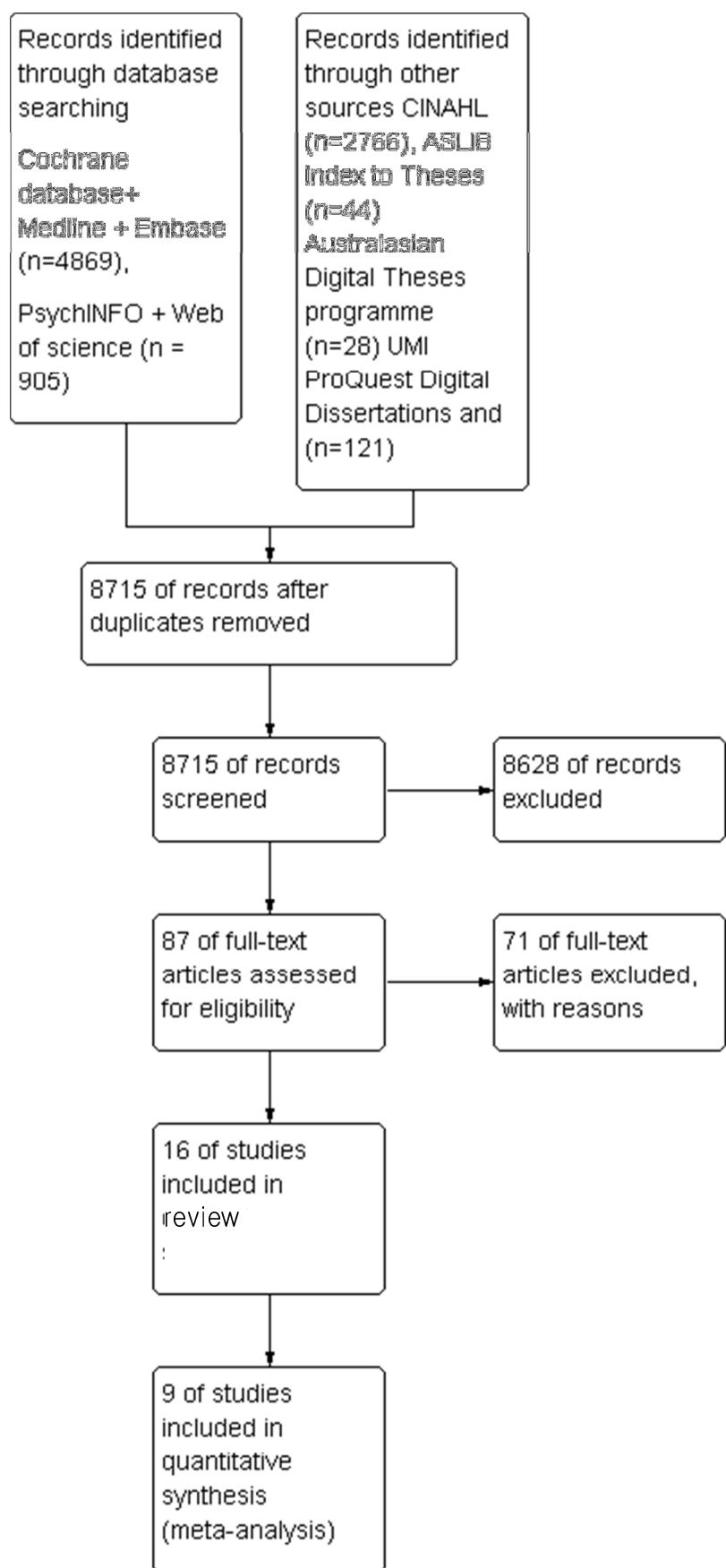
During the protocol stage there were some initial discussions regarding studies with mixed populations of type 1 and type 2 diabetes. As no decision had been reached at the protocol stage, the protocol stated all studies with mixed populations would be included. A final decision was reached in the steering

group after the protocol was published and it was decided that studies where a majority (i.e. greater than 50%) of participants had type 2 diabetes would be included. It was felt that populations of people with type 1 and type 2 diabetes are quite different and interventions for the two should not be combined if at all possible. Where not possible, it was decided that choosing studies with cut offs of either 60%, 70%, 80% or 90% of participants who had type 2 diabetes would be arbitrary so a simpler criteria of including studies where the majority of patients had type 2 diabetes was felt to be a simple and practical solution that would not bias the review process. Only two studies were excluded due to mixed populations (Laffel et al. 2007;Turnin et al. 1992) and both of these had 70% or more participants with type 1 diabetes.

When looking at different settings, the distinction between primary care, outpatient or community setting could not be meaningfully applied to self-management interventions. It was more meaningful to divide the interventions settings into clinic-based (touch screen or other clinic computer), home digital and mobile phone interventions. This was used as a basis for a subgroup analysis.

3.5 Results

Figure 3-1 Adapted PRISMA flow-chart



3.5.1 Description of included studies

The characteristics of the studies included in this review have been summarised in Table 3-1.

Table 3-1 Characteristics of included studies**Christian 2008**

| | |
|----------------------------|--|
| Methods | Study design: Parallel randomised controlled trial |
| Participants | <p>Inclusion criteria:</p> <ol style="list-style-type: none"> 1. Latin/Hispanic in ethnicity with a language preference of either English or Spanish 2. Aged 18 to 75 years with a diagnosis of type 2 diabetes 3. A BMI of 25 or greater 4. Uninsured, Medicaid eligible or Medicare beneficiaries. <p>Exclusion criteria:</p> <ol style="list-style-type: none"> 1. Substance use or abuse 2. Severe arthritis or 3. Other medical condition limiting physical activity 4. Recent MI or stroke or PVD 5. Undergone or scheduled for gastric bypass surgery. |
| Interventions | <p>Number of centres: 2</p> <p>Country: USA</p> <p>Setting: Outpatient clinic settings at 2 large urban community-based health centres - the Denver Health and Hospital Authority's Sandoz Westside Neighbourhood centre in Denver and the Pueblo Community Health Center, Pueblo.</p> |
| Outcomes | <p>Primary end point: weight loss, expressed as mean weight loss and the fraction of subjects in each group achieving a clinically meaningful weight loss defined as a 5% reduction in body weight.</p> <p>Secondary end points: change in physical activity estimated in metabolic equivalent task minutes, change in energy intake, change in lipids and HbA1c levels</p> |
| Study details | Not terminated before regular end |
| Publication details | <p>Language: English</p> <p>Funding: Supported by grant 5R44DK060272-3 from the US National Institute of Diabetes and Digestive and Kidney Diseases to PHCC LP Pueblo Colorado</p> <p>Publication status: Peer reviewed journal</p> |
| Stated aim of study | "To test the effect of physicians providing brief health lifestyle counseling to patients with type 2 diabetes mellitus during usual care visits." |
| Notes | Blinding of outcome assessment |

Glasgow 1997

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| Methods | Study design: Parallel randomised controlled trial |
| Participants | <p>Inclusion criteria:</p> <ol style="list-style-type: none"> 1. Having type 1 or type 2 diabetes 2. aged 40 or older 3. Primarily responsible for one's own diabetes dietary self-management (not institutionalised). <p>Exclusion criteria:</p> <p>Not stated</p> |
| Interventions | <p>Number of centres: 2</p> <p>Country: USA</p> <p>Setting: Offices of 2 Internists</p> |
| Outcomes | Dietary measures including the Kristal Food Habits Questionnaire and 4-day food record; BMI, cholesterol and HbA1c; Patient satisfaction and Cost assessment |
| Study details | Not terminated before regular end |
| Publication details | <p>Language: English</p> <p>Funding: Supported by grant 3DK-R01-35524 from the National Institutes of Diabetes, Digestive, and Kidney Diseases</p> <p>Publication status: Peer reviewed journal</p> |
| Stated aim of study | The primary purpose of the study was to evaluate the effectiveness of a brief medical office-based intervention in helping adult diabetes patients follow a healthy low saturated fat eating plan. Secondary purposes were to 1. evaluate the impact of intervention on physiological (cholesterol; GHb) and quality-of-life outcomes and 2) evaluate the effectiveness of the intervention for different patient subgroups. |
| Notes | Further information: allocation concealment, any blinding of outcome assessors, raw means and SDs for outcome measures |

Glasgow 2003

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|----------------------------|--|
| Methods | Parallel randomised control trial |
| Participants | <p>Inclusion criteria: All participants were living independently; had a telephone; read and wrote English; were diagnosed with type 2 diabetes for at least 1 year, and were not planning to move out of the area during the next year. Those patients taking insulin met the Welborn criteria for type 2 diabetes based on age at diagnosis, BMI, and age of insulin initiation</p> <p>Exclusion criteria: Not type 2, under 40 or over 75 years, incapacitated or too ill, diagnosed less than 1 year ago, moving or not in area, can't read or write English and Other</p> |
| Interventions | <p>Number of centres: Patients recruited from 16 physicians at 6 different medical offices</p> <p>Country: USA</p> <p>Setting: At home</p> |
| Outcomes | <p>Effectiveness was evaluated by improvement from baseline to the final assessment 10 months later using multiple measures within each of three different domains: behavioral, biological, and psychosocial outcomes.</p> <p>Dietary outcomes were assessed by improvements on the Kristal Fat and Fiber Behavior (FFB) scale and the Block/ NCI Fat Screener.</p> <p>Diabetes care was measured by a composite of care recommendations from the American Diabetes Association Provider Recognition Program.</p> <p>Physical activity was measured by the Physical Activity Scale for the Elderly.</p> <p>Biological outcomes were evaluated by changes in HbA1C and lipid ratios</p> <p>Psychosocial outcomes were measured by the Diabetes Support Scale and the Center for Epidemiologic Studies–Depression scale (CES-D)</p> <p>Delivery of intervention components and participant usage of the web site</p> |
| Study details | Not terminated before regular end |
| Publication details | <p>Language: English</p> <p>Funding: Supported in part by Grant RO1-DK-51581 from the National Institute of Diabetes, Digestive, and Kidney Diseases</p> <p>Publication status: Peer reviewed journal</p> |
| Stated aim of study | "To report on the longer-term implementation across interventionists, on program usage over time and across conditions, on 10-month follow-up results on behavioral, biologic, and psychosocial outcomes, and on generalization of results across patients from the different clinics participating in the study" |
| Notes | Further information needed: Method of sequence generation and allocation concealment, any blinding of participants or assessors, need to know numbers in each condition, details of participants |

Glasgow 2005

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| Methods | Randomized Control trial. Cluster Parallel RCT. |
| Participants | Inclusion criteria: the only inclusion criteria were age \geq 25 years, ability to read English, and type 2 diabetes, confirmed using the Welborn criteria Exclusion criteria: none stated |
| Interventions | Number of centres: Patients recruited from 52 physicians, 30 clinics Country: USA Setting: Primary Care practices in Colorado |
| Outcomes | Two primary outcomes: number of recommended laboratory screenings and recommended patient-centered care activities completed from the National Committee on Quality Assurance/ American Diabetes Association Provider Recognition Program (PRP). Secondary outcomes were evaluated using the Problem Areas in Diabetes 2 quality of life scale, lipid and HbA1c levels, and the Patient Health Questionnaire-9 depression scale. |
| Study details | Not terminated before regular end |
| Publication details | Language: English Funding: Agency for Health, Research and Quality, grant HS-10123 Publication status: Peer reviewed journal |
| Stated aim of study | To determine if a patient-centered, computer-assisted diabetes care intervention increased perceived autonomy support, perceived competence (from self-determination theory), and if these constructs mediated the effect of the intervention on ADA/NCQA recommended diabetes care outcomes. |
| Notes | Further information needed: details of randomisation, blinding; to check with authors that 1115 and 2053 same study, PAID-2 score: 6 month score SD is the same as 12 month score SE. |

Glasgow 2006

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|----------------------------|---|
| Methods | Parallel randomised control trial |
| Participants | <p>Inclusion criteria: Eligible participants were at least 25 years old, diagnosed with type 2 diabetes for at least 6 months, and able to read and write in English.</p> <p>Exclusion criteria: Physicians had the option of excluding patients for whom they felt the intervention would not be appropriate.</p> |
| Interventions | <p>Number of centres:multiple: Adults diagnosed with type 2 diabetes residing in the Denver, Colorado metropolitan area recruited from lists provided by 42 participating physicians (20% from mixed payer settings, and the remainder employed by Kaiser Permanente Colorado)</p> <p>Country: USA</p> <p>Setting: The primary intervention was conducted at a location external to the participant's primary care setting. This was typically a central clinic or medical office not too distant from the participant's home, including both mixed-payer, fee for-service and managed-care offices</p> |
| Outcomes | Outcomes were changes in dietary behaviours (fat and fruit/vegetable intake), haemoglobin A1c (HbA1c), lipids, weight, quality of life, and depression |
| Study details | Not terminated before regular end |
| Publication details | <p>Language: English</p> <p>Funding: National Institute of Diabetes & Digestive & Kidney Diseases, Grant #DK35524. Copic Insurance Company introduced the project to private physician offices</p> <p>Publication status: Peer reviewed journal</p> |
| Stated aim of study | The primary purposes of this article are to report on (1) the short-term (2-month) dietary, biological and quality-of-life outcomes from tailored self-management, (2) the implementation and feasibility of the programme, and (3) implications for broader dissemination |
| Notes | Further information needed: Details of sequence generation and allocation concealment, any blinding. Increase in fruit and veg score given in text (para 1 pg 34) does not correspond with the table for intervention |

Glasgow 2010

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| Methods | Randomised control trial |
| Participants | <p>Inclusion criteria: 25–75 years of age, diagnosis of type 2 diabetes, body mass index (BMI) of 25 kg/m² or greater, and at least one other risk factor for heart disease (hypertension, low-density lipoprotein [LDL] > 100 or on a lipid-lowering agent, haemoglobin A1c > 7%, or being a current smoker). Additional inclusion criteria were access to a telephone and at least biweekly access to the Internet, ability to read and write in English or Spanish, and to perform mild to moderate PA</p> <p>Exclusion criteria: 1. Sharing same household as other participants 2. Physicians not approved 3. Do not speak either English or Spanish</p> |
| Interventions | <p>Number of centres: The study was conducted in five primary care clinics within Kaiser Permanente Colorado (KPCO).</p> <p>Country: USA</p> <p>Setting: Clinics were selected based on variability in size, location, and socioeconomic status of neighbourhood, and to maximize percentage of Latino patients</p> |
| Outcomes | <p>Behavioral Outcomes: Eating behaviors were assessed using the Ammerman et al “Starting The Conversation” scale. Estimated fat intake was assessed using the National Cancer Institute’s Percent Energy from Fat Screener. The Community Health Activities Model Program for Seniors (CHAMPS) Questionnaire was used to estimate total weekly caloric expenditure in Physical Activity. Adherence to diabetes, blood pressure, and cholesterol medications were assessed through the medication-taking items of the Hill-Bone Compliance Scale.</p> <p>Biological Outcomes: Biologic variables included body mass index (BMI), hemoglobin A1c, lipids, and mean arterial pressure.</p> |
| Study details | Not terminated before regular end |
| Publication details | <p>Language: English</p> <p>Funding: This study was supported by grant #DK35524 from the National Institute of Diabetes and Digestive and Kidney Diseases.</p> <p>Publication status: Peer reviewed journal</p> |
| Stated aim of study | <p>Internet and other interactive technology based programs offer great potential for practical, effective, and cost-efficient diabetes self-management (DSM) programs capable of reaching large numbers of patients. This study evaluated minimal and moderate support versions of an Internet-based diabetes self-management program, compared to an enhanced usual care condition.</p> <p>The purposes of this paper were to (a) evaluate the feasibility of an Internet-based DSM program (MyPath/Mi Camino) using the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) model¹⁹ (www.re-aim.org); (b) present the 4-month behavioral and biological outcomes from a practical randomized trial; and (c) experimentally investigate the incremental effects of adding support to a minimal-contact version of the Internet-based program.</p> |
| Notes | |

Leu 2005

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| Methods | Parallel randomized control trial |
| Participants | <p>Inclusion criteria: Patients with HbA1c values between 8.0% and 9.4% at the time of recruitment, with either type 1 or type 2 diabetes.</p> <p>Exclusion: Three participants were found to be ineligible (two had pacemakers, and one was trying to conceive).</p> |
| Interventions | <p>Number of centres: 9 clinics, 20 primary care providers and two endocrinologists</p> <p>Country: USA</p> <p>Setting: University of Washington Physician's Network (UWPN) clinics located in Western Washington. This is a group of nine neighborhood clinics, of which Belltown (near Downtown Seattle), Auburn, Federal Way, Factoria, and Kent/Des Moines participated (20 primary care providers and two endocrinologists).</p> |
| Outcomes | <p>HbA1c was the primary outcome measure.</p> <p>Blood pressure was a secondary outcome measure. Patients' attitudes as self-reported by survey was another secondary outcome measure.</p> |
| Study details | Not terminated before regular end |
| Publication details | <p>Language: English</p> <p>Funding: American Diabetes Association (Medical Scholars Award), by the Warren G. Magnuson Institute for Biomedical Research and Health Professional Training (Magnuson Scholarship), and by an Alpha Omega Alpha Student Research Fellowship.</p> <p>Publication status: Peer reviewed journal</p> |
| Stated aim of study | This randomized, controlled study tested the effect of using a wireless two-way pager-based automated messaging system to improve diabetes control through facilitated self-management. |
| Notes | Further information needed: details of excluded cases, control conditions, definition of hypertension, method of sequence generation. |

Lim 2011

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|----------------------------|---|
| Methods | Block Randomized Controlled Trial |
| Participants | <p>Inclusion criteria: Age \geq 60. All enrolled participants had been diagnosed with type 2 diabetes for at least 1 year, and their A1C level was 6.5–10.5%</p> <p>Exclusion criteria: The study excluded patients with severe diabetes complications (e.g., diabetic foot or severe diabetic retinopathy), liver dysfunction (aspartate aminotransferase or alanine aminotransferase >2.5 times the reference level), or renal dysfunction (serum creatinine $>132 \mu\text{mol/L}$ [1.7 mg/dL]), or other medical problems that could affect study results or trial participation. The study enrollment excluded patients without a text message function on their cellular phone or who were unable to use text messages for any reason.</p> |
| Interventions | Number of settings: 1. Patients were recruited from the outpatient clinic of the Seoul National University Bundang Hospital (SNUBH). Participants used the intervention from home. |
| Outcomes | The primary end point of the study was the proportion of patients achieving an A1C level of $<7\%$ without hypoglycemia at 6 months. Secondary outcomes included weight, BMI, serum lipids, frequency of blood glucose monitoring, and fasting/post-prandial blood glucose. |
| Study details | Not terminated before regular end |
| Publication details | <p>Language: English</p> <p>Funding: "This study was supported by a grant of the Korea Healthcare technology R&D Project, Ministry for Health, Welfare & Family Affairs, Republic of Korea (A090001), a research grant (02-2008-036) from the SNUBH, and the Korea Science and Engineering Foundation grants funded by the Ministry of Science and Technology (M10642140004-06N4214-00410)"</p> <p>Publication status: Peer reviewed journal</p> |
| Stated aim of study | "To improve quality and efficiency of care for elderly patients with type 2 diabetes, we introduced elderly-friendly strategies to the clinical decision support system (CDSS)-based ubiquitous healthcare (u-healthcare) service, which is an individualized health management system using advanced medical information technology." |
| Notes | Details of randomization |

Lo 1996

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| Methods | Parallel randomized control trial |
| Participants | <p>Inclusion criteria: People with T1 and T2 diabetes at the Lismore base hospital diabetic clinic, diagnosed between 2 months and 10 years prior to this study.</p> <p>Exclusion criteria: None stated</p> |
| Interventions | <p>Number of centres: 1</p> <p>Country: Australia</p> <p>Setting: Community health centre office - Diabetes clinic at the Lismore base hospital</p> |
| Outcomes | Knowledge levels measured by multiple choice tests and Glycated haemoglobin levels |
| Study details | Not terminated before regular end |
| Publication details | <p>Language: English</p> <p>Funding: IRG grant from the University of New England, Northern Rivers, New South Wales</p> <p>Publication status: Peer reviewed journal</p> |
| Stated aim of study | <p>An evaluation study of the CAL program was conducted to test the following propositions:</p> <ol style="list-style-type: none"> 1. Subjects who complete the CAL program will achieve a greater increase in their knowledge of diabetes mellitus management than subjects who complete a conventional diabetes program. 2. The CAL program will motivate patients to achieve greater improvements in their glucose levels than a conventional diabetes program. - It is feasible to develop a CAL diabetes education program for home computers. |
| Notes | Further information needed: details of allocation and reasons for attrition |

Lorig 2010

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| Methods | Parallel randomized control trial for 6 months. After that a subset of American Indian/Alaska Natives were part of a wait-list control trial and were given the opportunity to use the intervention. |
| Participants | <p>Inclusion criteria: Participants were aged 18 years, were not pregnant or in care for cancer, had physician-verified type 2 diabetes, and had access to the Internet. Recruitment was largely via the Internet, although print and broadcast media were also utilized. Specific recruitment of AI/AN minorities into a separate sub-group</p> <p>Exclusion criteria: None stated</p> |
| Interventions | <p>Number of centres: Online trial Country: USA Setting: Internet based - all consents and questionnaires administered online and patients took HbA1C themselves with a postal blood-letting kit</p> |
| Outcomes | <p>The primary outcome measure was A1C, measured using capillary blood obtained with self-administered BIOSAFE kits. Secondary outcomes: Health-related distress was measured by the health distress scale The activity limitations scale, which measures the impact of disease on role activities such as recreation and chores Depression was measured by the Patient Health Questionnaire (PHQ)-9 A physical activities scale measured total minutes per week of aerobic exercise Tertiary outcomes: Tertiary measures included the 13- item short-form Patient Activation Measure (PAM) and diabetes self-efficacy</p> |
| Study details | Not terminated before regular end |
| Publication details | <p>Language: English Funding: The study was supported by National Institutes of Health Grant 1R18DK065729 and Robert Wood Johnson Foundation Grant 096223. Publication status: Peer reviewed journal</p> |
| Stated aim of study | "We hypothesized that participants in the IDSMP, compared with usual-care control subjects, would demonstrate 1) reduced A1C at 6 and 18 months, 2) have fewer symptoms, 3) have increased exercise, and 4) have improved self-efficacy and patient activation. We also hypothesized that participants randomized to a follow-up list serve, peer-support group would have better 18-month outcomes than participants receiving no follow-up." |
| Notes | Further information required: details of allocation concealment |

Quinn 2008

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| Methods | Parallel randomized control trial |
| Participants | <p>Inclusion criteria: The study enrolled patients 18–70 years old who had a diagnosis of type 2 diabetes for at least 6 months. Study patients were required to have an HbA1c 7.5% and to have been on a stable diabetes therapeutic regimen for 3 months prior to study enrollment.</p> <p>Exclusion criteria: None stated</p> |
| Interventions | <p>Number of centres: 3 Country: USA Setting: One community endocrinology and two community primary care practices</p> |
| Outcomes | Summary of Diabetes Self-Care Activities (SDSCA) questionnaire and HbA1c |
| Study details | Not terminated before regular end |
| Publication details | <p>Language: English Funding: Study was supported by LifeScan, Inc. and Nokia, Inc. Publication status: Peer reviewed journal</p> |
| Stated aim of study | The primary study aim was to assess the impact on A1c of a cell phone-based diabetes management software system used with web-based data analytics and therapy optimization tools. Secondary aims examined health care provider (HCP) adherence to prescribing guidelines and assessed HCPs' adoption of the technology. |
| Notes | Further information needed: details of sequence generation and allocation concealment |

Quinn 2011

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|----------------------------|--|
| Methods | Cluster randomized controlled trial |
| Participants | <p>Inclusion criteria:</p> <p>Physician diagnosis of type 2 diabetes for \geq 6 months Glycated haemoglobin \geq 7.5% within 3 months Age 18–64 years.</p> <p>Exclusion criteria:</p> <p>Medicare or Medicaid beneficiaries Uninsured Insulin pump users Not currently managed by study physicians Pregnant Active substance, alcohol, or drug abuser (sober $<$1 year) Psychotic or schizophrenic under active care Severe hearing or visual impairment No Internet or e-mail access.</p> |
| Interventions | <p>Number of centres: 26 primary care physicians enrolled and randomized Country: USA Setting: General practice physicians (internal medicine, family medicine) were recruited from four areas in Maryland, including urban, suburban and rural practices. Physicians in academic settings were not included</p> |
| Outcomes | <p>The primary outcome of the study was change in glycated hemoglobin (%) comparing UC and maximal treatment (CPDS) at baseline versus 12 months.</p> <p>Secondary outcomes were:</p> <p>The Patient Health Questionnaire-9 scores at baseline and at follow-up interviews to assess depressive symptoms. The 9-item version of the Self-Completion Patient Outcome Instrument to assess patient-reported symptoms associated with diabetes The 17-item Diabetes Distress Scale. Clinical measurement related to diabetes complications (blood pressure, lipid levels) Hypoglycemic events, hospitalization, and emergency room visits</p> |
| Study details | Not terminated before regular end |
| Publication details | <p>Language: English Funding: This study was funded through a contract between the University of Maryland Baltimore and WellDoc in addition to contributions by WellDoc, CareFirst Blue Cross/Blue Shield of Maryland, LifeScan, and Sprint. Additional funding was provided by the Maryland Industrial Partnerships program through the University of Maryland, an initiative of the A. James Clark School of Engineering's Maryland Technology Enterprise Institute. Publication status: Peer reviewed journal</p> |
| Stated aim of study | To test whether adding mobile application coaching and patient/provider web portals to community primary care compared with standard diabetes management would reduce glycated haemoglobin levels in patients with type 2 diabetes. |
| Notes | Diabetes Distress scale scores seem too low to be on the full scale - are these from a subscale? |

Smith 2000

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| Methods | Parallel randomized control trial |
| Participants | <p>Inclusion criteria: Women who participated in the Women to Women Diabetes Project had to meet the following study inclusion criteria: have diabetes (type 1 or 2), be between the ages of 35 and 60 years, be able to read and write English, and possess the sight and dexterity to use a computer (but not necessarily be computer literate). In addition, participants were required to have a telephone in their homes and live at least 25 miles outside the 6 major cities of Montana.</p> <p>Exclusion criteria: None stated</p> |
| Interventions | <p>Number of centres: n/a</p> <p>Country: USA</p> <p>Setting: From home</p> |
| Outcomes | <p>Over the telephone: change in health status scale, a sources of support scale and self-reported HbA1c</p> <p>Mail questionnaires for Personal Resource Questionnaire, Quality of Life index, Social Readjustment Rating Scale and the Psychosocial Adaptation to Illness Scale</p> |
| Study details | Not terminated before regular end |
| Publication details | <p>Language: English</p> <p>Funding: Financial support for this research was provided by the American Association of Diabetes Educators Foundation and US West.</p> <p>Publication status: Peer reviewed journal</p> |
| Stated aim of study | The aims were to (1) test the effects of the computer intervention in providing support, information and education on selected outcomes, and (2) evaluate the women's attitudes toward and satisfaction with the intervention and the support provided. |
| Notes | Further information needed: Method of sequence generation and allocation concealment. Number of participants completing the study. QOL etc scores after adjustment and any statistics on whether differences were significant or not. |

Wise 1986

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|----------------------------|---|
| Methods | Parallel randomized control trial |
| Participants | Inclusion: Patients regularly attending the diabetic clinic who were seen over a 2 month period at Charing Cross Hospital in London. Diagnosis of type 1/2 diabetes for at least 2 years. |
| Interventions | Number of centres: 1 Country: UK Setting: Diabetic clinic at Charing Cross Hospital, London |
| Outcomes | Knowledge status measured by knowledge-assessment program and HbA1c |
| Study details | Not terminated before regular end |
| Publication details | Language: English Funding: Supported by the British Diabetic Association and the North West Thames Regional Research Committee Publication status: Peer reviewed journal |
| Stated aim of study | The purpose of our study was to examine separately two programs recently developed in this department to define any effects on knowledge and diabetic control. |
| Notes | Details of allocation concealment and SD of outcome measures if available |

Yoo 2009

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|----------------------------|--|
| Methods | Parallel randomized control trial |
| Participants | <p>Inclusion: between 30 and 70 years of age, who met the following criteria: (i) a diagnosis of both Type 2 diabetes and hypertension at least 1 year previously by a physician; (ii) HbA1c 6.5–10.0%; (iii) blood pressure > 130/80 mmHg; and (iv) body mass index (BMI) $\geq 23.0 \text{ kg m}^2$ (overweight according to Asia-Pacific criteria)</p> <p>Exclusion: i) severe diabetic complications (e.g. diabetic foot or severe diabetic retinopathy); ii) liver dysfunction with aspartate aminotransferase or alanine aminotransferase > 2.5 times the reference level, or renal dysfunction (serum creatinine $> 132 \text{ lmo l}^{-1}$); iii) medical history of congestive heart failure, angina pectoris, myocardial infarction, or stroke based on a physician's diagnosis; iv) pregnancy or lactation; or v) other medical problems that could affect study results or trial participation or (Vi) excluded all subjects with CRP $\geq 15.0 \text{ mg}$ to rule out any occult inflammatory or infectious disorders.</p> |
| Interventions | <p>Number of centres: 2</p> <p>Country: South Korea</p> <p>Setting: 1. University hospital setting (Korea University) 2. Community healthcare centre (Guro-Gu Public Health Centre)</p> |
| Outcomes | BMI was calculated as weight/height ² (kg/m ²). Blood chemistry was analysed at the Korea University Guro Hospital laboratory (Seoul, Korea). The glucose oxidase method was employed to measure plasma glucose. A human insulin-specific radioimmunoassay kit (Linco Research Inc., St Charles, MO, USA) was used to measure insulin levels, with a coefficient of variation (CV) of 2.2%. This kit had a crossreactivity of < 0.2% with human proinsulin. Insulin resistance was calculated by the homeostasis model assessment. Serum total cholesterol, triglycerides, and high-density lipoprotein cholesterol were determined by enzymatic methods using a chemical analyser (Hitachi 747, Tokyo, Japan). HbA1c was analysed by high-performance liquid chromatography using a Variant II analyser (Bio-Rad Laboratories, Hercules, CA, USA). Plasma adiponectin levels were measured using an adiponectin enzyme immunoassay kit (Phoenix Pharmaceuticals, Belmont, CA, USA), with a CV of 3.2%. Plasma IL-6 levels were measured using a Quantikine kit (R&D Systems, Belmont, CA, USA) with a CV of 8.1%. Plasma high-sensitivity (hs) CRP levels were measured using a CRP kit (Immunodiagno, Bensheim, Germany) with a CV of 9.2%. |
| Study details | Not terminated before regular end |
| Publication details | <p>Language: English</p> <p>Funding: Seoul R & BD Project. The development of the HSA business model and technology was sponsored by the Ministry of Commerce, Industry and Energy</p> <p>Publication status: Peer reviewed journal</p> |
| Stated aim of study | Our goal was to examine whether a Ubiquitous Chronic Disease Care (UCDC) system using both the internet and cellular phones could facilitate chronic disease self-management and improve multiple metabolic parameters in overweight patients with both Type 2 diabetes and hypertension better than conventional healthcare in out-patient clinics. |
| Notes | Further information needed: clarify data for BPs - need clarification re. inconsistencies between tables and text re HbA1C, Full details of randomisation needed |

Zhou 2003

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|----------------------------|---|
| Methods | Parallel randomized control trial |
| Participants | <p>Inclusion criteria:</p> <p>Selection criteria: diagnosed according to WHO diagnostic criteria 1985, age over 35 years, previously received glucose lowering medication, and the dosage of medication remained constant at least two weeks prior to the selection.</p> <p>Exclusion criteria:</p> <p>Diabetes with other severe or acute complications and those with other endocrine disorders, hypertension (diagnosed according to WHO/ISH Hypertension guidelines), hypercholesterolemia (Principles for prevention of dyslipidemia) and glomerular disease (diagnosed according to Morgenson diagnostic criteria).</p> |
| Interventions | Number of centres: 1 Country: China Setting: Endocrinology Department in Second Affiliated Hospital of Zhejiang University |
| Outcomes | HbA1c, BMI, fasting blood glucose, 2 hour post prandial glucose, Lipids, urinary albumin excretion |
| Study details | Not terminated before regular end |
| Publication details | Language: Chinese Funding: Not stated Publication status: Peer reviewed journal |
| Stated aim of study | We developed 'Diabetes diet advisor V1.0 (PC-DR Vision 1.0)'. It consists of more than 20 thousand common food types of Chinese people. The objective of this research is to evaluate the efficacy of this software in clinical uses. |
| Notes | Further information required: details of allocation concealment and sequence generation |

3.5.2 Results of the search

The search results from the six electronic bibliographic databases for published articles and conference proceedings yielded 8715 unique abstracts (4869 from The Cochrane Library, MEDLINE and EMBASE; 905 from PsychINFO and Web of Science and 2766 from CINAHL). The search results from the three online databases for theses contained 193 abstracts (44 from ASLIB Index to Theses, 28 from the Australasian Digital Theses programme and 121 from UMI ProQuest Digital Dissertations). This is summarised in Figure 3-1. Ninety-four full-text articles were assessed for eligibility and assessed independently by two authors. Sixteen different studies with 3578 participants fulfilled the inclusion criteria and were selected for inclusion in the review.

3.5.3 Included studies

Sixteen studies met the inclusion criteria. A summary of the characteristics of the included studies can be found in the Table 3-1. Eleven studies were based in the USA (Christian et al. 2008;Glasgow et al. 1997b;Glasgow et al. 2003;Glasgow et al. 2005;Glasgow et al. 2006;Glasgow et al. 2010;Leu et al. 2005;Lorig et al. 2010a;Quinn et al. 2008;Quinn et al. 2011;Smith et al. 2000), two studies in the United Kingdom (Lo et al. 1996;Wise et al. 1986), two studies in South Korea (Lim et al. 2011;Yoo et al. 2009) and one in China (Zhou et al. 2003). Fifteen of the studies had reports published in English, one report was translated from Chinese by a paid external interpreter (Zhou et al. 2003).

3.5.4 Excluded studies

The majority of studies excluded were tele-health interventions (44). They were excluded on the basis that the interventions did not fit our criteria for self-management interventions, rather they were tele-health interventions with the main aim of enabling health professional – patient interaction at a distance. Other reasons for exclusion included studies on participants with type 1 diabetes only (2), studies with more than 50% type 1 diabetes (2) and studies that were not randomised controlled trials (4).

3.5.5 Study design

All of the studies included in the review were randomised controlled trials. The duration of follow-up ranged from 2 to 12 months: two studies followed up for two months (Glasgow et al. 2006; Zhou et al. 2003), three studies followed up for three months (Lo et al. 1996; Quinn et al. 2008; Zhou et al. 2003), one study followed up for four months (Glasgow et al. 2010), two studies followed up for five months (Leu et al. 2005; Smith et al. 2000), three studies followed up for six months (Lim et al. 2011; Lorig et al. 2010a; Wise et al. 1986), one study followed up for 10 months (Glasgow et al. 2003) and four studies followed up for 12 months (Christian et al. 2008; Glasgow et al. 1997b; Glasgow et al. 2005; Quinn et al. 2011).

Participants

The included studies provided results from 3578 participants. A summary of the characteristics of the populations of included studies can be found in Appendix 3. The number of participants in a single study ranged from 30 (Quinn et al. 2008; Smith et al. 2000) to 886 (Glasgow et al. 2005). One study only included women (Smith et al. 2000). In 13 studies all participants had type 2 diabetes; three studies involved mixed populations with both type 1 and type 2 diabetes (Glasgow et al. 1997b; Leu et al. 2005; Smith et al. 2000); the percentage of participants with type 1 diabetes was about 20%. Participants in one study were all Latino or Hispanic (Christian et al. 2008; Smith et al. 2000). Three studies reported participants who were over 70% white or non-Hispanic white (Glasgow et al. 2005; Glasgow et al. 2006; Lorig et al. 2010a), although the last study had a separate arm which exclusively recruited American Indians and native Alaskans. Six studies reported mean duration of diabetes (Glasgow et al. 1997b; Lim et al. 2011; Quinn et al. 2008; Quinn et al. 2011; Wise et al. 1986; Yoo et al. 2009) which ranged between 6 and 13 years. The mean age of participants ranged from 46 (Smith et al. 2000) to 67 years (Lim et al. 2011).

Characteristics of interventions

Aims of the interventions: Four interventions aimed to support patients with goal setting when visiting clinic. One intervention was a brief touch screen assessment of dietary barriers (Glasgow et al. 1997b); one intervention was a 30-minute touch screen assessment and printout for action planning for self-

management (Glasgow et al. 2005); two interventions were digital assessments that also provided printouts for barriers to physical activity and diet (Christian et al. 2008;Glasgow et al. 2006);

Four interventions provided peer support and education online, mostly through moderated forums (Glasgow et al. 2003;Glasgow et al. 2010;Lorig et al. 2010a;Smith et al. 2000).

Five interventions used mobile devices to engage users with self-management at home. One study used pagers (Leu et al. 2005) and four studies used mobile phones (Lim et al. 2011;Quinn et al. 2008;Quinn et al. 2011;Yoo et al. 2009). The pager study (Leu et al. 2005) sent reminders about medication, blood glucose testing, exercise reinforcement, meal time reinforcement, laboratory results and custom participant-defined messages to participants and they were able to respond to messages. One of the mobile phone-based interventions (Yoo et al. 2009) provided alarms for twice daily blood pressure and blood glucose measurements and daily weight measurement; it also provided texts with advice about lifestyle, exercise and tailored advice from health professionals. Another mobile phone-based intervention (Quinn et al. 2008) used a blue tooth adapter to allow blood glucose data to be transferred to a mobile phone and use mobile phone-based software to generate personalised feedback. Lim et al (Lim et al. 2011) described an intervention that sent text messages to participants based on self-monitored blood glucose levels with advice about medication or lifestyle. Quinn et al used a mobile phone-based based software coach that delivered mostly SMS messages (Quinn et al. 2011). One intervention used a computer to provide a tailored dietary plan for participants (Zhou et al. 2003).

Two interventions provided digital education sessions (Lo et al. 1996;Wise et al. 1986).

Frequency and intensity: Patterns of use of the interventions varied widely across the different studies. Seven studies had interventions where exposure to the intervention was participant-driven and the frequency and intensity was mainly determined by how often and how long patients chose to use the intervention (Glasgow et al. 2003;Glasgow et al. 2010;Lorig et al. 2010a;Quinn et al. 2008;Quinn et al. 2011;Smith et al. 2000;Zhou et al. 2003). The remaining

interventions were more prescriptive: six interventions were low intensity and the number of exposures to the intervention varied between one and four "doses". Two interventions used one interaction (Christian et al. 2008; Glasgow et al. 2005), two interventions used two interactions (Glasgow et al. 1997b; Glasgow et al. 2006), one intervention used three interactions (Wise et al. 1986) and one intervention used four interactions (Lo et al. 1996). Three interventions were relatively intensive and had, on average, more than two interactions a day with participants (Leu et al. 2005; Lim et al. 2011; Zhou et al. 2003).

Uptake and usage: Uptake was variable across the interventions. Recruitment and acceptability of the interventions was not reported by six studies. For the other studies recruitment rates ranged between 42% to 100% (for some of the smaller studies). The lowest rate of follow up was 61% (Quinn 2011) and the highest was 100% (Zhou 2003) with two studies not reporting follow up rates (Glasgow 1997; Glasgow 2003). Most studies had retention rates of around 80%. Intervention usage was poorly reported and only one study reported usage data (Glasgow 2003). The mean logons per participant in the first three months was 9.4 which decreased to 3.6 in months 7-10.

.

Comparator groups: The comparison group for five studies was usual care (Leu et al. 2005; Lorig et al. 2010a; Quinn et al. 2011; Wise et al. 1986; Yoo et al. 2009). Two studies provided printed information to participants (Christian et al. 2008; Smith et al. 2000). Two studies used touch screens for assessment or data collection but provided no feedback to participants (Glasgow et al. 1997b; Glasgow et al. 2005). The remaining studies all used different controls; two studies provided face-to-face diabetes education in the control arm (Lim et al. 2011; Lo et al. 1996), one study provided blood glucose meters and encouraged participants to fax their results to their healthcare providers every two weeks until blood glucose was stabilised (Quinn et al. 2008); one study provided fixed carbohydrate content meals decided by the doctor (Zhou et al. 2003); one study provided digital access to articles about diabetes (Glasgow et al. 2003) and two studies provided computer-assisted generic health risk appraisal (Glasgow et al. 2006; Glasgow et al. 2010).

Theoretical basis for the interventions: Seven interventions mentioned a theoretical basis for designing the intervention (Christian et al. 2008; Glasgow et al. 1997a; Glasgow et al. 2003; Glasgow et al. 2005; Glasgow et al. 2006; Glasgow et al. 2010; Lorig et al. 2010b). The theories mentioned were Self-determination theory, Chronic Care Model, Social support theory, Social Learning theory and systems approaches to diabetes self-management, Self-efficacy theory, TTM, Social Ecological Theory, Social Cognitive theory and the 5 As self-management model. Two interventions mentioned multiple theories. This is summarised in Table 3-2 below.

Table 3-2 Theories and constructs mentioned in intervention design

| Study | Theory mentioned | Constructs measured |
|----------------|---|--|
| Glasgow 1997 | Social Learning/ Social Cognitive theory and systems approaches to diabetes self-management | Self-efficacy, barriers to adherence, problem-solving skills, social support |
| Glasgow 2003 | Social support theory | Social support, reduced negative affect, self-care |
| Glasgow 2005 | Self determination theory | autonomy support, perceived competence |
| Glasgow 2006 | Chronic Care Model | Self-efficacy |
| Christian 2008 | Self-efficacy | Motivational interviewing, self efficacy |
| Lorig 2010 | Self-efficacy | Self-efficacy |
| Glasgow 2010 | Social Ecological Theory, Social Cognitive theory, the 5 As self-management model | Self-efficacy |

3.5.6 Risk of bias in included studies

Details of the risk of bias of the included studies can be found in Appendix 2 and have been summarised in Figures 3-3 and 3-4.

Allocation (selection bias): Two studies used a random number table to generate the randomised sequences (Glasgow et al. 1997b; Lorig et al. 2010a). Two studies used a computer-generated random number sequence (Christian et al. 2008; Glasgow et al. 2010). One study used an Excel (TM) spreadsheet to

randomly allocate participants (Leu et al. 2005). Allocation concealment was done using padded envelopes in two studies (Christian et al. 2008;Leu et al. 2005) and these were assigned a low risk of selection bias. One older study used inadequate randomisation by year and month of birth (Wise et al. 1986). Reports for the remaining studies did not describe the method of generating the random number sequences.

Blinding (performance bias and detection bias): The study design for 11 of the included studies would make it difficult to blind the participants (Christian et al. 2008;Leu et al. 2005;Lim et al. 2011;Lo et al. 1996;Lorig et al. 2010a;Quinn et al. 2008;Quinn et al. 2011;Smith et al. 2000;Wise et al. 1986;Yoo et al. 2009;Zhou et al. 2003). The remaining studies did not comment on blinding of participants.

There was no comment on assessor blinding for 15 studies. One study used self-reported data collection; however patients were not blinded so the potential for performance and detection bias remained (Lorig et al. 2010a).

Incomplete outcome data (attrition bias): Four studies performed intention-to-treat analysis on the results (Christian et al. 2008;Glasgow et al. 2006;Glasgow et al. 2010;Lorig et al. 2010a). One study used weighted estimating equations to address missing data (Quinn et al. 2011); however, as the attrition rates were high in the intervention group (39%) and differed significantly from the control group (10%), we deemed the results to be at high risk of attrition bias. One study had no missing data (Zhou et al. 2003). Four studies described their attrition rates which were between 4% to 16% (Glasgow et al. 1997b;Glasgow et al. 2006;Lim et al. 2011;Yoo et al. 2009). The remaining studies did not provide details about missing data.

Selective reporting (reporting bias): We were able to find a published protocol for only one of the included studies (Quinn et al. 2011). We found no evidence of selective reporting of outcomes.

Other potential sources of bias: One study noted a larger reduction in HbA1c for patients in the control arm who had their antihyperglycaemic drugs

increased compared with the intervention group (Christian et al. 2008). The control group for one study received a potentially active intervention that contained automated dietary change goals (Glasgow et al. 2003).

Figure 3-2 Risk of bias graph

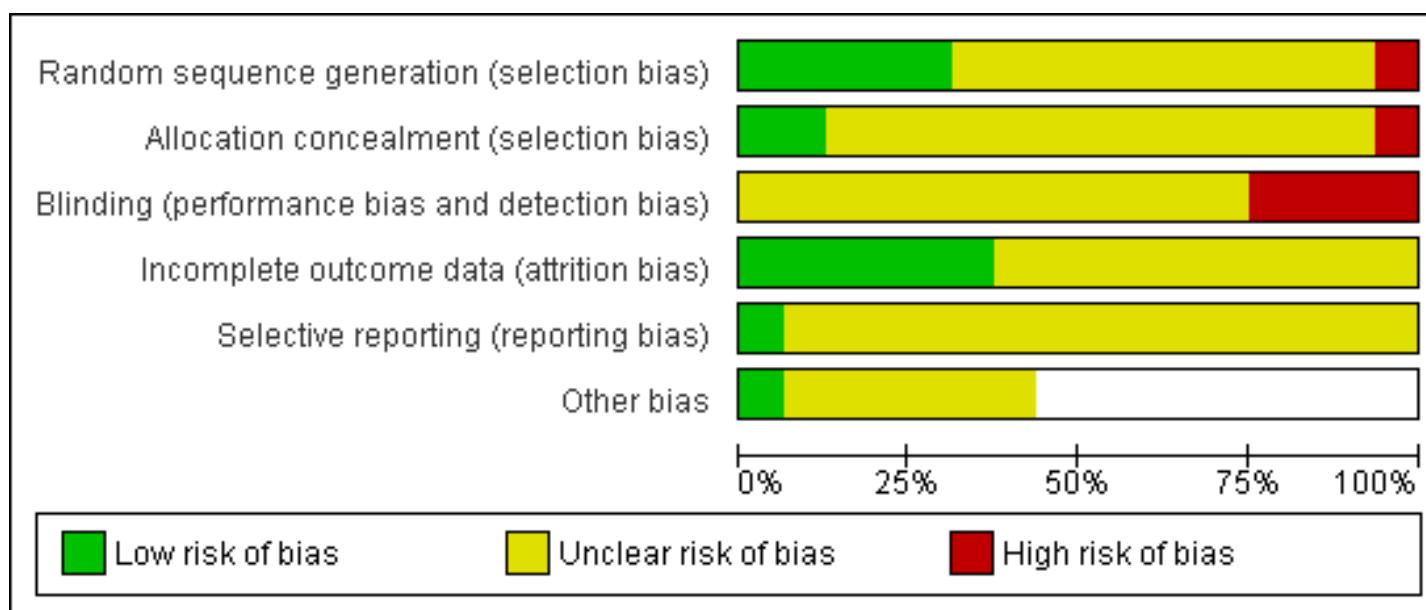


Figure 3-3 Risk of bias summary

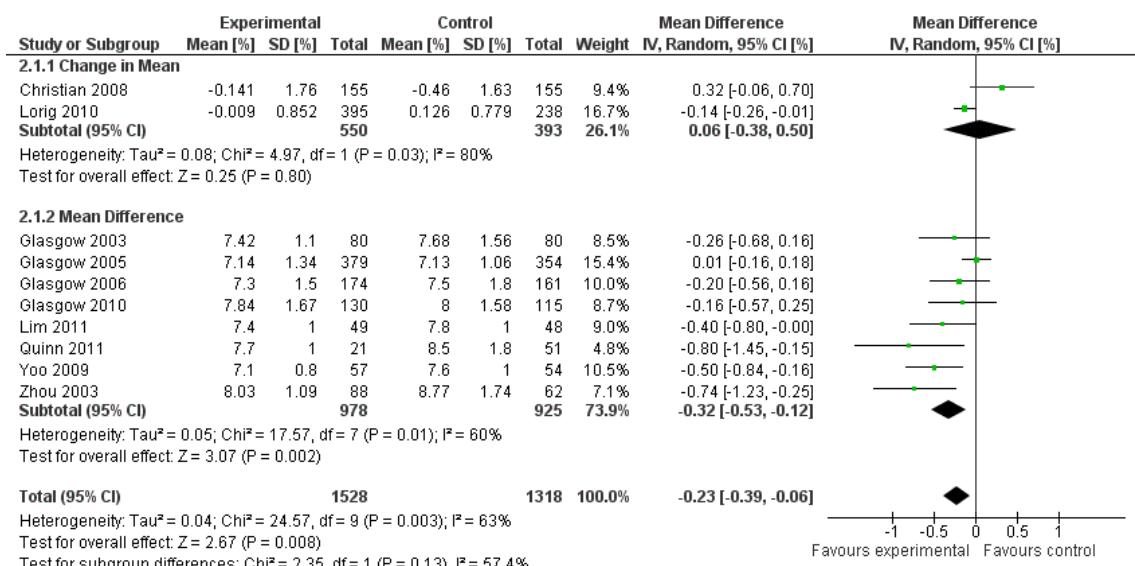
| | Random sequence generation (selection bias) | Allocation concealment (selection bias) | Blinding (performance bias and detection bias) | Incomplete outcome data (attrition bias) | Selective reporting (reporting bias) | Other bias |
|----------------|---|---|--|--|--------------------------------------|------------|
| Christian 2008 | + | + | ? | + | ? | ? |
| Glasgow 1997 | + | ? | ? | ? | ? | |
| Glasgow 2003 | ? | ? | ? | ? | ? | ? |
| Glasgow 2005 | ? | - | ? | ? | ? | |
| Glasgow 2006 | ? | ? | ? | + | ? | ? |
| Glasgow 2010 | + | ? | ? | + | ? | |
| Leu 2005 | + | + | - | ? | ? | |
| Lim 2011 | ? | ? | ? | ? | ? | + |
| Lo 1996 | ? | ? | ? | ? | ? | |
| Lorig 2010 | + | ? | ? | + | ? | |
| Quinn 2008 | ? | ? | - | ? | ? | ? |
| Quinn 2011 | ? | ? | - | + | + | ? |
| Smith 2000 | ? | ? | ? | ? | ? | ? |
| Wise 1986 | - | ? | ? | ? | ? | |
| Yoo 2009 | ? | ? | - | ? | ? | |
| Zhou 2003 | ? | ? | ? | + | ? | |

3.5.7 Effects of interventions

Primary Outcomes

HbA1c: The effects of the interventions on HbA1c were mixed. One study relied on self-reported HbA1c monitoring and did not receive enough results to make any meaningful comment (Smith et al. 2000). Of the remaining 15 studies the individual results were as follows: six studies reported small but statistically significant improvements in HbA1c (Lim et al. 2011;Lorig et al. 2010a;Quinn et al. 2008;Quinn et al. 2011;Yoo et al. 2009;Zhou et al. 2003), three studies reported results that favoured the intervention but did not reach statistical significance (Glasgow et al. 2003;Lo et al. 1996;Wise et al. 1986) and six studies reported no significant difference between control and intervention groups (Christian et al. 2008;Glasgow et al. 1997b;Glasgow et al. 2005;Glasgow et al. 2006;Glasgow et al. 2010;Leu et al. 2005). Eleven studies provided enough data to combine in a meta-analysis (Christian et al. 2008;Glasgow et al. 2003;Glasgow et al. 2005;Glasgow et al. 2006;Glasgow et al. 2010;Leu et al. 2005;Lim et al. 2011;Lorig et al. 2010a;Quinn et al. 2011;Yoo et al. 2009;Zhou et al. 2003) as shown in Figure 3-4. The pooled results indicate that there is a small, statistically significant difference in the outcomes between intervention and comparator groups of 2.3 mmol/mol or mean difference (MD) - 0.2% (95% CI -0.4 to -0.1; 2637 participants, 11 trials). There was substantial heterogeneity in the effects of the interventions ($I^2 = 58\%$).

Figure 3-4 Pooled effect on HbA1c



One study commented on a subgroup analysis looking at participants with higher HbA1c at baseline (Lorig et al. 2010a). Lorig 2010 found that for patients with a baseline HbA1c equal to or greater than 7.0%, the difference between treatment and control arms increased from -0.14% (overall) to -0.6% (P = 0.010) suggesting patients with HbA1c greater than 7% might benefit more than patients with better baseline glycaemic control.

Two studies seemed to favour the control group for HbA1c (Christian et al. 2008;Leu et al. 2005). Christian 2008 suggested a potential for bias in their report. Fifty-one per cent of participants in the study had their hypoglycaemic medication adjusted by their healthcare providers during the trial: the control group patients who had their medication changed saw their HbA1c reduce by 0.9% while intervention group patients who had their medication changed saw their HbA1c reduced by just 0.04% (P = 0.02). The effect of the change in treatment of the control group appears to be much larger than the treatment effect of the interventions and could be a confounding factor. A subgroup analysis removing this study did not significantly change the heterogeneity of the overall meta-analysis ($I^2 = 56\%$) but the pooled effect of the interventions on HbA1c improved slightly to -2.7 mmol/mol or -0.3% (95% CI -0.4 to -0.1). Leu et al was the only study included in the meta-analysis carried out on a mixed population of people with type 1 and type 2 diabetes (74% had type 2 diabetes). A subgroup analysis removing this study did not significantly change the heterogeneity of the overall meta-analysis ($I^2 = 56\%$) but the pooled effect of the interventions on HbA1c improved slightly to -2.5 mmol/mol or -0.2% (95% CI -0.4 to -0.1).

Health-related quality of life: Five studies reported health-related quality of life scores (Glasgow et al. 2005;Glasgow et al. 2006;Lorig et al. 2010a;Quinn et al. 2011;Smith et al. 2000) but none showed statistically significant differences. In one study, both the control and the intervention group showed improvement on the PAID-2 scale (Glasgow et al. 2005) but there was no significant difference between the two groups at 12 months. The study Lorig 2010 using the health distress scale showed no change between intervention and control groups at six months. Another study used PAIS (Smith et al. 2000) and found no difference between intervention or control groups after five months. The final two studies

using the diabetes distress scale (Glasgow et al. 2006;Quinn et al. 2011) showed no difference between control and intervention groups at two months and 12 months respectively.

Death from any cause: A total of three deaths out of 3578 participants were reported in the 16 studies. Two participants died in one study (Lorig et al. 2010a) and one participant died in another study from complications of a cerebrovascular attack (Leu et al. 2005). No further details were provided in the study reports.

Secondary outcomes

Cognitions:

Change in knowledge and understanding: four of four studies reported positive effects of the interventions on knowledge (Lo et al. 1996;Lorig et al. 2010a;Quinn et al. 2008;Wise et al. 1986). Lo 1996 showed an increase from 10.9 to 14.3 (mean scores) on the DKN diabetes knowledge scale but this was not significantly different to a control face-to-face education group. The intervention group in Quinn 2008 was more likely to report being able to better control their diabetes based on their knowledge of food choices compared with the control group (91% versus 50%), measured using SDSCA diabetes self-care questionnaire. Wise 1986 showed a statistically significant increase in knowledge-based assessment scores expressed as a knowledge index. Lorig 2010 showed statistically significant improvements in knowledge, skill and confidence measures using the Patient Activation Measure (PAM) at six months and 18 months.

Self-efficacy: both studies measuring self-efficacy suggested positive effects of interventions (Lorig et al. 2010a;Quinn et al. 2008). Lorig 2010 showed a statistically significant increase in self-efficacy at six months, measured on the diabetes self-efficacy scale, and this persisted up to 18 months after the start of the trial. Quinn et al used the SDSCA diabetes self-care questionnaire as above to show patients using the intervention were more likely to report being able to better control their diabetes based on their confidence (100% versus 75%).

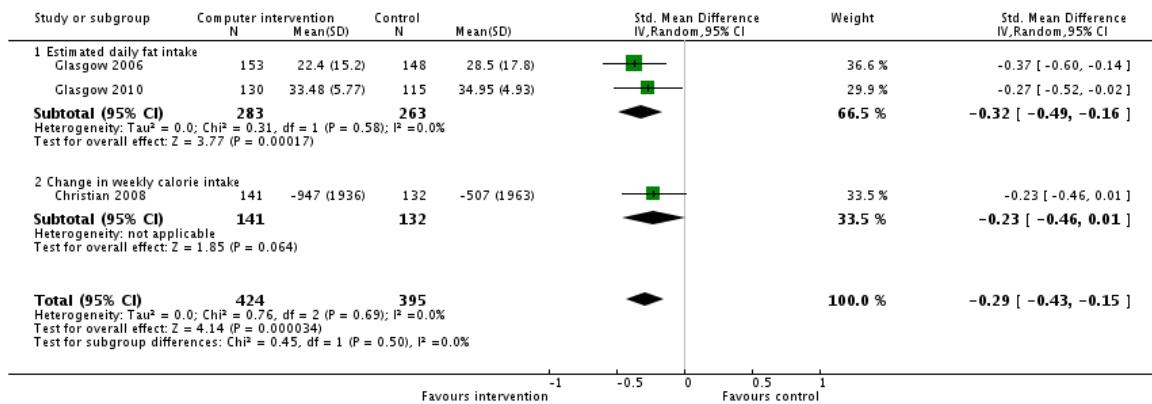
Behaviours

Physical activity: data for this outcome was extracted from five studies. The effects of interventions on physical activity were mixed. Christian 2008 showed that the percentage of intervention patients who achieved a metabolic equivalent minutes (MET- min equivalent) of 150 or more minutes of physical activity or exercise per week at a moderate level of intensity increased from 26% at baseline to 53% at 12 months ($P = 0.001$), compared to the control group which showed an increase from 30% to 37% ($P = 0.27$). Two studies showed small increases in physical activity that did not reach statistical significance (Glasgow et al. 2003;Lorig et al. 2010a). One study reported statistically significant improvements in physical activity in the intervention group based on subgroup analysis (Glasgow et al. 2010). One study found no improvement in diabetes self-care SDSCA questionnaire scores for exercise after three months (Quinn et al. 2008).

Diet: six studies looked at changes in diet and five reported statistically significant improvements (Christian et al. 2008;Glasgow et al. 1997b;Glasgow et al. 2003;Glasgow et al. 2006;Glasgow et al. 2010;Quinn et al. 2008). Glasgow 1997 demonstrated a statistically significant improvement in the food habits questionnaire and four-day food record in the intervention group. The intervention group in Glasgow 2003 showed a statistically significant improvement in Kristal Fat and Fiber Behavior (FFB) scale and the Block/NCI Fat Screener. The study Glasgow 2006 showed a significant and clinically meaningful reduction in dietary fat intake; however, there were no overall differences in fruit and vegetable consumption between control and intervention groups. Quinn 2008 showed a statistically significant improvement in the diabetes self-care SDSCA score for diet. Glasgow 2010 reported a statistically significant improvement in healthy eating habits measured on the Starting the Conversation scale. Christian 2008 showed a statistically non-significant improvement in the intervention group, who reduced total self-reported energy intake by a mean of 947 kcal/wk (8.3%) per patient versus a 507 kcal/wk (4.4%) reduction for controls ($P = 0.06$). When data about changes in dietary behaviour from three studies (Christian et al. 2008;Glasgow et al. 2006;Glasgow et al. 2010) were combined in a meta-analysis (looking at dietary fat intake, healthy

eating habits and energy intake respectively), it suggested a statistically significant improvement in dietary change scores from using digital interventions: pooled effect standardised mean difference (SMD) -0.29 (95% CI -0.43 to -0.15; 819 participants; 3 trials; Figure 3-5).

Figure 3-5 Pooled effect on diet



Social support

Change in social support: two studies reported data on this. Glasgow 2003 showed a small increase in diabetes total support scale from a baseline mean of 4.14 to 4.96, $P < 0.05$. Smith 2000 measured social support using the Personal Resource Questionnaire (PRS) but there was no statistically significant change.

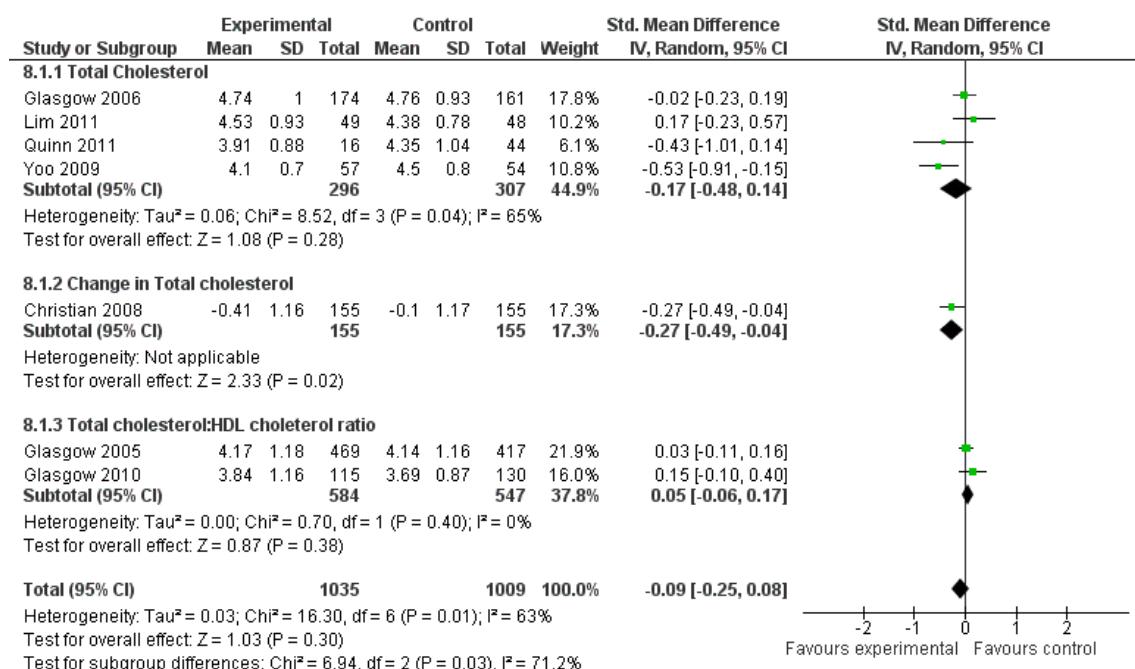
Biological outcomes

Blood pressure: Five studies looked at changes in blood pressure (Christian et al. 2008; Glasgow et al. 2010; Leu et al. 2005; Quinn et al. 2008; Quinn et al. 2011; Yoo et al. 2009). Two studies looked at differences in mean systolic and diastolic blood pressures and found no significant difference between intervention and control groups (Christian et al. 2008; Quinn et al. 2011). Glasgow 2010 reported mean arterial pressures and found no significant differences between control and intervention groups after four months. One study reported percentages of the groups that were hypertensive (Leu et al. 2005) and found that at the end of the study 64% of intervention patients were "hypertensive" (not defined) in the intervention group compared with 68% in the control group ($P = 0.041$). Yoo 2009 reported mean systolic and diastolic blood

pressures and found a statistically significant decrease in the intervention group - systolic blood pressure dropped from 127 ± 14 mm Hg to 120 ± 19 mm Hg, $P = 0.001$ and diastolic blood pressure decreased from 78 ± 10 mm Hg to 74 ± 8 mm Hg, $P < 0.001$.

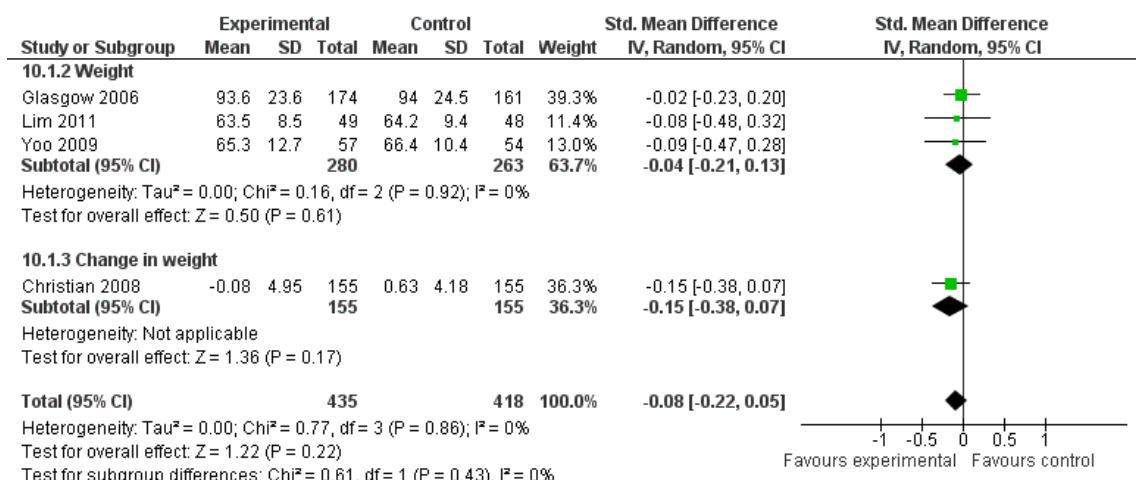
Blood lipid levels: Ten studies reported blood lipid results (Christian et al. 2008; Glasgow et al. 1997b; Glasgow et al. 2003; Glasgow et al. 2005; Glasgow et al. 2006; Glasgow et al. 2010; Lim et al. 2011; Quinn et al. 2011; Yoo et al. 2009; Zhou et al. 2003). The results were mixed. Four studies found statistically significant improvements in blood lipid profiles: Christian 2008 - reduced total cholesterol and LDL, Glasgow 1997 - reduced total cholesterol; Glasgow 2003, Yoo 2009 - reduced total cholesterol, LDL and triglycerides; however one of those studies (Christian 2008), attributed the difference in lipids to differences in the use of lipid-lowering medication. Six studies found no evidence of improvement in blood lipid levels in the intervention groups (Glasgow et al. 2005; Glasgow et al. 2006; Glasgow et al. 2010; Lim et al. 2011; Quinn et al. 2011; Zhou et al. 2003). Seven studies provided enough data to combine in a meta-analysis and the overall result was not statistically significant: pooled effect SMD -0.11 (95% CI -0.28 to 0.05; 1625 participants; 7 trials; Figure 3-6)

Figure 3-6 Pooled effect on blood lipids



Body mass index (BMI) and weight: five studies reported changes in BMI (Glasgow et al. 1997b;Glasgow et al. 2010;Lim et al. 2011;Yoo et al. 2009;Zhou et al. 2003). Four of those studies reported no significant difference in BMI between intervention or control groups (Glasgow et al. 1997b;Glasgow et al. 2010;Lim et al. 2011;Yoo et al. 2009). The study Zhou 2003 showed a statistically significant drop in BMI from 24.0 to 23.1, $P < 0.01$. Four studies reported changes in weight (Christian et al. 2008;Glasgow et al. 2006;Lim et al. 2011;Yoo et al. 2009). Christian 2008 reported that when mean changes in body weight were compared between intervention and control groups, no significant differences were found; however, 21% of intervention patients sustained a weight loss of 5% of total body weight or greater at 12 months compared with 10.6% of controls, $P < 0.01$ while 32% of intervention patients at 12 months had sustained a weight loss of 2.7 kg or more compared to 19% of control patients, $P = 0.01$. Glasgow 2006 found a small but statistically significant reduction in weight in the intervention group of 0.7 kg, $P = 0.007$. Yoo 2009 and Lim 2011 found no significant differences in the weight of intervention and control groups after three months and six months respectively. Five studies provided enough data to combine in a meta-analysis which showed no statistically significant evidence of benefit pooled effect: SMD -0.07 (95% CI -0.20 to 0.05; 1025 participants; 5 trials; Figure 3-7).

Figure 3-7 Pooled effect on weight



Anxiety or depression: six studies that looked at depression showed no significant change in mood. Glasgow 2003 used the Centre for Epidemiologic depression scale but found no statistically significant improvement with the intervention. Three studies using PHQ-9 questionnaires did not show any statistically significant improvement in scores (Glasgow et al. 2006;Lorig et al. 2010a;Quinn et al. 2011). Two studies looked at incidence of depression in the intervention and control groups, and there was no statistically significant difference at the end of the trial (Glasgow et al. 2005;Quinn et al. 2008).

Adverse effects: one study reported a participant withdrawing due to anxiety related to the study (Wise et al. 1986). One study noted non-statistically significant increase in minor hypoglycaemic episodes in the intervention group but no difference in major or nocturnal hypoglycaemic episodes (Lim et al. 2011). Quinn 2011 specifically stated there were no study-related adverse events.

Cost-effectiveness and economic data:

Glasgow 1997 looked at the cost per patient for a touch screen dietary intervention. Depending on the volume of patients seen, the cost per patient in 1997 ranged from \$115 to \$139, with a cost per unit reduction of cholesterol between \$7 to \$8.40 and a cost per 1% reduction in fat of \$52 to \$63. One study looked at health behaviour and resource utilisation but found no significant difference between intervention or control groups (Lorig et al. 2010a).

Behaviour Change Techniques (BCTs)

The behaviour change techniques used in each intervention are described in Table 3-3. These have been grouped according to their apparent impact on HbA1c when used in interventions included in this systematic review in Table 3-4. The two behaviour change techniques used most commonly by interventions that had a significant impact on HbA1c were: 'Prompt self-monitoring of behavioural outcome' and 'Provide feedback on performance'. In contrast, 'Provide information on consequences of behaviour in general', 'Goal setting (behaviour)' and 'Barrier identification/Problem solving' were the behaviour change techniques most commonly associated with interventions that had no significant impact on HbA1c.

To facilitate the interpretation of the subgroup analysis described in section 3.5.8 looking at the impact of mobile-phone based interventions, the BCTs used by mobile phone interventions have been shown in Table 3-5.

Table 3-3 Behaviour Change Techniques used by interventions

| Characteristic Study ID | Intervention | Control |
|----------------------------|--|---|
| Christian 2008 | Provide information on consequences of behaviour in general Goal setting (behaviour) Goal setting (outcome) Barrier identification/Problem solving Prompt review of behavioural goals Motivational interviewing | Provide information on consequences of behaviour in general |
| Glasgow 1997 | Goal setting (behaviour) Goal setting (outcome) Barrier identification/Problem solving Prompt review of behavioural goals Use of follow up prompts | Not stated |
| Glasgow 2003 | Peer support intervention: Provide information on consequences of behaviour in general Facilitate social comparison | Provide information on consequences of behaviour in general Goal setting (behaviour) |
| Glasgow 2005 | Goal setting (behaviour) Barrier identification/ Problem solving Use follow-up prompts | Provide information on consequences of behaviour in general |
| Glasgow 2006 | Goal setting (behaviour) Barrier identification/Problem solving Prompt review of behavioural goals Use follow-up prompts Motivational interviewing | Provide information on consequences of behaviour in general |
| Glasgow 2010 | Provide information on consequences of behaviour in general Goal setting (behaviour) Barrier identification/Problem solving Provide feedback on performance | Provide information on consequences of behaviour in general |
| Leu 2005 | Teach to use prompts/cues | Not stated |
| Lim 2011 | Prompt self-monitoring of behaviour Provide feedback on performance Teach to use prompts or cues | Not stated |
| Lo 1996 | Provide information on consequences of behaviour in general | Provide information on consequences of behaviour in general |
| Lorig 2010 | Provide information on consequences of behaviour in general Provide information about others' approval Provide normative information about others' behaviour Barrier identification/Problem solving Prompt self-monitoring of behavioural outcome Emotional control training | Not stated |
| Quinn 2008 | Prompt self-monitoring of behavioural outcome Provide feedback on performance Provide information on where and when to perform the behaviour | Prompt self-monitoring of behavioural outcome |
| Quinn 2011 | Prompt self-monitoring of behavioural outcome Provide feedback on performance | Not stated |
| Smith 2000 | Provide information on consequences of behaviour in general Plan social support/social change | Provide information on consequences of behaviour in general |
| Wise 1986 | Provide information on consequences of behaviour in general | Not stated |
| Yoo 2009 | Provide information on consequences of behaviour in general Provide information on consequences of behaviour to the individual Prompt self-monitoring of behaviour Prompt self-monitoring of behavioural outcome Provide feedback on performance Provide information on where and when to perform the behaviour Teach to use prompts or cues Fear arousal | Not stated |
| Zhou 2003 | Action planning | Goal setting (behaviour) |

Table 3-4 Behaviour change techniques grouped by impact on HbA1c

| Behaviour change technique (BCT) | Number of interventions using BCT with a significant impact on HbA1c | Number of interventions using BCT with no impact on HbA1c |
|---|--|---|
| Prompt self-monitoring of behavioural outcome | 4 | |
| Provide feedback on performance | 4 | 1 |
| Provide information on consequences of behaviour in general | 2 | 5 |
| Prompt self-monitoring of behaviour | 2 | |
| Provide information on where and when to perform the behaviour | 2 | |
| Teach to use prompts or cues | 2 | 1 |
| Provide information on consequences of behaviour to the individual | 1 | |
| Provide information about others' approval | 1 | |
| Provide normative information about others' behaviour | 1 | |
| Fear arousal | 1 | |
| Emotional control training | 1 | |
| Barrier identification / problem solving | 1 | 5 |
| Facilitate social comparison | | 1 |
| Goal setting (outcome) | | 2 |
| Motivational interviewing | | 2 |
| Prompt review of behavioural goals | | 3 |
| Use of follow up prompts | | 3 |
| Goal setting (behaviour) | | 5 |

Table 3-5 Behaviour change techniques: mobile phone interventions

| Study: | Behaviour change techniques used |
|-----------|--|
| Lim 2011 | Prompt self-monitoring of behaviour |
| | Provide feedback on performance |
| | Teach to use prompts or cues |
| Quin 2011 | Prompt self-monitoring of behavioural outcome |
| | Provide feedback on performance |
| | Provide information on where and when to perform the behaviour |
| Yoo 2009 | Provide information on consequences of behaviour in general |
| | Provide information on consequences of behaviour to the individual |
| | Prompt self-monitoring of behaviour |
| | Prompt self-monitoring of behavioural outcome |
| | Provide feedback on performance |
| | Provide information on where and when to perform the behaviour |
| | Teach to use prompts or cues |

Classification using taxonomy for education:

There were too few papers with too little detail about the education components to allow meaningful use of the taxonomy for educational interventions.

3.5.8 Subgroup analysis

There were sufficient data to perform subgroup analyses on the following.

- Duration of intervention.
- Settings: when looking at different settings, the distinction between primary care, outpatient or community setting could not be meaningfully applied to self-management interventions. It was more meaningful to divide the interventions settings into clinic-based (touch screen or other clinic computer), home digital and mobile phone-based interventions.

It was not possible to gather enough data to undertake the other planned subgroup-analyses.

The studies were divided into short-to-medium term outcomes (follow-up less than six months) and medium-to-long term outcomes (follow-up for six months or longer). When outcomes at less than six months were combined (Glasgow et al. 2006;Glasgow et al. 2010;Leu et al. 2005;Yoo et al. 2009;Zhou et al. 2003), heterogeneity was reduced ($I^2 = 43\%$) with a larger effect size for HbA1c of -3.5 mmol/mol or -0.3% (95% CI -0.6 to -0.1). Combining studies with outcomes measured at six months or later (Christian et al. 2008;Glasgow et al. 2003;Glasgow et al. 2005;Lim et al. 2011;Lorig et al. 2010a;Quinn et al. 2011) the overall effect size for HbA1c was smaller and no longer statistically significant: MD -1.5 mmol/mol or -0.1% (95% CI -0.3 to 0.1). Heterogeneity was still substantial ($I^2 = 61\%$).

Combining the three mobile phone-based interventions in the meta-analysis (Lim et al. 2011;Quinn et al. 2011;Yoo et al. 2009) found a statistically and clinically significant reduction in HbA1c of -5.5 mmol/mol or MD of -0.5% (95% CI -0.7 to -0.3) and heterogeneity decreased dramatically ($I^2 = 0\%$). Interventions delivered at home (Glasgow et al. 2003;Glasgow et al. 2010;Lorig et al. 2010a;Zhou et al. 2003) appeared to have a smaller effect: MD -2.7 mmol/mol or -0.3% (95% CI -0.5 to -0.04%) and the result was still associated with moderate heterogeneity ($I^2 = 47\%$).

3.5.9 Sensitivity analysis

There were insufficient data to perform most of the sensitivity analyses proposed in the protocol stage. The studies that had mixed populations of type 1 and type 2 diabetes did not have enough data to be used in the main meta-analysis. Using a fixed-effect model for the meta-analysis of effects of the interventions on HbA1c, the pooled effect on HbA1c is -1.7 mmol/mol or -0.2% (95% CI -0.3 to -0.1) - smaller than when using the random-effects model, but still statistically significant.

A sensitivity analysis to look at unit of analysis issues was carried out by removing two studies that were cluster-randomised (Glasgow et al. 2005; Quinn et al. 2011). The pooled effect on HbA1c increased slightly to a MD of -2.4 mmol/mol or -0.2% (95% CI -0.4 to -0.1) and remained statistically significant.

One study included in the meta-analysis (Glasgow et al. 2003) did not provide details of numbers of participants in each group. It was assumed that equal numbers of participants were allocated to each arm of the trial but no allowance was made for attrition and therefore, the study is likely to be over-powered in the final meta-analysis. Removing this study from the meta-analysis had no significant effect on the results other than slightly smaller confidence intervals: pooled effect size is a MD of -2.3 mmol/mol or -0.2% (95% CI -0.4 to -0.04%).

3.6 Discussion

3.6.1 Summary of main results

16 randomised controlled trials with 3578 participants fit the inclusion criteria. These studies included a wide spectrum of interventions covering clinic-based brief interventions, Internet-based interventions that could be used from home and mobile phone-based interventions. The mean age of participants was between 46 to 67 years old and mean time since diagnosis was 6 to 13 years. The duration of the interventions varied between 1 to 12 months. There were three reported deaths out of 3578 participants. Overall, digital diabetes self-management interventions showed evidence of limited effectiveness. They appear to have small benefits on glycaemic control (pooled effect on glycosylated haemoglobin A1c (HbA1c): -2.3 mmol/mol or -0.2% (95% confidence interval (CI) -0.4 to -0.1; $P = 0.009$; 2637 participants; 11 trials). The

effect size on HbA1c was larger in the mobile phone subgroup (subgroup analysis: mean difference in HbA1c -5.5 mmol/mol or -0.5% (95% CI -0.7 to -0.3); $P < 0.00001$; 280 participants; three trials). Interventions did not show adequate evidence for improving depression, health-related quality of life or weight. Four (out of 10) interventions showed beneficial effects on lipid profile. One participant withdrew because of anxiety but there were no other documented adverse effects. Two studies provided limited cost-effectiveness data - one study suggested costs per patient of less than \$140 (in 1997) or 105 Euros and another study showed no change in health behaviour and resource utilisation.

3.6.2 Primary outcomes

Eleven studies provided enough data about glycaemic control to use HbA1c in a meta-analysis. The pooled results indicate that there is a small, statistically significant difference in the outcomes between intervention and comparator groups of -2.3 mmol/mol or -0.2% (95% CI -0.4 to -0.1) that favours the interventions. This was associated with substantial heterogeneity ($I^2 = 58\%$). However, the impact on HbA1c was larger in the mobile phone subgroup with a pooled effect on HbA1c from three studies of -5.5 mmol/mol or -0.5% (95% CI -0.7 to -0.3) and no heterogeneity ($I^2 = 0\%$). The effects of digital interventions may wear off over time as combining results from studies lasting six months or longer showed the overall effect size for HbA1c was smaller and no longer statistically significant: -1.5 mmol/mol or -0.1% (95% CI -0.3 to 0.1).

Five studies looked at health-related quality of life (Glasgow et al. 2005; Glasgow et al. 2006; Lorig et al. 2010a; Quinn et al. 2011; Smith et al. 2000), but there was no evidence to show any significant improvement with the digital interventions.

A total of three deaths out of 3578 participants were reported in the 16 studies.

Cognitive impact of digital diabetes self-management interventions

There was some evidence to show digital interventions have positive effects on two possible mediators: knowledge and self-efficacy. However, there seemed to be difficulty in converting the positive effects on knowledge and self-efficacy into behavioural change such as physical activity: in only two out of five studies did there appear to be an increase in physical activity.

Six studies measured effects on diet and five showed some statistically significant improvements in questionnaire scores - but the clinical benefits and impact on health outcomes of these changes is unknown as the effects of interventions on weight or body mass index (BMI), were not convincing with no statistically significant improvements in weight seen when the results from five studies were combined in a meta-analysis (Figure 3-7).

3.6.3 Effect of the interventions on biological outcomes

The evidence for digital self-management interventions improving blood pressure was mixed. A brief touch screen intervention aimed at increasing physical activity had no significant effect on blood pressure but two more intensive interventions - a pager intervention and a mobile phone-based intervention - showed statistically significant improvements in blood pressure. This might suggest that improving blood pressure requires more frequent interactions and helps increase adherence with medication.

Effects of these interventions on cholesterol were quite mixed. Four studies showed evidence of improvement, three showed no difference. One of the studies that demonstrated a statistically significant improvement in lipid profile attributed this effect to changes in medication rather than the intervention - so it appears there were three studies showing benefits and three showing no difference. Overall, when seven studies providing sufficient data were combined in a meta-analysis, the pooled effect showed no statistically significant effect.

3.6.4 Behaviour change techniques used by the intervention and mechanisms of action

There is a cluster of techniques associated with positive outcomes that have been identified in meta-regression analyses of interventions to increase physical activity and healthy eating (Dombrowski et al. 2011; Michie et al. 2009a). The cluster of techniques is consistent with Control Theory (Carver et al. 1982) which postulates that there is a synergistic association between receiving information about one's behaviour (via 'self-monitoring' or 'feedback') and having a strategy for acting on this information ('action planning' or 'information on where and when to perform the behaviour'). The former provides a cue and/or motivation for the latter. Overall, in the interventions we looked at in this

review, goal setting was associated with ineffective interventions. This may be because goal setting was very rarely included in the same interventions as feedback or self-monitoring. Five interventions used goal setting as part of the intervention (Christian et al. 2008;Glasgow et al. 1997b;Glasgow et al. 2005;Glasgow et al. 2006;Glasgow et al. 2010), but only one of the interventions provided feedback on how the participant was doing (Glasgow et al. 2010). Control theory would predict that goal setting would be less effective if presented without feedback. The finding may also be the result of goals being suggested by health professionals or computer programs rather than being set by participants themselves or in a collaborative way. However, this level of detail was not provided in the descriptions of the interventions in published reports.

On the subgroup analysis looking at mobile phone-based interventions (Lim et al. 2011;Quinn et al. 2011;Yoo et al. 2009), all of these interventions provided feedback on performance and provided prompts or cues for desired behaviour around blood glucose self-monitoring (see Table 3-5). This subgroup was associated with a larger improvement in HbA1c than other interventions, which suggests that the effects of interventions for blood glucose self-monitoring might be explained by control theory. Developing an understanding of the theoretical basis of effective interventions can inform the future development of more effective interventions.

Theoretical basis for the interventions:

Only seven interventions mentioned a theoretical basis. However there was little detail as to how the theories were applied. Social Cognitive Theory was the most commonly used theory and five interventions measured self-efficacy as a potential mediator for the intervention action. It was not clear from the reports what the active ingredients of the interventions were and how they might affect proposed causal mechanisms. When the interventions were coded using the BCT taxonomy the most common mechanism of action that linked interventions with their stated models was using problem solving and barrier identification to improve self-efficacy. Lorig 2010 was the only study that measured self-efficacy and this study reported a statistically significant improvement in self-efficacy and an improvement in HbA1c. This study report provided evidence that

supported the proposed theoretical basis for the intervention design. However the majority of BCTs used by this intervention did not focus on self-efficacy so it is also possible that mechanism of action was not purely mediated through self-efficacy. The use of the BCT taxonomy to analyse proposed mechanisms of actions facilitated a more detailed exploration of the potential causal pathways of these complex interventions than simply relying on study reports.

3.6.5 How the findings of this review fit in with existing evidence

The findings of this review complement reports from other reviews of the literature. These reviews have reported positive effects of interventions on knowledge and some showed evidence of short-term improvements in HbA1c, (Costa et al. 2009; Cotter et al. 2014; Jackson et al. 2006; Pereira et al. 2015). These findings are similar to the pattern of outcomes reported in this review and reviews of face-to-face self-management interventions (Norris et al. 2002). Sustained improvements in self-care behaviour might require more intensive or sustained interventions. A recent review of education interventions found that education programmes offering ongoing support beyond education (usually 11 or more contact hours) were more effective and people with poor glycaemic control benefitted the most (Pillay et al. 2015).

The types of interventions being developed has also evolved with mobile phone based applications (mHealth) becoming more popular, particularly the use of text messaging (Bin-Abbas et al. 2014; Capozza et al. 2015). Given the potentially higher efficacy of such interventions seen in this review and the growing uptake of mobile phones and mobile internet, this has the potential to continue to improve the reach and impact of digital interventions for diabetes self-management.

3.6.6 Quality of the evidence

All of the studies included in the review are RCTs but the quality of the trials was variable. Most studies did not provide details about the randomisation process and assessor blinding so it is difficult to make a judgement about how biased some of the studies are. The nature of some of the trials and the intervention/control combination would have made it impossible to blind the

participants. Some of the control groups had quite active treatment - e.g. apparent significant increases in hypoglycaemic medication, a control arm that included goal setting or increased monitoring by healthcare providers - that might reduce the apparent effectiveness of the interventions.

Most of the study reports did not provide details about how hypoglycaemic medication changed in groups over the duration of the trials. Potentially this is an important issue - one study (Christian et al. 2008) suggested that the control group had significantly larger increases in hypoglycaemic medication during the study as part of usual care and this is why the control group had better glycaemic control at the end of the trial. However, the opposite is also possible - if better informed or self-managing patients take more interest in their treatment and are therefore more likely to increase their medication then the success of these interventions would be due to improved concordance with treatment rather than due to changes in lifestyle. If digital self-management interventions mainly act through improving effectiveness of existing treatments rather than directly affecting patient outcomes this would still be an important potential benefit of these interventions as long as this was due to change in patient behaviour. However, if intervention groups had their medication increased by their medical teams simply due to increased monitoring as part of trial procedures, it would not be appropriate to describe this as a beneficial effect of the interventions.

The interventions appear to be quite heterogenous and the length of follow-up varied from 2 to 12 months. All the interventions looked at effects on HbA1c as an important outcome, but the other primary and secondary outcomes varied greatly and the instruments used to measure them were often different, which made it very difficult to compare or synthesise the results from different studies.

3.6.7 Potential biases in the review process

The searches were performed on electronic bibliographic databases but most of these were medical. We did not explore non-medical sources so we might have missed some digital research. Intervention descriptions were usually brief so in spite of clearly defining our intervention in the protocol, deciding which interventions fitted our definition of a digital self-management intervention often required discussion with the steering group and judgements based on limited

descriptions and interpretation. Although we looked for unpublished data, we were unable to find any unpublished RCTs that fulfilled the inclusion criteria so the review contains published data only. The complex nature of these interventions meant that there were a large number of primary and secondary outcomes for which data were extracted, but these were specified in advance in the protocol and we have only reported on outcomes specified in the protocol.

3.6.8 Mode of delivery

A more recent review focused only on the effect of mobile phone interventions for diabetes on glycaemic control (Liang et al. 2011) and reported on a meta-analysis of 22 trials with 1657 participants. This showed that mobile phone interventions for diabetes self-management reduced HbA1c values by a mean of 6 mmol/mol or 0.5% (95% CI 0.3 to 0.7) over a median follow-up duration of six months. This is similar to the effect size seen in this review when the effects of the three mobile phone interventions were pooled (Lim et al. 2011; Quinn et al. 2011; Yoo et al. 2009).

3.6.9 Duration and intensity of interventions

A meta-analysis of 47 randomised controlled trials of self-care management intervention in type 2 diabetes has been mentioned previously (Minet et al. 2010). The meta-regression undertaken in this review suggested that 1. self-care management interventions might have a higher effect if the programme was compact with sessions closely grouped together; and 2. the effect of self-care management interventions might decrease over time. The authors suggested that providing sessions more closely grouped together, as noted in the shorter interventions, might have allowed participants to remember and better synthesise the information, thus potentially increasing their effectiveness. Uptake and usage of interventions was poorly reported. The challenges faced by online interventions with attrition were discussed in Chapter 1 and therefore data regarding users' interactions with the intervention would have been useful and should be better reported for future interventions.

3.6.10 Effects on diet and weight

A recent systematic review looked for evidence that the use of interactive electronic media to facilitate dietary behaviour change and found no evidence of their effectiveness and that they were at least as expensive as other individual behaviour change interventions (Harris et al. 2011).

3.6.11 Summary

This review supports the findings of the reviews above which suggest that, although popular, digital diabetes self-management interventions have limited evidence supporting their use. These interventions are poorly understood and more research is needed into their design, delivery and effectiveness and future interventions would benefit from evidence-based components and more detailed reporting and evaluation. This review also supports the suggestions that 1. mobile phone-delivered interventions may be more effective than interventions delivered over the Internet and 2. compact programmes with frequent sessions might be more effective, but the benefits could be short-lived.

3.7 Conclusions

3.7.1 Implications for practice

The interventions included in this review showed a heterogeneous and small, often short-term improvement in HbA1c, although they did not show adequate evidence for improving other biological outcomes or any cognitive, behavioural or emotional outcomes. The effect on blood glucose was larger in the mobile phone subgroup - possibly due to interventions using control theory being more effective than interventions based on other theories. There was no evidence of harm from using such interventions. Patients wanting to use such interventions might benefit but evidence of more effective interventions would be necessary prior to actively recommending their widespread use.

3.7.2 Implications for research

There findings summarised above show that there was scope to significantly improve the impact of digital self-management interventions and the remainder of this thesis has described the approach taken to designing a new intervention

that built on this evidence, starting with the work done on developing the theoretical basis described in Chapter 2.

The small treatment effect (2.3 mmol/mol or 0.2%) on glycosylated haemoglobin A1c (HbA1c) with digital self-management interventions is a difference that would be important if it could be achieved and sustained across the population via the Internet at very low cost, but far from cost-effective if it required significant nursing support and/or additional drugs. However, there is currently no clear distinction in the literature between interventions that use information technology (IT) to deliver relatively automated digital behaviour change support, and those interventions that use information technology to deliver health professional-based behaviour change support by using IT for remote consultations ('tele-health'). In view of the adoption of such interventions based on potential cost-effectiveness, making that distinction is likely to be important and it would be helpful if interventions were designed, described and tested with that in mind.

There were few published protocols for the studies and the theoretical basis, active ingredients and 'dose' of the intervention were not always clearly described in the published reports. As these interventions are therapeutic agents, it may be beneficial to explicitly 'prescribe' interventions for trials and formally state the active ingredients (behaviour change techniques), dose (frequency and intensity of interactions), route (mode of delivery - Internet, mobile phone etc) and duration of treatment.

It is not clear why interventions delivered over mobile phones appear to be more effective - it could be due to convenience (and therefore adherence), intensity of the interventions (mobile phone interventions were more likely to have multiple daily contacts) or the behaviour change techniques used by the interventions (mobile phone interventions were more likely to use cues to prompt behaviour and provide rapid feedback afterwards).

Most studies did not report on any changes in hypoglycaemic medication in intervention or control groups. Without that information it is difficult to determine

whether changes in HbA1c are due to changes in behaviour or changes in medication. It is possible that the benefits of self-management interventions might be due to better concordance with existing treatment or more intensive treatment requested by more engaged patients. It would be helpful if future studies provided more detail on changes in hypoglycaemic medication during the study to explore this further.

All the studies that looked for improvements in possible mediators such as knowledge and self-efficacy reported positive effects, but more research is needed into translating those improvements into improvements in health outcomes. It is also currently not obvious what the clinical significance of the small improvements in diet and blood pressure seen in current interventions is likely to be, so more research is needed on this.

This review suggests that current interventions do not improve depression, weight loss, physical activity or blood lipid profiles so interventions to target these areas need to be designed differently to existing interventions.

More studies need to be done looking at the cost-effectiveness of different types of digital interventions. Studies with longer follow-up are needed to determine the long-term impact on health outcomes of these interventions and look for evidence of harm.

There also needs to be more research to determine which population groups will benefit the most from these interventions, e.g. HbA1c greater than 53 mmol/mol or 7%. It would also be important to explore the impact of these interventions on older patients. However, it is important to consider that older patients would include people with new onset type 2 diabetes that is slowly progressive, and those that have long-standing diabetes with more advanced disease and the same intervention might not be appropriate for both groups.

3.7.3 Implications for design of an online self-management intervention for adults with type 2 diabetes

This review informed the development of the intervention described in this thesis in a number of ways.

There was clear evidence that online self-management interventions could improve HbA1c and it provided an estimate of effect size. The larger impact was through mobile phones interventions which often interacted with patients through Short Message Service (SMS) text messages. This highlighted the potential importance of new modes of delivery and the need to have SMS functionality and be able to push content to users.

The review also highlighted the potential for theoretically grouped clusters of BCTs and the importance of prompts and feedback in addition to goal setting and action planning when supporting behaviour change. Control theory was one of the key theories of behaviour change used to help guide the intervention development.

The review also highlighted areas where such interventions have struggled to make an impact. The absence of evidence supporting improvements in depression, weight loss and physical activity encouraged us to seek better evidence-based components to integrate into the intervention. As computerised Cognitive Behavioural Therapy (cCBT) has been shown to be effective for treating depression, a specific cCBT programme (Living Life to the Full) was incorporated into the programme rather than relying on generic self-management support to improve low mood. Similarly, a proven online intervention (POWeR) was incorporated to support weight loss and physical activity.

4. Patient preferences for an online diabetes self-management intervention

4.1 Chapter outline

The first three chapters have focused on the elements of diabetes self-management described in the literature and linked theoretical concepts. This chapter has focused on user defined requirements by describing a study to determine patient preferences for a self-management intervention for adults with type 2 diabetes. This was a qualitative study with 20 participants and the following sections have described the rationale for this work, a description and justification for the chosen methods for data collection, a summary of the important findings from the data and the conclusions drawn from a thematic analysis. The way in which these findings were used to develop the intervention has been described in Chapter 6.

4.2 Introduction

The importance of diabetes self-management education has led to the publication of national diabetes self-management education standards in the guidance for the care of type 2 diabetes in many countries e.g. Standards of Medical Care in Diabetes published by the American Diabetes Association (Diabetes Care 2013) and CG87 Type 2 diabetes published by the National Institute for Health and Care Excellence (NICE) in the UK (National Institute for Health and Care Excellence 2009). The International Diabetes Federation has also produced a curriculum for professional self-management education (International Diabetes Federation Consultative Section on Diabetes Education 2009). However patient priorities for education can be very different to professional priorities (Beeney et al. 1996;Genev et al. 1992). Therefore simply designing an intervention based on professional perspectives may not meet patient needs.

Another key challenge is that internet interventions often have problems attaining sufficient user engagement. This can include difficulties with low uptake in the target population (Kohl et al. 2013;Linke et al. 2007) and/or high levels of attrition and decreasing usage over time (Wangberg et al. 2008). User

engagement with interventions can be influenced by user perceptions (Crutzen et al. 2011) and intervention design (Brouwer et al. 2011b). User perceptions have both cognitive and affective elements (Cyr et al. 2009). Proposed cognitive drivers for user engagement include efficiency (ease of finding what users are looking for), effectiveness (impact of use) and trustworthiness. Important affective elements have been identified as enjoyment and interest (Crutzen et al. 2014). Enjoyment can be defined as a general positive disposition and liking of media content (Nabi et al. 2004), while interest motivates learning about something new and complex (Silvia 2008). Users need to be interested to initially visit the website and then need to enjoy using the intervention to stay engaged (O'Brien et al. 2008). With regards to understanding attrition, revisiting a website is associated with higher levels of education, being older and a positive affective user experience (Van't Riet et al. 2010). Creating interventions that are interesting, enjoyable and useful for participants is therefore an important objective for effective intervention design and qualitative work to explore and understand the patient perspective can help this.

The existing literature gives us some idea of whether adults with type 2 diabetes are likely to use a web based self-management programme and what they would want from it. According to data published in the last 2 years, 40-50% of adults in the US and in the UK already use the internet to access health information (Amante et al. 2015;Office for National Statistics 2014;Pew Internet & American Life Project 2013).

A previous qualitative study looked at a broad spectrum of patients with chronic illnesses (including diabetes, heart disease and hepatitis C) to look at what patients would want from a high quality internet intervention (Kerr et al. 2006). Examples of features identified include:

1. The information content should be detailed, specific and of practical use and should take into account the changing requirements as patients became more experienced at self-management
2. Users should have control over the information and it should be easily accessible and pitched at the right level for the user
3. The web design should make the intervention attractive, engaging, understandable, varied and easy to navigate.

Tailoring such features for a defined patient group requires an understanding of the specific healthcare needs of people living with that condition. Healthcare need is the capacity to benefit from health care, and these benefits can be a change in clinical status but can also include reassurance, supportive care, and the relief of carers (Stevens et al. 1998). Needs include both met and unmet needs, and this allows for prioritising the allocation of resources for improving the quality of service provision (Boberg et al. 2003). Doing a needs assessment for people suffering with a chronic illness requires a combined approach that assumes that neither healthcare providers nor patients, on their own, have a complete view of what the healthcare needs are for the patient (Gustafson et al. 1993). Seeing the whole picture requires a combination of literature review and qualitative methods to explore the professional perspective (derived from clinical experience and the current evidence base), combined with ways of exploring the patient perspective through tools like surveys, focus groups and in-depth interviews (Boberg et al. 2003).

Previous studies have illustrated how professionals and patients vary slightly in their priorities – e.g. around the time of being diagnosed with diabetes, both patients and professionals focus on injections and the impact on lifestyle (Beeney et al. 1996). However, professionals can significantly overestimate the threat of complications as a major concern to patients soon after diagnosis and not recognise uncertainties such as perceived inability to cope and the importance of dietary restrictions. Professionals can also over-estimate the emotional impact of diagnosis and under-estimate the information requirements at diagnosis of diabetes (Peel et al. 2004a).

This study built on the previous work to explore patient defined needs for internet-based self-management interventions for adults with type 2 diabetes. It explored patient defined elements that would improve their ability to self-manage their illness and engage and retain their interest.

However, the ultimate aim of this work was to inform the development of an effective self-management intervention. It was also therefore necessary to put the findings into the context of effective intervention design. Examples of design features that may be important for effective interventions include social context

and support, intervention usage and tailoring (Morrison et al. 2012). The intervention should also reflect a whole systems approach for self-management that targets patients, professionals and health care systems (Kennedy et al. 2007b).

Interaction design is the process of designing interactive products to support the way people communicate and interact in their everyday and working lives (Rogers et al. 2011). It is a multi-disciplinary process that can require input from

- stakeholders with domain specific knowledge (e.g. doctors and nurses)
- user representatives (e.g. people living with type 2 diabetes)
- interaction designers (e.g. experts in human-computer interactions)
- graphic designers
- systems analysts (IT professionals who specialise in analysing, designing and implementing information systems to assess the suitability of information systems in terms of their intended outcomes and liaise with end users, software vendors and programmers in order to achieve these outcomes)
- software engineers (e.g. programmers).

Integrating multi-disciplinary perspectives can be challenging due to different terminology and disciplinary norms (Kim 1990). However the synthesis of these skill sets is crucial to achieving the aims of interaction design, which fall into 2 main categories – usability goals and user experience goals (Rogers et al. 2011).

Usability goals can be defined by the questions they seek to address as illustrated in Table 4-1 below.

Table 4-1 Usability goals and questions that can be used to evaluate their implementation [adapted from Rogers and others 2011]

| Goal | Assessment |
|---------------|---|
| Effectiveness | Is the product capable of allowing people to achieve what they want to do with the product? |
| Efficiency | Once users have learned how to use a product to carry out their tasks, can they sustain a high level of productivity? |
| Safety | What is the range of errors that are possible using the product and what measures are there to permit users to recover easily from them? |
| Utility | Does the product provide an appropriate set of functions that will enable users to carry out all their tasks in the way they want to do them? |
| Learnability | Is it possible for the user to work out how to use the product by exploring the interface and trying out certain actions? How hard will it be to learn the whole set of functions this way? |
| Memorability | What kinds of interface support have been provided to help users remember how to carry out tasks, especially for things used infrequently? |

User experiences are more subjective and can be viewed as desirable or undesirable and common examples of such experiences can be found in Table 4-2.

Table 4-2 Common examples of different types of user experience [Adapted from Rogers and others 2011]

| Desirable experiences | Undesirable experience |
|-------------------------|--------------------------|
| Satisfying | Boring |
| Enjoyable | Frustrating |
| Pleasurable | Making users feel guilty |
| Exciting | Annoying |
| Entertaining | Childish |
| Helpful | Unpleasant |
| Motivating | Patronizing |
| Challenging | Making users feel stupid |
| Enhancing sociability | Cutesy |
| Supporting creativity | Gimmicky |
| Cognitively stimulating | |
| Fun | |
| Provocative | |
| Surprising | |
| Rewarding | |
| Emotionally fulfilling | |

Examples of features used in existing interventions to improve the user experience include making fonts consistent, use of logos and pictures, use of bold to emphasise key points and improve design, repeatedly emphasising the basic structure of the site and the programme, including a screencast video to demonstrate the site, removing unhelpful jargon and terminology, managing expectations about the site in general and personalising the 'source' by providing details about the development team (Michie et al. 2012a). User expressed needs about the detail and degree of tailoring of information

provision varies considerably and it may not be possible to have a consensus on a format that satisfies all users (Yardley et al. 2010).

Electronic medical records

An online intervention has the potential to interface with the electronic medical record. Improving patient access to medical records has a number of potential benefits including improving doctor-patient communication, supporting patient empowerment, improving the quality of medical documentation and improving patient satisfaction (Ross et al. 2003). However increasing patient access to electronic medical records is a challenging area where patient-centred care, political mandates, information governance standards, data sharing concerns, limited evidence and health professional anxieties about litigation and workload create a complex environment with conflicting priorities (Rafi et al. 2013). The concern about increasing health professional workload from patient anxiety or medico-legal challenges has contributed to resistance to increasing patient access to medical records from health professionals (Ross et al. 2003). When this study was conceived and the interviews done there was some evidence that suggested potential for benefits with patient access to medical records (Bhavnani et al. 2011), but such access was not widely available to patients often due to resistance from health professionals.

As the benefits of patient to medical records were not clearly established and there were professional concerns about improving access, we wanted to explore the views of patients to understand if patients felt access to records was important and how it might be used and this was incorporated into the topic guide.

4.3 Aims of the study

Primary objective

To determine the patient perspective on essential and desirable features of an online self-management intervention (OSMI) for adults with type 2 diabetes.

Secondary objectives

1. To explore patient perspectives on features that would promote ongoing engagement with a OSMI for adults with type 2 diabetes
2. To explore patient views on access to their electronic health records

4.4 Methods

4.4.1 Design

The objectives described above are focused on exploring the patient perspective on a type of intervention that most participants would not currently be using – when the study was conceived there were no online self-management interventions for diabetes widely used by people in the UK. Participants were being asked to reflect on their current experience and extrapolate this to a hypothetical scenario of using a new online intervention.

The use of qualitative methods allowed an in-depth exploration of the existing needs of patients, the context in which the intervention might be used and potential uses of new technology and an OSMI. Participants could explore the issues of importance to them, in their own words, generating their own questions and focusing on their own priorities (Ritchie et al. 2014).

Group discussions can help people explore and clarify their views in ways that might be more difficult in individual interviews (Kitzinger 1995). The interplay between participants allows for ideas to be generated, reflected on and debated (Ritchie et al. 2014); and it was hoped understanding the spectrum of responses to possible features could provide valuable data for intervention design and prioritising development. For potentially controversial issues like access to electronic medical records, such discussions could yield richer data than simply exploring individual ideas or preferences on this topic. For this reason, focus groups were chosen as the main method for data collection.

Group dynamics also involve many different forms of communication that people use in day to day interaction, like jokes, anecdotes, teasing, and arguing. These “natural” forms of communication could allow a more nuanced appreciation of what people know or experience and reveal “shared truths”. It is likely that a self-management intervention that reflects the language used by

patients and deals with the questions that are important to them will be able to engage with users better. Another potential advantage of focus groups was that the safety of a well-run group could draw contributions from naturally shy or withdrawn participants and encourage participation by people who cannot read or write or have low health literacy. This was particularly important as internet interventions may be at risk of excluding certain populations on the wrong side of the “digital divide” - this is explored in more detail below. The disadvantage of focus groups was the risk of dominant participants suppressing views that fall outside the social norms of the group and some participants may find it difficult to discuss sensitive or potentially embarrassing topics like sexual dysfunction that can be a common complication of diabetes.

If data about sensitive topics like erectile dysfunction was absent from focus groups, individual interviews would have been arranged to explore these. However these topics were raised from the first focus group and therefore further individual interviews were not needed.

4.4.2 Ethics and research governance

The study was reviewed by the North West London Research and Ethics Committee and granted ethical and R&D approval on 10/11/2011. The REC reference number is 10/H0722/86. Ethical approval was granted for the work described in this chapter, the work done in chapter 6 and development of the intervention. A copy of the approval letter can be found in Appendix 5. The ethics committee and our funding body (NIHR) had both advised that pregnant patients be specifically excluded from the intervention as the needs and risks associated with diabetes in pregnancy were significantly different.

4.4.3 Sampling strategy

Participants were purposively recruited from an adult population (aged 18 or over) with type 2 diabetes. Purposive sampling was used to recruit a maximum variety sample in terms of gender, age, ethnicity, length of time of diagnosis, treatment regimen (diet controlled, oral medication, insulin or both), educational attainment, internet use, presence or absence of diabetes related complications

and previous experience of self-management programmes. The rationale for sampling on these characteristics is described below.

4.4.3.1 Gender

Type 2 diabetes has similar prevalence in men than women in the UK, around 5% (Diabetes UK 2014a). There is evidence of gender differences in help-seeking behaviour and online interactions and so it was important to have both genders well represented to capture this potential variation in intervention use and preferences (Galdas et al. 2005;Klemm et al. 1999).

4.4.3.2 Age, education and internet access: the digital divide

Another consideration was the “digital divide”: this is commonly defined as the gap between those who have and do not have access to computers and the Internet and access is usually highly correlated with income, age, education and occupation (van Dijk 2006). Oxford Internet Surveys (OxIS) provide data about internet use in the UK - the data below in

Table 4-3 illustrates the differences in access in the UK according to income, age and education (Dutton et al. 2013).

Table 4-3 Percentage of people in the UK using the internet in 2013, stratified by income, age and education

| Characteristic | Percentage of people using the internet |
|---------------------|---|
| Income | |
| <£12,500 | 58% |
| >£40,000 | 99% |
| Age | |
| 14-17 years old | 100% |
| 45-54 years old | 85% |
| Over 65 | 39% |
| Education | |
| No qualification | 40% |
| Basic qualification | 84% |
| Higher education | 95% |

Participants selected for the study were purposively sampled to ensure the inclusion of older patients, those with the lowest educational attainment and people not in employment.

4.4.3.3 Ethnicity

There were a number of reasons why ethnicity was an important consideration for sampling. People of South East Asian origin are more likely to develop diabetes and develop diabetes at lower BMIs. Supporting changes to lifestyle factors like diet, physical activity and medical treatment requires a sensitive understanding of religious and social customs. Cultural sensitivity is also an important consideration in trying to engage users from a diverse range of ethnic backgrounds by making the intervention acceptable and relevant to the way they live their lives.

4.4.3.4 Diabetes related complications

Diabetes is a progressive condition and evolving microvascular and macrovascular complications mean that over time the demands on self-management will increase. Early on in the condition, it is likely that management can focus on diet and physical activity and some oral medication. As the condition progresses, people may need to learn to live with problems like poor vision, kidney damage, nerve pain or the consequences of heart attacks, strokes or reduced blood supply to limbs. Treatment is likely to become more intensive with an increase in the number/dose of oral medication and insulin or other injectable medication. Learning to live with new medication or new complications of the condition will place new demands on users and needs will evolve over time. Therefore it was important to have users who represented different stages along the illness trajectory so the full spectrum of needs could be determined.

It was also important to consider the special case of the newly diagnosed patient who is likely to have higher needs for support and information and may be more motivated to engage with a self-management programme.

4.4.3.5 Experience of DSME

Having participants with a range of experience other diabetes self-management education programmes was felt to be important to allow discussions about what

people found helpful, what they disliked and any barriers to attending other self-management programmes.

Recruitment and data collection continued until we reached theoretical saturation with no new themes emerging.

4.4.4 Recruitment

In order to target a broad representative sample of people living with type 2 diabetes, the recruitment strategy focused on community diabetes services which would be expected to have contact with the whole spectrum of people living with this condition. Printed leaflets with information about the study and posters were distributed to GP surgeries in London. Self-management programmes run by local Diabetes support groups were given copies of this material. An advertisement was also placed in Balance magazine printed by Diabetes UK. A copy of the patient information leaflet can be found in Appendix 4.

4.4.5 Data collection:

Demographic questionnaire: all participants were invited to complete a questionnaire to collect details of age, gender, ethnicity, first language, duration of diabetes, current treatment, educational attainment, computer literacy and access to the internet, presence of diabetes related complications and previous experience of self-management programmes. This information was used to recruit a maximum variety sample based on the theoretical rationale described in section 4.4.3. A copy of the questionnaire can be found in Appendix 7.

As the literature already described generic information (including data from some people with type 2 diabetes) about user needs, preferences and criteria for web-based self-management programmes (Kerr et al. 2006), this study was task-oriented, focusing on specific needs and preferences for diabetes self-management supported by an online tool.

The structure of the focus group sessions was based on the way data was collected in a previous extensive review of patient information materials (Coulter

et al. 1998). At the start of the focus group, participants were shown examples of pre-existing diabetes information website and asked to review them. The websites were selected based on a number of criteria. As we were searching for websites that were examples of good practice, a short-list of potential sites recommended by health professionals was selected, supplemented by online searches of national and international diabetes services and charities.

4.4.5.1 Diabetes websites shown during focus groups

The websites were selected based on a number of criteria. They needed to be up-to-date, provide reliable information targeted at lay people with diabetes and written in English. The sites had a range of interactive tools and social media functions providing online self-management support and education. We selected three sites which could be fitted into the allotted time for the focus group discussions. The final sites selected were:

1. The website and social media page of Diabetes UK (www.diabetes.org.uk)
2. My Diabetes My Way - provided by NHS Scotland with sections on self-management support and links to electronic medical records (<http://www.mydiabetesmyway.scot.nhs.uk/>)
3. An educational intervention hosted on the website of the American Diabetes Association (<http://www.diabetes.org/>)

This encompassed a spectrum of websites that showed examples of information provision in the UK and abroad, social media and online self-management support and education.

Asking participants to review the websites served a number of purposes. It allowed an early transition through some of the initial stages of group working with strangers (Tuckman et al. 1977) which meant that when the actual discussion started, participants were more comfortable and nearer optimal group performance. It also grounded the discussions with real examples – although in theory any functionality desired can be created bespoke through the use of technology, the most feasible solutions are likely to represent an evolution or modification of existing functions through iterative improvements. Suggestions or ideas from participants that were based on existing functions

were more likely to be feasible. The risk of showing people existing websites would be narrowing the focus too much and ending up with a limited range of ideas that reproduce current websites and stifle creative suggestions. To counter this, participants were also encouraged to engage in “blue sky thinking” about an “ideal” web-based self-management programme.

4.4.5.2 Focus group discussions

The four focus groups were held in 2 community centres in Camden. The facilities had computer access and rooms suitable for small-group discussions. A venue outside healthcare settings was chosen to put participants at ease and to minimise the impact of the power differentials that might be created in such settings from participants taking on the role of a patient.

Each focus group was run by 2-3 facilitators and lasted up to 4 hours in total. I led two of the focus groups and was a co-facilitator for the two other focus groups. The first 15 minutes was allocated to welcoming participants and introductions, followed by up to 90 minutes exploring the three websites. This was followed by a 30 minute break and then 90 minutes of group discussion. Having more than one moderator was helpful as they took a more observational role to monitor the interactions between facilitator and participant and could pick up on undue prompting or dominance from the main facilitator (Sim 1998). As discussed later in the section on reflexivity, a risk of being a ‘doctor’ in a room full of ‘patients’ could be to inherit the social norms and power inequalities common in that relationship. Having non-medical co-facilitators helped monitor for dynamics that would limit the data generated from the focus groups if the facilitator took on the role of the ‘expert’ and inhibited participant discussions (Sim 1998).

Discussions were semi-structured with a list of topics to be covered (not necessarily in a defined order) during the session and can be found in Appendix 4. The topic guide was piloted in an interview with a patient with type 2 diabetes who had been a PPI representative on previous research done by the unit and then used in the first focus group which was run by EM. There were no

problems with wording or prompts and the discussion flowed well. Minor changes were made to questions about engagement as data emerged suggesting GP practices were unlikely to have the resources to actively promote engagement.

The main topics included discussions about features that patients liked and disliked and the degree to which these interventions could meet their needs. Participants were also asked about self-monitoring, data sharing and engagement with such interventions.

All the focus groups were audio recorded and data stored securely in accordance with the Data Protection Act (1998). Audio files were transcribed by an external company and then personal identifiable data were removed from transcripts. Personal details were kept in encrypted password protected files that were stored in an ISO27001 certified Data Safe Haven provided by UCL.

4.4.6 Data Analysis

4.4.6.1 Cycle 1: Content and Design

Data analysis was done through iterative cycles. The first cycle of analysis was focused deciding the main content and design features of the intervention. This was done with a multidisciplinary team consisting of an experienced medical sociologist (FS), a psychologist (CD), two fully qualified GPs (EM and me) and one GP trainee in the final year of her training (EG). This team represented a broad range of perspectives so the coding and analysis was sensitive to the clinical, sociological and psychological context of the data. Two of the analysts had significant qualitative experience.

Transcripts were independently read by each researcher and themes were extracted. The themes were descriptive (Miles et al. 2014), and used to label design and content features of a digital self-management intervention for adults with type 2 diabetes. This first cycle of analysis was a rapid review to determine the most important features and direction of intervention development. Due to time and financial restrictions for the research programme guiding this study (a

pragmatic one to inform intervention development), this analysis was also used as the basis to make decisions about data saturation and data collection continued until no new data were emerging regarding design or content.

4.4.6.2 Cycle 2: Thematic analysis

The second section of the analysis was a more in-depth exploration of the experiences of patients of living with type 2 diabetes. This work complemented the analysis above as it was focused on understanding the needs of patients, many of which were not currently being well served by existing health or online services. This work had the potential to help a new OSMI move beyond simply offering a better version of what was already available, define and target areas of unmet needs and gain a deeper understanding of the context in which the intervention would be used.

The second cycle of analysis was done by a multidisciplinary team consisting of an experienced medical sociologist (FS), two psychologists (CD and JR) and two fully qualified GPs (EM and me). Once again, transcripts were independently read by each researcher and important themes were identified. The thematic framework was expanded to describe phenomena beyond a simple description of desirable features of the intervention and include the full range of experiences shared by participants to provide a deeper understanding of the needs and wants identified by participants. The emerging themes were discussed at a multi-disciplinary meeting and I led the discussion. These discussions were used as a sensitising framework and I read the transcripts line by line and coded the data. This lead to the generation of more interpretive codes that looked at more macro level phenomena like meanings and relationships (Lofland 1971). I then further revised the coding framework and re-read the data to allow for later stage analysis procedures such as “filling-in” (adding codes or reconstructing a coherent scheme based on new insights), “extension” (returning to materials coded previously and re-interpreting them) and “surfacing” (identifying new categories) (Lincoln et al. 1985). Arrangements were also made for check coding by 2 of the team mentioned above who were familiar with the data (EM and FS). This was to improve the clarity of the definition of the codes and improve reliability (Mishler 1986). The results of the first cycle of analysis were used to guide the initial development of the

intervention while the data presented in the results section and the discussion are based on the second cycle of analysis led by me.

The generation of codes was done inductively based on the data. The underlying sociological theory used to understand the needs of patients was based on Corbin and Strauss' work on managing chronic illness at home as discussed in Chapter 2 (Corbin et al. 1988). The main constructs of the model were used to sensitise and encourage a holistic perspective to explore (i) the impact of type 2 diabetes on people's day-to-day activities, relationships and emotions (life work) (ii) the burden of having to take medicines or make lifestyle changes for the medical management of the condition (illness work) and (iii) the disruption or changes to the roles that patients played within their families and at work (biographical work). I did not use this model to define a priori codes or categories but used it as a sensitising tool to guide an inductive thematic analysis and I generated codes based on the data. The codes were then used in a latent analysis to describe and understand the higher level concepts (Braun et al. 2006) – these were used to define the needs of users and the themes that emerged like the emotional burden of living with type 2 diabetes, the triggers for negative emotions and strategies to try and maintain a positive outlook could all be explained by the types of work described by Corbin and Strauss. This contrasts with the more semantic, descriptive approach taken in the first analysis that was focused on trying to inform an intervention specification for a new OSMI.

Atlas Ti was used to manage data retrieval, transcript coding and to make data analytic notes.

4.4.6.3 Rationale for using thematic analysis

Thematic analysis is a method for identifying, analysing and reporting patterns (themes) within data (Braun et al. 2006). It can be used flexibly across a range of theoretical frameworks to generate rich descriptions of the data set or a detailed account of a particular aspect. This flexibility allowed the creation of deductive themes derived from Corbin and Strauss' model e.g. understanding the emotional work of living with type 2 diabetes or inductive themes generated from the data that described how health services were struggling to meet the needs of people living with type 2 diabetes.

4.4.6.4 Reflexivity

I was reflexive in my analysis by consciously reflecting on issues arising from my personal and professional characteristics. I am a GP from an ethnic minority background with two parents who have type 2 diabetes, and a researcher trying to build a digital intervention that I wanted to believe could benefit people with type 2 diabetes. My questions and interpretations have been influenced by personal and professional experiences, pre-study beliefs, my motivation and qualifications for the research, and the theoretical foundations related to my education and interests (Malterud 2001).

The advantage of being a GP was training in communication skills and the ability to build a rapport with strangers and feeling comfortable talking about personal difficulties, potentially embarrassing topics and illness. However the downside of being a medical professional was the risk of assuming that I already understood the challenges facing patients, feeling defensive of criticisms of health professionals and the risk of perceived power imbalances in interactions with participants in the focus groups. Having parents living with type 2 diabetes has also meant I had personal and emotional experiences associated with the condition and pre-conceived ideas about the challenges facing patients.

I was mindful of my behaviour during focus groups and focused on my role as a researcher and facilitator of discussions. However it was a strength of the research team that it was multi-disciplinary and included a number of non-medical members. Watching how they interacted with the focus group participants and understanding their perspectives on the data helped me evaluate my behaviour and analysis. One example would be comparing my initial reactions to the data and my surprise at other members of the team focusing on the failures of the health care system to meet patient needs. My initial reaction had been to “normalise” these experiences and a tendency to sympathise with the challenges facing the healthcare system. Reflecting on my background and comparing my views with colleagues helped me understand my own perspective and how it was influencing my interpretations.

4.4.6.5 Reactivity

My training as a health professional and experience of taking histories from patients was a significant help in being able maintain a rapport without sharing my opinions and avoiding leading questions. The challenge to my neutrality was the risk of assuming I understood what participants were saying without fully exploring their perspective and letting assumptions or my own interpretations distract me from listening to participants' stories.

4.4.6.6 Rigour

The advantage of this study was the presence of a multi-disciplinary team who provided multiple perspectives that complemented my background and had the skills and experience to interrogate and guide my research work. Data was collected by different people from different professional disciplines (medicine, sociology, psychology) and my analyses were discussed with my supervisors and colleagues on multiple occasions.

4.4.6.7 Transparency

All the material associated with this study was carefully documented and recorded in shared folders that other members of the team had access to. The rationale and methods used for design, sampling and analysing the data have been described above and results have been supported with quotes and clearly labelled sources with participant numbers. Divergent views were sought in the analysis and presented where found. One example would be participant views on peer support. While most participants valued input from peers and felt that lived experience gave opinions a greater weight, others could not bring themselves to believe information that was not from a trusted authority figure.

4.5 Results

4.5.1 *User demographics*

The demographics of the 20 participants are summarised in Table 4-4. Just over half the participants were male, with a mean age of nearly 57. Almost half the participants were retired and over half had degree level qualifications. Seventy per cent of participants (14/20) were White British but Black, Asian and Other (Iranian) ethnicities were also represented. Time since diagnosis ranged from 3 months to 36 years. Treatment modalities included diet only, tablets, insulin and other injectable medication. The overwhelming majority of participants had home internet access and most had used the internet to look up information about diabetes. Sixty per cent of participants (12/20) had been on a diabetes self-management course, but most had never used a computer based self-management programme. Some participants had used spreadsheets to build their own digital self-monitoring systems.

4.5.2 *Overview of results*

Section 4.5.3 describes an analysis of the needs of participants living with type 2 diabetes and the degree to which these were being met by existing services. It uses the Corbin and Strauss model described in Chapter 2 as a framework to help understand the burden that living with this chronic condition placed on participants and how they coped with illness work, life work and biographical work. The main themes and sub-themes have been summarised in Table 4-5. Based on their interactions with the interventions demonstrated in the focus groups and past experience, participants were able to give very clear guidance about what they liked and disliked and how a new OSMI could meet the needs described in Section 4.5.3. The desired features that participants wanted were grouped into content and design elements and these have been summarised in Tables 4-6 and 4-7. They have also been described in more detail below in section 4.5.4.

Table 4-4 Summary of participant demographics

| | Total | |
|--------------------------------------|-------|------|
| | N=20 | (%) |
| Gender | | |
| Male | 12 | (60) |
| Female | 8 | (40) |
| Age in years: | | |
| Mean | 56.8 | |
| Range | 36-77 | |
| Employment status: | | |
| Employed | 5 | (25) |
| Not working but looking for work | 2 | (10) |
| Retired | 8 | (40) |
| Retired (semi) | 1 | (5) |
| Not working and not looking for work | 2 | (10) |
| Other - Full time student | 1 | (5) |
| Other – Volunteer | 1 | (5) |
| Education: | | |
| School Leaver | 4 | (20) |
| A Level | 5 | (25) |
| Degree | 11 | (55) |
| Ethnicity: | | |
| White British | 14 | (70) |
| Black | 4 | (20) |
| Asian (Indian) | 1 | (5) |
| Other (Iranian) | 1 | (5) |
| Duration of diabetes: | | |
| <1 year | 2 | (10) |
| 1-5 years | 7 | (35) |
| 6-10 years | 5 | (25) |
| >10 years | 6 | (30) |
| Diabetes management: | | |
| Diet only | 3 | (15) |
| Diet + tablets | 10 | (50) |
| Diet + tablets + victoza injection | 1 | (5) |
| On insulin | 6 | (30) |
| Home internet access: | | |
| No | 1 | (5) |
| Yes | 19 | (95) |

| Demographics (contd.) | Total | (%) |
|---|-------|------|
| Attended diabetes education: | | |
| No | 8 | (40) |
| Yes | 12 | (60) |
| Used the internet to look up diabetes related information: | | |
| No | 3 | (15) |
| Yes | 17 | (85) |
| Used a computer self-management intervention before: | | |
| No | 16 | (80) |
| Yes | 2 | (10) |
| Yes (own spreadsheets) | 2 | (10) |

Table 4-5 Main themes and sub-themes about the work of living with type 2 diabetes described in the dataset

| Level 1 | Level 2 | Level 3 |
|------------------------------------|---|---|
| | Negative emotions associated with living with type 2 diabetes | Burn-out Denial Indifference Depression Anger Frustration Self-blame Guilt Shame |
| Life work and emotional management | Triggers for negative emotions | Food Seeking medical help Lack of understanding from family members Intrusive comments from family members |
| | Strategies for keeping a positive outlook | Maintaining optimism Accept limits on control Treat depression |
| | Sources of support | Caring family members Peers |

| Level 1 | Level 2 | Level 3 |
|---------------------------------------|---|---|
| Illness work and medical management | Barriers posed by the healthcare system | 'Tick-box' consultations Conflicting advice Professionals not keeping up to date Difficulty getting appointments with GP Difficult accessing DSME Poor quality information (too much, too little, too complicated, not relevant) |
| | Enablement by the healthcare system | Supportive doctors and nurses Taking time to explain results Timely access to DSME |
| | Low priority of illness work | Lack of time Access to blood results Access to a medical summary Transparency and being able to correct errors Control data sharing |
| Biographical work and role management | Self-image | Bereaved – loss of health Deserving punishment Feeling like a criminal |
| | Changes in parent role | Dependence on children |
| | Changes in working roles | Lack of support for making adaptations to work roles Impact of changing needs of patient role on working role |

Table 4-6 Content that participants wanted

| Area: | Specific topics mentioned: |
|---|--|
| Medical information | Medication Side effects Hypoglycaemia News and research |
| Dietary advice | Controlling blood glucose Weight loss Controlling cholesterol Understanding food Recipe ideas |
| Physical activity | Benefits of exercise Advice about weight loss Self-monitoring tools Easy to do physical activities Resources for group activities |
| Alternative medicine | Relaxation therapy and stress reduction Complementary therapies |
| Peer support | Advice from peers Emotional support Social comparisons Role models Not much enthusiasm for social media |
| Pregnancy | Safe conception and what to do if pregnant |
| Practical advice about living with type 2 diabetes | Travel Insurance Financial advice e.g. benefits Advice about work e.g. shift work Managing families Managing social situations and eating out |
| Information about health services | Services that patients should have access to Local support groups Telephone support lines |

Table 4-7 Design features that participants wanted

| | |
|------------------------------|--|
| Design and navigation | <ul style="list-style-type: none"> Easy to use Clear, concise, consistent Minimise scrolling Use videos Pages can be printed Have interactive features like quizzes Provide self-monitoring tools Webinars with medical professionals Ask the expert functions Act as a central hub for all diabetes related queries with links to other resources |
| Language and tone | <ul style="list-style-type: none"> Accessible Use medical terminology where needed so users can become comfortable with terms used by professionals, but include accessible definitions of terms used Be encouraging and supportive Not shy away from difficult truths Have a sense of humour |
| Trust | <ul style="list-style-type: none"> Thorough proofreading Have no advertising Working links to/from good websites Use trusted brands |
| Avoid irritants | <ul style="list-style-type: none"> Poor design Not relevant/ localised Out of date Boring/ static |
| Keeping users engaged | <ul style="list-style-type: none"> Regularly adding new content Articles about latest research findings Regular emails Use of video and interactive tools Booking appointments |

4.5.3 Participant defined needs for diabetes self-management

4.5.3.1 Life work and emotional management

Negative emotions associated with living with type 2 diabetes.

Affective states and relationships had a significant impact on the abilities of participants to self-manage. The emotional burden of living with diabetes was wide-ranging and participants reported problems with burn-out, denial, indifference, depression, anger, frustration, self-blame, guilt and shame. None of the participants talked about any potential benefits or positive changes that had come about in their lives from the diagnosis or treatment or diabetes.

"Low, angry, frustrated. Everything. Because, you know, sometimes you're frustrated because the doctor hasn't told you what you want to hear. Or you're angry with the world, and you take it out on your children, your partners, everybody. And then you've got the depression that takes you down, because you're just thinking one thing after another."

P18, 51 year old female, DM 10 years, expert internet user

Triggers for negative emotions

One of the challenges of living with diabetes was the way in which everyday activities or relationships that might normally be a source of comfort often triggered negative emotions. Food was a frequently cited trigger, particularly as foods that would normally make participants happy ("treats") were associated with guilt or shame. Interactions with health professionals and seeking medical help for problems could also become a source of distress if patients were made to feel ashamed for seeking help or they had difficulty getting appointments. Relationships with family members could precipitate negative feelings through ignorance or over-reactions. Cultural norms were also relevant as one patient described her family reacting badly to her attempts to eat healthily and avoid certain foods as it was interpreted as showing a lack of respect. Not all interactions with family were described negatively, and for some participants, family was an important source of support and this is discussed later.

"You see, I'm quite stupid, obviously. I wouldn't find myself in such a position...yes, and end up in hospital"
P5, 77 year old male, DM 23 years, experienced internet user
[speaking about having to go to hospital after a hypoglycaemic event when his blood glucose levels dropped dangerously low]

"...to even ring your GP surgery normally to make an appointment can be very tiresome for a lot of people. You can't get through."
P13, 56 year old female, DM 15 years, experienced internet user

"I go to my family, and when I say I can't eat that food, they usually think that's disrespecting them, so you've got all that as well to deal with. And I say I'm diabetic. Yes, right. And it's like, you know, I can't have sugar... they think we can't have sugar."
P18, 51 year old female, DM 10 years, expert internet user

"I mean, my dad bless him used to drive me mad, you go to a restaurant... 'he's got diabetes, he's got type 2 diabetes'... the waiters, kind of, gone into a complete panic, turning green and fallen down... I said, 'shut up dad'.. But it's absolutely irritating."
P27, 60 year old male, DM 14 years, experienced internet user

Strategies for staying positive

To cope with the emotional burden described above, participants described a number of strategies to try and stay positive. However even when trying to keep an optimistic view of things and using humour as a way of coping, diabetes cast a shadow of negativity that some people felt they could never be free of. One way of avoiding anxiety or feelings of failure was for people to accept a lack of control and acknowledge that in spite of their best efforts, there would be times when the illness would not be well controlled. A number of participants had encountered problems with depression after being diagnosed with diabetes, and getting treatment for depression was a key step to engaging positively with self-management and becoming healthier.

"I think you've always got to look at the positive side of your illness. But yes, you're always going to have a negative side, and sometimes you've got to have a funny side."

P13, 56 year old female, DM 15 years, experienced internet user

"I think that people have to learn to accept being out of control, and not become control freaks, like some of these people ...oh, my blood sugar is ten, help, I'm going to die, sort of thing."

...I think that the worst thing that makes me depressed about diabetes is that there are times when you do everything right for a number of times, and it just doesn't work"

P48, 64 year old female, DM 36 years, experienced internet user

"So after medication of that depression... now, I wanted to live, so why wouldn't I take the time and give myself to eat healthier, exercise? If it is going to give me my life back, I would invest all the time I could have, I am having."

P19, 41 year old female, DM 3 years, experienced internet user

Sources of support

For many participants, family and friends were a valuable source of support in overcoming barriers like perceived stigma. One participant talked about how his spouse kept calm and helped him by telling people on his behalf. Peer interactions were also important to participants e.g. sharing information through informal patient networks was highlighted as an important mechanism for supporting self-management. Information provided by other people living with diabetes was, for some participants, preferable to advice from health care professionals.

"I didn't want to tell anyone, and my wife calmly insisted and did it for me, really..."

....my wife was the only person that said anything that was reasonably sensible"

P36, 58 year old male, DM 3 months, experienced internet user

"And lots of other people... I suppose people do share information all over... you know, there's such and such a service here, or this optician's pretty good, or..."

P55, 41 year old female, DM 5 years, expert internet user

"...the one I would go for every time ...it's been written by people who have got the complaint and not by so-called experts."

P16, 70 year old male, DM 6 months, experienced internet user

4.5.3.2 Illness work and medical management

Barriers posed by the healthcare system

Tick-box consultations

The key focus of healthcare systems is treating medical problems yet there were many elements of healthcare that were unhelpful for people living with type 2 diabetes. One source of frustration for participants was the experience of 'tick-box' medicine and a perceived lack of empathy from professionals, often during annual reviews. Template-based consultations were felt to be impersonal with yes/no answer questions that appeared of little or no benefit to patients.

"I'm asked that, once a year, that question, do you feel depressed?

Yes. Next question. It's not like, what are you going to do about it?

And when I see the nurse, every six months, she just says, are you exercising? And she ticks a little box if I say yes or no. And that's it."

P9, 54 year old male, DM 10 years, expert internet user

Conflicting or out of date advice

A major difficulty that participants faced was dealing with conflicting or changing guidance and inconsistency in advice from healthcare professionals. There were also challenges in reconciling differences in opinions between professionals and peers. Some participants found it difficult to manage the uncertainty that arose when advice from health professionals evolved over time. Others felt that healthcare professionals who did not change were a bigger concern when routine clinical practice was slow to adopt changes in guidance, denying patients the benefits of current best practice.

"So if we can't, if people can't decide what is the most important thing, is it your total weight, is it mass body index, is it your waist, you know where you're going, you know? I've lost weight and now I'm told it's not the weight you lose it's your waist."

P6, 66 year old male, DM 1 year, basic internet user

“...opinion amongst academics is rather like an oil tanker; it takes a generation before a certain conception of what is actually the truth disappears with that generation of doctors, if you like, because they were taught that when they were at school and it was good enough for them for 40 years.”

P16, 70 year old male, DM 6 months, experienced internet user

Difficulty accessing GP appointments or DSME

Participants also reported encountering difficulties with making appointments and a found a lack of understanding if they were late for appointments. Some participants reported problems with a lack of provision of self-management education and had received minimal or no access to education or support around the time of getting a diagnosis.

“When I was diagnosed, I was only given the Metformin, and I was sent. That's all.”

P19, 41 year old female, DM 3 years, experienced internet user

Poor quality information

Many participants had struggled to get the information they felt they needed to understand and take control of their condition. Patients were very clear that they wanted access to as much information as possible, but controlling the flow of information was very important to avoid “information overload”.

“...but sometimes it's a question of having too much information and you can't take it all on board and you can't make all the changes overnight”

P55, 41 year old female, DM 5 years, expert internet user

“Yes, not just to overload me with facts and give me some information.”

P36, 58 year old male, DM 3 months, experienced internet user

But if it was a choice between too much information, and too little - one participant felt it was better to have more:

“But it's better to be overwhelmed than be underwhelmed and having to... Trust me... Yes, it's horrible when you're just left to your own devices, I mean, because in those days, that's 1997, the doctors were not as aware of how serious the impact was, they thought it was just something minor. In fact, it was like, you've only got Type 2 diabetes.”

P27, 60 year old male, DM 14 years, experienced internet user

Some participants struggled with complex information, for example understanding nutritional content and guidance about recommended daily allowances. Participants felt it was more meaningful when information was relevant to their personal circumstances.

“And where are the tools that help me to understand it? You know, I’m looking at carbs and sugar, and it’s all very confusing and highly complicated....”

P36, 58 year old male, DM 3 months, experienced internet user

“Proper guideline daily amounts, for me as an individual, not an average person”

P36, 58 year old male, DM 3 months, experienced internet user

Enablement by the healthcare system

Participants valued healthcare professionals who took the time to look at their results and explain trends. When participants spoke about positive experiences of healthcare services, the main characteristic was accessibility. Being able to get onto a self-management course easily or feeling able to easily access advice from a health professional (diabetes nurse) were highly valued by participants.

“Some people will say, oh, your HbA1c is such and such, with a reminder as to what it was last time, and others don’t”

P55, 41 year old female, DM 5 years, expert internet user

“Yes, I mean, I can’t, you know, speak highly enough of the way everything’s kicked in now to... I was put onto a course, and got onto it quite quickly.”

P36, 58 year old male, DM 3 months, experienced internet user

“I mean, I was very lucky in a lot of ways because the nurse was absolutely brilliant, our diabetic nurse was absolutely brilliant and I got onto the Xpert course very quickly... the nurse was always great, I mean... I could always phone up and say, could you ask her to just give me a ring.”

P23, 58 year old female, DM 1 year, basic internet user

Low priority of illness work

Most participants thought that it was important to be looking after their health but felt there were limits on how much time they were willing to spend on the work involved as it was not their top priority.

“It’s also a time thing. If there were 28 hours in the day, yes, sure ...but I just haven’t got time for that [self-management].”

P7, 55 year old male, DM 5 years, experienced internet user

Interviewer: Would you spend an hour a day [on self-management]?

“What, when I could be reading or shopping or...?”

P23, 58 year old female, DM 1 year, basic internet user

Access to medical records

Patients were generally keen on having access to electronic medical records but there was little experience of this. When it came to accessing electronic medical records, participants were broadly positive about this, especially having access to results of blood tests or a summary of their medical records. However participants wanted to be able to control what information was shared with other professionals. They also expressed curiosity about what was being written and a desire to correct any inaccuracies.

“P18 A summary. The whole record would be too long.

P18, 51 year old female, DM 10 years, expert internet user

P03 I wouldn't want my dentist to be able to access my medical information.”

P3, 59 year old female, DM 15 years, experienced internet user

“I think it might be useful to correct things, if you find anything that's been recorded incorrectly, that at the moment, you've got no idea if there's anything... anything's wrong or not.”

P36, 58 year old male, DM 3 months, experienced internet user

4.5.4 Biographical work and role management

Self-image

A diagnosis of type 2 diabetes could deeply affect how participants saw themselves and it often had a very negative impact on their self-image. Many participants associated living with type 2 diabetes with losing a part of who they were. This feeling of bereavement at the time of diagnosis was common. When asked what participants felt the loss of, the responses were “*liberty*”, “*freedom*” and “*health*”. One participant felt it was an unwelcome reminder of his mortality. The language used to describe the illness and ways of living with it was often strongly emotive. Good health often seemed to carry virtuous overtones, with poor health or worse diabetes control being described as bad and associated with feelings of shame. Behaviour that led to poor health was described as something worthy of punishment. One participant cast himself in the role of a criminal needing correction from the “*diabetes police*” who could stop him from the self-destruction of binge-eating.

[talking about diagnosis] I've heard it was like a bereavement. It was all the same points as that, and it was just before my 50th birthday."
P7, 55 year old male, DM 5 years, experienced internet user

"Well, it's more to do with the mortality business, isn't it? Without wanting to sound grim, but..."

P16, 70 year old male, DM 6 months, experienced internet user

"So I'm not doing away with my treats, but then I know if I have a treat I've got to take the punishment for it."

P7, 55 year old male, DM 5 years, experienced internet user

"There's diabetes police, if you want to call them that, they're a very necessary part of your life, and they do help, because there are times when you go into robotic mode, you know, like you have carb binges, you know, where you start eating carbs and you can't stop..."

P27, 60 year old male, DM 14 years, experienced internet user

Changes in parent role

Two women highlighted contrasting ways in which type 2 diabetes affected their roles as parents and how this might evolve over time. One participant had only had type 2 diabetes for 3 years and less advanced disease. She held onto her caring role and did not want to worry her children. She wanted her children to be reassured about her health and she wanted a medical information leaflet for their reassurance rather than education or transferring responsibility for providing care. The other participant had more advanced disease and poorer physical health, and she was more dependent on her children for care. Her children checked on her regularly and were responsible for monitoring her health. This participant had medical information material dotted around her house for their reference – influenced by an episode where the patient had a “mini-stroke” (Transient Ischaemic Attack) and her children did not recognise the symptoms. Medical information for her played a different role – it was to support the transfer of responsibility of care giving to her children as her relationship with her children became one where she was needing rather than providing care.

"...a leaflet would have been helpful for my sons, because they would have perhaps understood it a little bit better. Because, mum's okay, if mum says she's okay, she's okay, end of story."

P12, 65 year old female, DM 3 years, experienced internet user

"And they do check on me throughout the day, especially now I'm at home, because I will forget to eat, because I don't get hungry as such. So those are the things that my children need to know. Again, when I had that mini stroke, they didn't realise that I had something wrong with me, so basically identifying the symptoms. I mean, I've got things all over in my house. I've got like leaflets, I've got little cards."

P18, 51 year old female, DM 10 years, expert internet user

Changes in working roles

Even patients not requiring insulin struggled with maintaining their roles at work. Taking time to eat regularly or take medication was difficult, especially in the context of shift work. Work roles seemed to struggle to provide people with the flexibility needed to combine illness work with their life work. One successful adaptation was instigated by the participant's manager – although this seemed to be prompted by risk management issues rather than concern for the participant's welfare. Another patient spoke about having to give up the working role to accommodate the needs of the patient role. The participant who gave up her work felt it was necessary as she blamed work for making her ill and contributing to her having a stroke. This was the same patient who above talked about transferring responsibility for her care to her children above. Her narrative is consistent with one of increasing dependence as care needs escalate with worsening health and the evolution of the patient role with disease progression.

You know, and again, they took me off shifts, because I couldn't remember if I'd taken my pills one week, you know? One week, I'm working early and next week, I'm working lates, and then I'm working nights, and I used to go, I can't remember if I've taken them or not. My manager said, that's no use, is it? We can't have you falling over, you know?

P43, 54 year old male, DM 8 years, experienced internet user

"So I just found it really, really difficult to manage... when I was working. I've just given up work about four weeks ago, so it's just really hard to tell you the truth. And I think that's why I had the stroke, because I didn't eat properly. I didn't eat when I should do; take my medication properly."

P18, 51 year old female, DM 10 years, expert internet user

4.5.5 Content and design features participants wanted from a digital self-management intervention

As mentioned previously, in order to facilitate the discussion around the desired characteristics of the intervention, focus groups discussions included looking at existing examples of online diabetes resources. Using these as a starting point, participants were quite clear in articulating their preferences for what they wanted from such interventions to help meet the needs described in the previous section. These preferences described a wide range of content and four aspects of intervention design: (i) ease of use (ii) supportive language and tone (iii) trustworthiness and (iv) avoiding irritants

4.5.5.1 Wide range of content

Participants voiced a desire for a wide range of information around living with type 2 diabetes. They were interested in content that covered:

- medical information
- dietary advice
- physical activity
- alternative medicine
- peer support
- pregnancy
- practical advice (for things like travel and insurance)
- information about health services
- interactive tools.

Medical information

The specific areas of interest about the more biomedical aspects of diabetes were focused on the practical aspects of managing the condition.

Users wanted as much information as possible on medication and possible side effects. There was a tension between the needs of participants who had experienced rare side effects who wanted as much information about medication as possible and participants who felt overwhelmed by too much information.

"So... if... the side effect are not fully recorded in those sites so what are the site, so what are the point if I go to the site and I don't find the whole side effects?"

P19, 41 year old female, DM 3 years, experienced internet user

“But the trouble with that is it's so vast isn't it. I think it's information overload, that we're getting too much information in my opinion and well, I don't know what the answer is.”

P3, 59 year old female, DM 15 years, experienced internet user

The second participant quoted above also felt frustrated that some other websites visited had described possible side effects, but then had no practical advice about what to do if suffering from those side effects.

“Because on one of those websites it had things like side effects, but then there's no information to say, well, what... how can you control the side effects, whether you can control the side effects”

P3, 59 year old female, DM 15 years, experienced internet user

Hypoglycaemia was a very important topic for one participant, as he had ended up in hospital following a hypoglycaemic episode and had felt embarrassed by the experience.

“And that is why, see, I was, I say, well, if I don't know about hypos.....these are the sorts of things that are important, very important, to help you can look it up on the computer”

P5, 77 year old male, DM 23 years, experienced internet user

Users were also keen to be kept up to date on the latest news and research on diabetes. They wanted to be able to access detailed information if needed at the level used by healthcare professionals.

“What is important in my opinion on the website is it's all got to be up to date and inform you of what's going on”

P6, 66 year old male, DM 1 year, basic internet user

“....And I think also, I'd be quite interested because I would be interested to see the healthcare professional site, or part of it; I'd like to see that as well...I'd like to see the information that's on there... If it was, kind of, articles from the British Medical Journal, or something of that ilk..”

P55, 41 year old female, DM 5 years, expert internet user

Another aspect of medical content highlighted by that participant was the importance of dealing with multi-morbidity:

“...for me it's not just diabetes, it's other conditions, and I think a lot of people find that. So, might have diabetes, but it's also, you know, other conditions as well”

P55, 41 year old female, DM 5 years, expert internet user

Participants also felt that there were many people with misconceptions about type 2 diabetes and it was important to dispel common myths around the condition. Two examples of commonly held incorrect beliefs were the ideas that type 2 diabetes was not a serious health condition and that it was caused by overeating and unhealthy lifestyles.

"P48 Yes, and then there are of course the whole myths around type 2 diabetes, that it's mild diabetes. They've mentioned that on most of the websites, you know? ... I mean, I think some people think that the only reason for getting type 2 diabetes is bad eating habits and being overweight, you know? So..."

P43 Exactly. Very much so.

P48 Usually people say, oh, you must have had a bad lifestyle, something or whatever, which may be true sometimes, but it's not the only reason, so...

P43 No, it's not the only reason."

P48, 64 year old female, DM 36 years, experienced internet user

P43, 54 year old male, DM 8 years, experienced internet user

Dietary Advice

Food was one of the most important frequently mentioned elements mentioned by participants. The discussions covered both the emotional aspects surrounding food in diabetes discussed later in this chapter as well as the practical aspects of nutrition for self-management. Understanding diets that were good for controlling blood glucose levels, losing weight and addressing specific needs like high cholesterol were particular concerns.

"Well, I think this diet thing is quite as an important aspect."

P12, 65 year old female, DM 3 years, experienced internet user

"Dieting.... Yes. Well, what you should eat and what you shouldn't eat."

P9, 54 year old male, DM 10 years, expert internet user

A particularly difficult challenge is turning eating from an unconscious automatic habit into a conscious behaviour controlled by an understanding of the nutritional content of the food being consumed.

"You know, the one digestive a day then will put on three, three and a half pounds over the year. But until somebody says that to you, it's just a biscuit."

P7, 55 year old male, DM 5 years, experienced internet user

Users also wanted recipe suggestions and the option to share recipes with others.

P48 Recipes are good.

P43 I've actually used them, one or two.

P48 Yes, I have as well."

P43, 54 year old male, DM 8 years, experienced internet user

P48, 64 year old female, DM 36 years, experienced internet user

Physical activity

Participants were aware of the importance of physical activity and were interested in ways that an intervention could help them with exercise and weight loss. One participant felt that self-monitoring would be helpful and might enable users to see the benefits of physical activity.

"I've noticed that, just the amount of exercise that I do, obviously that affects my HbA1c, but it also affects my energy levels and my sleep patterns, and all of those things; they all have a connection. So, there's lots of information that you could... that, I think, could be recorded, and that it would be useful to see."

P55, 41 year old female, DM 5 years, expert internet user

Other participants felt it was important to inform users about the benefits of exercise but also signpost ways of making exercise accessible for people who might not want to go to the gym or go running e.g. local groups or encouraging walking.

"...it doesn't actually take very much exercise for you to radically improve your health. I think that's one of the key things, actually, that it's just come to me, that with a small amount of effort you radically improve your diabetes situation. It's the same with diet."

P16, 70 year old male, DM 6 months, experienced internet user

"...okay I hate swimming, I don't like cycling, I hate running but I can walk, and it really makes a difference and none of these websites were really emphasising that a lot."

P3, 59 year old female, DM 15 years, experienced internet user

"But the other thing that I've said, which I think would have been useful, would have been some kind of group exercise, with other people"

P9, 54 year old male, DM 10 years, expert internet user

Alternative medicine

The concerns of participants with mainstream pharmacological agents means that unsurprisingly a number of people were interested in alternatives.

Participants felt that stress management and alternative medicine were topics they would find interesting.

“I feel you can have the relaxation music or videos, meditation or yoga.”

P45, 36 year old male, DM 8 years, experienced internet user

“One of the things that I thought was lacking from any of the three sites was any alternative writing.”

P16, 70 year old male, DM 6 months, experienced internet user

Peer support

Participants were interested in connecting with peers and in lay person generated content. As described previously in this chapter, this includes information about how peers manage their condition and support from peers. Some participants also expressed the potential for social comparisons as a motivating tool, with the advantages being group interactions without needing to travel and the ability for social comparisons.

“So you get that, kind of, motivation, but you don’t have to go to a class, and you don’t see anybody, and you don’t have to meet anybody, and you can have a private setting, and all the rest of it.”

P55, 41 year old female, DM 5 years, expert internet user

“...if we could see more data of what real people are like, then you’d have an idea where you are, and you’d be able to go, I’m doing okay, or hmm, I really need to get better at this”.

P28, 54 year old male, DM 7 years, expert internet user

Other perceived benefits from peer interactions included support for group activities and the ability to promote potential role models – although participants highlighted the potential difficulties of relating to aspirational role models who might foster resentment in some if they are achieving goals that would not be feasible for others.

“...you go along and you find all these other people, who’s, sort of, got exactly the same, and you find other people who’ve got exactly the same problems as you’ve got, and even just to have a chat to somebody helps.”

P12, 65 year old female, DM 3 years, experienced internet user

“P48 Yes, some people hate that, don’t they? They complain in Balance, and say that there’s always these, sort of, super heroes, you know, with diabetes, who sort of, I don’t know, have been up and down, you know, Mount Everest three times, or something.”

P43 *That's it, yes.*

P48 *But, in fact, other people think it's good, having some, you know, good role models to go for."*

P43, 54 year old male, DM 8 years, experienced internet user

P48, 64 year old female, DM 36 years, experienced internet user

Interestingly, although participants felt that they valued the opinions of other people with type 2 diabetes and felt there were potential benefits in building online communities, there were quite mixed feelings about the use of social media. Most participants did not see themselves as active users of social media.

"I wouldn't. Well, not at the moment. I'm not saying I wouldn't ever, but I've failed to be convinced by my two daughters of the merit of it all..."

P16, 70 year old male, DM 6 months, experienced internet user

"P3 No, I wouldn't use Facebook.

P18 No, it's a waste of space."

P3, 59 year old female, DM 15 years, experienced internet user

P18, 51 year old female, DM 10 years, expert internet user

However there was one participant who had found the use of a social networking site helpful and used it to get support at a difficult time. Another participant felt that social media was good because it was topical and reflected matters of current importance.

"...it's not only for teenagers, because I don't use it regularly, but I do feel a little bit like... But one time I was overwhelmed with my diabetes. It was really very high, my blood glucose. I was depressed. I didn't know anything what to do. And then I just went and I asked questions. And getting some advice and responding from people is really nice."

P19, 41 year old female, DM 3 years, experienced internet user

"And I think people would find it useful because it was, like, you know, more or less like live commentary and it was very up to date on what's happening there."

P9, 54 year old male, DM 10 years, expert internet user

And even if participants weren't using it themselves, most had family (usually younger) who were active users.

"I don't think it's that, but I think the positive thing about Facebook is accessibility because I'm at an age where I don't use it, but my children use it all the time, so I've got three children."

P28, 54 year old male, DM 7 years, expert internet user

Some participants felt that there was a generation issue and found it difficult to imagine sharing personal details online. One participant commented that she would rather pick up the phone and talk to someone.

“...but certainly youngsters I know they put everything on Facebook. You think, how on earth can you? Whereas I think the older you are the more personal and private things you want to be kept.”

P3, 59 year old female, DM 15 years, experienced internet user

“I'm much more a person to phone up somebody to speak to them direct than to communicate via the computer.”

P12, 65 year old female, DM 3 years, experienced internet user

Some were not convinced about the usefulness of the messages posted. Participants also were concerned about how much they could trust the accuracy of the information from material posted anonymously.

“Yes, you see, the trouble with that is, it might be interesting to read, but it could be full of misinformation and bad fact.”

P36, 58 year old male, DM 3 months, experienced internet user

“P03 There's too much whinging on it.

P06 There is, isn't it?”

P3, 59 year old female, DM 15 years, experienced internet user

P6, 66 year old male, DM 1 year, basic internet user

“I don't think it's got enough information on there for me to actually self-manage myself, which is what it's all about. It's about that... you know, how you go out and get information to help you manage yourself. And that's what I need, or want.”

P18, 51 year old female, DM 10 years, expert internet user

“...you can't tell who's actually writing it, can you? It could be me writing something, and I'm absolutely anti someone with diabetes, so I tell them something”

P6, 66 year old male, DM 1 year, basic internet user

Pregnancy

As pregnancy was specifically excluded from the remit of the project being funded, this was not covered in any significant depth during the discussions. However one participant felt it was important to signpost help as diabetes and some of the medication used by people with this condition have the ability to adversely affect pregnancy.

"Yes, so through my doctor and I was going to a hospital consultant, and I had mentioned that I was, you know, planning to become pregnant, but nobody said, well, let us know.....then, suddenly when I told them. Oh, it's far too late. You know what I mean? There was this panic, about the whole thing...."

P48, 64 year old female, DM 36 years, experienced internet user

Practical advice

Participants liked sites that supported them with useful tips about day to day living with type 2 diabetes e.g. advice about travel, insurance and benefits.

"...it actually gave you something which is very important; travel agencies, who should you get your insurance from, costs. No one else did that. All the... they were treating you as a human being, I felt."

P13, 56 year old female, DM 15 years, experienced internet user

"...and I know we all hate buying insurance, but if you want to go and buy something, you want to buy it from somebody who you're going to trust."

P28, 54 year old male, DM 7 years, expert internet user

Information about health services

As previously discussed, participant experiences of healthcare services was quite variable. Participants felt that it was important to highlight information about health services so participants would be aware of the services they should have access to from medical professionals and pharmacists.

"...something like along the lines of what treatment you could expect or who's going to be part of your diabetic team, and within there you could through in the idea that generally your pharmacist would offer you an annual review to talk about your medicines and if you've got problems".

P3, 59 year old female, DM 15 years, experienced internet user

This was also felt to be an opportunity to signpost local services like support groups and also national services like telephone support lines.

"...a list of local support groups that would possibly help."

P12, 65 year old female, DM 3 years, experienced internet user

Tools

Most of the conversations covered the sorts of information content that the intervention would need. Users also talked about the functionality they might like from a self-management intervention. As mentioned above when talking

about physical activity, tools to track personal data for self-monitoring was felt to be a useful tool. Users also talked about tools to help them find out more about symptoms, learn from webinars, have frequently asked questions and videos with lectures from experts in the field.

"P19 Sometimes it would be good if we got a website like you put a little bit of your symptoms and then it just..."

P18 Like NHS Direct.

P19 They have... but sometimes they don't have everything, you have to call them. I don't want to call sometimes every time I just want to... yes it would be good."

P18, 51 year old female, DM 10 years, expert internet user

P19, 41 year old female, DM 3 years, experienced internet user

"Yes, that would be really interesting. You could have a web blog or a web conference with... that would get me, if it was a web conference with such and such."

P55, 41 year old female, DM 5 years, expert internet user

Some participants trusted opinions formed from personal experience and focused on the contributions from peers as described previously in this chapter. Others felt authority derived from professional expertise, while one participant felt that the opinion he valued most was from a health professional who had diabetes as it combined professional and personal experience.

"what I find very interesting was they've got the group of experts.... it's great, because they're the ones whom you really want to hear about."

P5, 77 year old male, DM 23 years, experience internet user

Although smartphones weren't something that all participants used, the convenience of apps was an attractive proposition with at least one participant expressing an interest in investing in a smartphone if the right application that fit his needs was available.

"I would actually invest in a smartphone, if there was an application I could use, as and when I'm eating, not try and remember it seven hours later when I'm sitting at the PC"

P36, 58 year old male, DM 3 months, experienced internet user

"And, especially for me now, what's transformed so many of the things that I do, is iPhone apps, where you know, it's so easy, you don't have to turn it on or anything. You just go into your iPhone app and you just go click, click, click and the things are done."

P28, 54 year old male, DM 7 years, expert internet user

4.5.5.2 Design features that participants wanted

Ease of use

Participants clearly wanted something that was easy to use. Navigation was important with the website being clear, concise and consistent. Participants felt it was very easy to be overwhelmed with options so keeping things simple and easy to find was an important design feature.

“I think I would like very clear... a very clear site map, so, with a search engine, but, you know, some things are just too messy and there’s too much content ...it just puts you off.”

P55, 41 year old female, DM 5 years, expert internet user

Keeping pages short to minimise scrolling was felt to be one way to reduce the chance of missing important information.

“It was nice that the homepage actually fitted the screen. I didn’t actually have to move it down to find anything, so I thought that was very important.”

P12, 65 year old female, DM 3 years, experienced internet user

Videos were felt to be important as they could engage users and make information more accessible. It was also felt to be a useful tool for learning skills like using a blood glucose meter or checking feet.

“Video’s great. People want to look at videos, especially when you’re... you’ve just been diagnosed or you’re an older person or something like that, you know, you don’t want to read through reams and reams of paper.”

P7, 55 year old male, DM 5 years, experienced internet user

However, some potential users felt more comfortable reading material off paper so they wanted a print option that could be used to print text without any images. The ability to produce a short printed leaflet was also felt to be something that could be helpful for informing family and friends about the condition.

“I think a very short leaflet that you could hand to... especially, sort of, I’m on my own, you know, I’m a widow, for someone... I could have handed it to my two sons, to explain it, would have been helpful.”

P12, 65 year old female, DM 3 years, experienced internet user

Another interactive element that users liked were quizzes. Again, this was an element that could be informative but also facilitate active engagement with the intervention and make it more enjoyable.

“So, that was quite fun. So, it was, kind of... it was, sort of, medical information that was presented in a really fun, interactive way, rather than it being really, kind of, dry and medicalised, and quite serious, and I don’t... and I would not have gained as much information from it in the same amount of time.”

P55, 41 year old female, DM 5 years, expert internet user

“They include some quizzes, I think they’re interactive, fun part is good.”

P36, 58 year old male, DM 3 months, experienced internet user

One participant summed up a crucial potential selling point for the intervention – the ability to be a convenient single access point to all the information and tools that people with type 2 diabetes would need.

“there isn’t anything that’s centralised, so I suppose that would be something that I would hope... that if there was all... information, kind of, centralised...”

P55, 41 year old female, DM 5 years, expert internet user

Supportive language and tone

Participants felt that the language used by the intervention was important and needed to strike a delicate balance. They felt that the intervention should not shy away from using medical terminology but at the same time take steps to ensure that the information was accessible.

“Well, maybe there’d be different... I mean, I’m sure if you’re having something that is on research or something that’s more medical based, then you’re going to have more terminology, but then you don’t want to feel like you’re reading, I don’t know, some really archaic textbook... Yes, and one wouldn’t want it too dumbed down, either... so I think it’s got to be something that is accessible for most people.”

P55, 41 year old female, DM 5 years, expert internet user

The tone needed to be encouraging and supportive yet be able to discuss difficult truths about the risks associated with diabetes. One participant was concerned that some people he knew did not take their diabetes seriously while others felt that focusing too much on the negatives and complications of diabetes was disheartening.

“...away from the heat of... This, sort of, politically correct idea, oh, we mustn’t scare diabetics, you know, we mustn’t, sort of, discourage them, we mustn’t tell the brutal truth. A lot of diabetics I know would really appreciate being told, if you don’t do anything about your condition, you’re going to die a horrible death. Now that sounds very extreme, but we’re getting, you know, at work, I see these diabetics and they are just killing themselves slowly.”

P27, 60 year old male, DM 14 years, experienced internet user

“So that’s the big problem, it seems to me. The mainstream medical opinion seems to be all doom and gloom”

P16, 70 year old male, DM 6 months, experienced internet user

Most participants felt that humour would help keep users engaged with the intervention and it was a good thing.

“I think you’ve always got to look at the positive side of your illness. But yes, you’re always going to have a negative side, and sometimes you’ve got to have a funny side..... Yes, humour doesn’t... it always has, I would say, a positive effect rather than a negative effect.”

P13, 56 year old female, DM 15 years, experienced internet user

Trustworthiness

As mentioned previously in this chapter, participants often felt they were exposed to multiple and often conflicting opinions and advice. Therefore it is important that any information provided is felt to be trustworthy so participants have confidence in what they are being advised.

“I think the big problem, for me at least, is the fact that I don’t have that much interest in what’s online unless I know it’s good, if you see what I mean.”

P16, 70 year old male, DM 6 months, experienced internet user

As mentioned previously, many participants were wary about the accuracy of material posted online. Ways to overcome these suspicions included the need for recommendations for good websites, the use of trusted brands, absence of commercial conflicts of interest and thorough editing and proofreading.

“[talking about one particular website....] it brings the brand with it, and you know that if you go on there, you can, as much as you can see, it will be true... It’s not driven by commercial imperatives. There’s not big drug companies trying to flog you things, and that to me, is one of the most crucial things about it.”

P28, 54 year old male, DM 7 years, expert internet user

“I say it’s proofreading and it’s very important because if you start finding mistakes and obvious mistakes in the document, well I do, as

far as I'm concerned the whole thing's wrong. You can't... if somebody can't be bothered to proofread it..."
P6, 66 year old male, DM 1 year, basic internet user

Avoiding irritants

There were a number of elements that participants felt might drive potential users away from the site. Poorly designed sites (e.g. lots of text, inappropriate music, amateurish feel) evoked strong negative reactions in some participants.

"I didn't like the music. Unnecessary, you didn't need it"
P43, 54 year old male, DM 8 years, experienced internet user

[Interviewer: "Is there anything you would say is really awful and we definitely shouldn't put into our site?"]
"Just loads and loads of text."

P48, 64 year old female, DM 36 years, experienced internet user

Content that was not localised was likely to make the site feel irrelevant – both in terms of presentation (e.g. foreign accents) and content (e.g. medication names, mixed information about type 1 and type 2). Sites that were out of date or had no interactive elements did not appeal very much to users.

"It's a bit Americanised... it's not interactive, it's just too passive Well if you don't say how often it's updated... There's nothing more discouraging than seeing something updated about two years ago, you think, well they're not obviously interested"
P27, 60 year old male, DM 14 years, experienced internet user

"it's not giving us any practical tools that we'd go back to and use again and again for further information, it's not particularly up-to-date..."

P36, 58 year old male, DM 3 months, experienced internet user

Improving engagement with the intervention

As discussed previously in this chapter, a specific area for discussion was engagement strategies to combat the problem of attrition.

Therefore participants were encouraged to discuss potential features that might help keep potential users engaged with the intervention. Participants thought that highlighting new content would encourage users to come back to the site, either through text messages or emails. Other ideas included articles about the latest research findings and regular emails promoting content from the intervention.

"Latest research put on... So, be put on there, sort of, you know, latest findings. That'd be quite interesting, I would actually, sort of, go into that on a regular basis if it was there, to see how, you know, the research-side of, you know, managing it all".

"...can we email you, not too regularly, but on a regular basis but not too often, about interesting things that are happening, and then you just give a little teaser, and that would draw them right...."

P12, 65 year old female, DM 3 years, experienced internet user

Videos and tools that provided functionality beyond simple information provision were also felt to be important.

"Video's great..... what normally happens is if it's a page long, if it hasn't got your interest in the first two lines you forget about it"

P7, 55 year old male, DM 5 years, experienced internet user

"if it's a tool, well then you'll go back and keep using it, whereas if it is just information, you'll read it... you'll read it to begin with and then forget about it."

P36, 58 year old male, DM 3 months, experienced internet user

One participant wanted the ability to book appointments through the intervention and felt that would be something that would be regularly used and therefore bring him back to the website more often.

"I would like to be able to make my regular appointments through there. If I could do that rather than them ring me, and I think if people could make their appointments through there, they'd probably use it more."

P9, 54 year old male, DM 10 years, expert internet user

4.6 Discussion

The data described above explored the work that people had to do when living with type 2 diabetes. It highlighted the challenges that people faced from the burden of negative emotions and the mismatch between their needs and the help provided by healthcare and other support systems like family or friends. Type 2 diabetes could also cause significant disruptions in how people saw themselves - the identities that people constructed around their illness and the patient role tended to be influenced by a sense of loss and self-blame. The patient role evolved over time and increasing care needs could lead to a loss of work and independence. Given the extent of unmet needs participants described, there are many areas that an OSMI could target, and participants

shared many ideas about the design features and content that they wanted from such an intervention.

4.6.1 The importance of emotional management

Improving self-management is seen as a key element of improving outcomes in long-term conditions and reducing demands on healthcare resources, but successful self-management is a complex multi-faceted task that requires the mobilisation of a wide range of personal, social and healthcare resources.

The impact of diabetes is often first felt at the point of diagnosis. Diagnosis of a chronic condition is often described as being associated with strong negative reactions (Parry et al. 2004); this was certainly true for many of the participants in this study. However the experience of getting a diagnosis of type 2 diabetes can also be less of a “shock” than might be expected as some research, professional, and lay intuition have suggested (Peel et al. 2004b). This could be due to a number of reasons. In the UK and many other countries, the diagnosis and routine care of type 2 diabetes is increasingly managed in primary care settings (Goyder et al. 1998) and the diagnosis may be made by family physicians or medical staff who are familiar to the patient. Diabetes has a high profile due to its high prevalence and the high burden placed on health services – with direct costs of around £9 billion and indirect costs estimated to be around £13 billion in the UK (Hex et al. 2012). Many people will have heard about or know someone living with the condition and other family members are often affected. Finally, people with type 2 diabetes are often well at the time of diagnosis and the implications for poor health outcomes are much later down the line. The study by Peel et al mentioned above did in-depth interviews with forty patients newly diagnosed with type 2 diabetes. They found that there were three routes to diagnosis – suspected, illness and routine. Where people suspected they had type 2 diabetes or it was picked up as part of another illness, getting the diagnosis was often a relief and any shock was minimal or short-lived. Shock was more of an issue in asymptomatic people who found out as part of routine checks – but even in this case, the reactions were not all strongly negative. For some, it was just part of the multiple morbidity they had to deal with and it was just “another illness”. Many felt grateful that their condition

had been picked up before it had caused them problems. However, there were some participants who were shocked and even scared by the diagnosis. And there was also some evidence of difficulty accepting the diagnosis in asymptomatic individuals.

The emphasis on the shock value of the diagnosis in previous studies might be misplaced: for the participants in this study, the main impact was a sense of loss rather than shock. This was augmented by the negative patient identities constructed following this bereavement - feelings of shame and self-blame left one participant feeling like a criminal who needed monitoring by the "diabetes-police". The emotional distress of living with type 2 diabetes was much more than just shock at diagnosis and the participants in this study often struggled with a burden of negative emotions like guilt, shame and sadness. These are concerns not just for participants and their families but also for health services. As mentioned in Chapter 2, numerous studies have shown links between adequate self-management and emotional wellbeing. Negative emotional reactions to diabetes (diabetes-related distress) have been correlated with poor blood glucose control, while depressive symptoms have been correlated with poorer self-management behaviours (Aikens 2012; Tsuji et al. 2012). Yet in spite of the adverse psychological and physical health consequences of diabetes-related distress, there was often inadequate support from health professionals, family and friends. For many participants such interactions were actually a source of increased stress due to perceived indifference, stigma or ignorance. Finding ways of helping patients with type 2 diabetes manage diabetes-related distress should be a key priority for new services like an OSMI.

4.6.2 The challenges facing healthcare services

As mentioned above, many participants felt that healthcare services were not able to provide the support they needed. Problems people encountered included difficulties accessing self-management education, frustration with 'tick-box' medicine, variability in care, concerns about health professionals keeping up-to-date and difficulty accessing primary care services. In many countries, there has been a significant shift in the care of chronic conditions away from secondary care into primary care. This transfer of workload may not have been

accompanied by adequate increases in capacity or training and the problems are likely to be exacerbated by increasing longevity and prevalence of chronic diseases. It has also been argued that current models of healthcare are not well suited for supporting self-care in chronic disease and a more integrated 'whole systems' approach is needed (Kennedy et al. 2007b). Many participants in this study felt that the healthcare services they were using were difficult to access and many consultations provided regimented, protocol-driven care that was not responsive to their needs or agendas. If healthcare services could provide an OSMI for type 2 diabetes, it could potentially meet these unmet needs described by participants as digital interventions are well placed to provide a more tailored and accessible solution that could be available round the clock whenever and wherever users want (Murray 2012).

Another challenge facing healthcare services is the requirement for providing patient access to electronic medical records as discussed in the introduction to this chapter. Participants in this study were generally keen on having access to electronic medical records but there was little experience of this. Although there is not much data from the UK, systematic reviews of access to medical records suggest that patients with online access to records reported improved satisfaction and improved communication with clinicians (de Lusignan et al. 2014; Mold et al. 2015). The main concerns expressed by participants in this study were centred on controlling the flow of information and being able to limit what allied health professionals outside the surgery had access to. The challenges for healthcare services lie in balancing the security and accessibility needs of patients, and the concerns of healthcare professionals to empower patients with useful information. Examples of the concerns raised by health professionals are discussed in Chapter 6.

4.6.3 Type 2 diabetes and role management

Living with a chronic illness like type 2 diabetes is an experience where the structures of everyday life and the usual knowledge that informs them are radically disturbed – a critical situation that has been described as biographical disruption (Bury 1982). Assumptions about health and bodily function are challenged, explanations for illness and symptoms are sought and patients

need to mobilise resources in response to this disruption (Williams 2000). Many participants in this study were still in mourning for the loss of their previous disease-free identity, their “sick-role” perhaps made even more puzzling by the often asymptomatic nature of the condition. A systematic review of psychological adjustment to chronic disease identified four elements of successful adjustment – i) remaining active ii) acknowledging and expressing emotions in a way that allowed taking control of life iii) engaging in self-management and iv) trying to focus on potential positive outcomes of the illness (de Ridder et al. 2008). Most people living with type 2 diabetes are overweight and may have co-morbidities like arthritis or heart disease that can limit their physical abilities. In this context physical activity is challenging and eating healthily was consistently seen as an uphill struggle for most of the participants in this study. The medication burden for diabetes is significant as it usually involves multiple agents to control blood glucose levels, blood pressure and cholesterol - and this increases over time with decreasing pancreatic function and the development of complications like nerve damage or heart disease. Remaining active and engaging in self-management behaviours (e.g. physical activity, health eating and taking medication) can be significant challenges in type 2 diabetes. The emotional distress reported by participants and discussed earlier was significant and none of the participants brought up potential benefits or positive outcomes from their condition. Therefore all four aspects of successful adjustment face significant obstacles for people with type 2 diabetes, so it is perhaps unsurprising that many participants seemed to struggle with their post-diagnosis identity.

The challenges posed by biographical disruption and the difficulty of adjusting to the diagnosis are compounded by feelings of stigma (Schabert et al. 2013). Health stigma can be defined as an adverse social judgment on a person or group that experiences or anticipates labelling, stereotyping, blame, devaluation, and/or exclusion because of a disease or health problem (Kato et al. 2016). The stigma of diabetes is both external where patients are judged by others, and internal when those negative judgements are internalised and applied by patients to themselves (Kato et al. 2016). Stigma in type 2 diabetes comes from patients feeling like they caused their own condition, being subject

to negative stereotyping, being discriminated against or having restricted opportunities in life (Browne et al. 2013). All of these are likely to contribute to the negative self-image and diabetes-related distress that seemed to affect many of the participants. The importance of dealing with diabetes-related has already been discussed, but to counteract the effects of stigma, there is a need to help patients construct a positive self-image and feel valued. This underlined the importance of a positive tone and support in self-management interventions as advised by participants when talking about design and content of the new OSMI.

The disruption caused by diabetes affected different people differently and changed over patients' illness trajectory. As the disease progressed and complications accumulated, participants could face increasing dependence and problems staying in employment. Two participants talked about their difficulties with work and one eventually felt too ill to continue. The other participant was supported with a change in his role to reduce the problems caused by shift work. People with type 2 diabetes in England are protected by the Equality Act 2010 and the practical advice desired by participants in the OSMI needed to include information and support with making changes to working roles as the impact of type 2 diabetes could be significant and increased with disease progression.

4.6.4 What participants wanted from an OSMI for type 2 diabetes

Participants in this study wanted access to interventions that could achieve a delicate balance between being comprehensive yet simply written, maintain a supportive tone but not shy away from difficult truths, deliver a consistent message in the face of evolving or conflicting guidance and provide access to professional- and peer-generated content.

The information and design features desired by participants in this study are consistent with findings from previous studies. Qualitative work with patients living with a range of chronic conditions has shown that participants want detailed, specific and practical advice (Kerr et al. 2006). Principles of good website design include elements like the use of images where possible, keeping

text brief, consistent and straightforward navigation and having a professional look (Michie et al. 2012a). They are consistent with the literature on the cognitive and affective elements that define user perceptions (Cyr et al. 2009). The cognitive elements of user perception include attention, perception, memory, learning, communicating and executive functions like problem solving, planning, reasoning and decision making. Supporting these processes requires an interface that is not cluttered with too much information and uses animation, colour, underlining, ordering, sequencing and spacing of elements on a page with salient information provision (Rogers et al. 2011). Cognitions can be viewed on an individual level or as a distributed phenomenon spread across multiple agents – e.g. using the intervention with health professionals to use their knowledge and skills as an extra resource to help understand or tailor difficult information which would also fit with the whole system approach advocated for supporting self-management (Kennedy et al. 2007b). However this was not something discussed by participants – it is easy to see practical barriers to this as many patients described experiences of protocol driven consultations where there was little time or inclination from health professionals to explore patient interests.

Satisfying cognitive drivers for intervention use requires the intervention to be efficient, effective and trustworthy (Cyr et al. 2009). Efficiency is a feature of good design while effectiveness requires meeting the patient needs described in this chapter. Participants in this study were also quite clear about what would make them trust an intervention and they wanted it to be edited to a high standard with no typographical errors, have no advertising, be up to date, display visible branding from trusted providers like the NHS and have working links to reputable websites.

Models for affective elements of design can describe visceral, behavioural and reflective levels of response (Ortony et al. 2005). This is similar to psychological models for behaviour where the visceral (reflex) and behavioural levels map onto impulsive processes, while reflective processes are similarly named (Strack et al. 2004). Positive affective drivers of user behaviour require the intervention to be enjoyable and interesting while avoiding frustrating or irritating

design flaws. Participants in this study did not focus on the technical flaws that can be irritating – but these are well described in human-computer interaction literature and include elements like the intervention not working or crashing, not meeting user expectations, providing insufficient information for use, obtuse or vague error messages and visual elements that are too noisy, garish, gimmicky or patronising (Krug 2013; Rogers et al. 2011). A specific annoyance was language – participants found American English irritating and they also wanted the intervention to be relevant for people with type 2 diabetes living in the UK. In terms of making the intervention likeable – participants wanted interactive features like quizzes and the tone to be supportive and encouraging. The difficulties that might arise from trying to balance this with the participants' desire for detailed and accurate information about the consequences of diabetes are discussed later.

Participants in this study wanted a website that would be a central, trusted resource for all their diabetes related needs. One of the unique features of this study is the description of the specific content that could meet the patient-defined needs for people with type 2 diabetes and this was quite broad with relatively little emphasis on medical aspects. Most of the content that participants wanted was non-medical information on topics like diet, alternative medicine, practical advice for travel and insurance and peer support.

4.6.5 Strengths and limitations of this study

Qualitative study design

The use of qualitative methods allowed the exploration and understanding of complex topics like work of living with type 2 diabetes and the desirable features of an OSMI that could help them with that work. It supported a deeper exploration of the social and cultural context of the condition and environment in which a OSMI would be used. The data were rich and extended beyond the medical management of type 2 diabetes that can be the focus of health professionals and existing DSME programmes. The curiosity about what was important for participants revealed the extent of the emotional burden of living with type 2 diabetes and the mismatch between patient needs and current health service provision. However this was combined with a more practical

element focused on content and design that contained useful guidance that informed the design of a new OSMI for adults with type 2 diabetes. Focus groups may also generate more critical comments than interviews and they can be a powerful tool for exploring the limitations of existing services (Kitzinger 1995). This potentially made it easier for participants to express their areas of unmet needs that have been explored in this study.

There were limitations inherent in the design of the study. People are not always consciously aware of the habits, emotions and impulses that drive their behaviour so simply meeting consciously expressed needs may not be sufficient to engage participants or predict future behaviour (Yardley et al. 2015). Therefore this data needed to be supplemented by more observational data and usability testing to guide intervention development. The data gathered from focus groups could also be at risk of being overly influenced by dominant personalities within the groups which would limit transferability (Kitzinger 1995). However the groups were carefully moderated to ensure all participants were drawn into discussions so the data does contain contributions from all participants, although the opinions they shared would reflect the group dynamics and interactions with the facilitator.

Representation and transferability

The sample of participants contained a good proportion (8/20) of women and older people as the mean age was 56 with a range of 36 to 77. However, under-represented groups could be people currently in work (only 5/20 currently employed – although 8/20 were retired), those with low educational achievement (4/20 participants below A levels), ethnic minorities (only 6/20) and those with no access to the internet at home (1/20). Recruitment to the study was opt-in and therefore required patients to take the initiative in order to participate. In the context of studying self-management behaviours, this could have implications for transferability. The participants who volunteered for the study were well-educated and computer literate. The sample may have over-represented patients who were highly motivated and actively engaged in self-management. People with lower health literacy and from other cultures may have different needs that were not described in this study.

Influence of interviewer(s)

One of the strengths of the study was the use of multiple interviewers from diverse disciplinary backgrounds. Being a doctor did have an impact on my interactions with participants. There were two or three occasions where participants directed questions at me and asked for a professional opinion. I did not answer these questions during the focus group but offered to discuss the issues at the end after the focus group was over. I confined my input to facilitation of discussions. However the power differential between patients and doctors can be deeply engrained and based in perceived differences in status and knowledge (Alexander et al. 2012). To minimise the impact of this, the focus groups were done in non-clinical settings to normalise the interactions and help participants not feel like they had to take a patient role. Some of the focus groups were run by non-medical colleagues and the focus groups I ran had non-medical co-facilitators to dilute the influence of doctor-patient dynamics on the focus groups.

Data saturation

The study was focused on being a pragmatic study that was part of a programme to develop an OSMI. Therefore the initial analyses were focused on content and design issues that would inform development and decisions regarding saturation were based on data relevant to design and content. The thematic analysis to understand the work of self-management was done later in the development cycle and explores a larger and more complex topic. The data in this study is unlikely to have reached saturation when considering the full spectrum of challenges facing people living with type 2 diabetes. Therefore I did not attempt to develop new theories to explain the work of self-management in type 2 diabetes but used the literature to inform my analysis and placed the findings into context with data from other studies in this field to inform my discussion.

4.6.6 Implications for diabetes self-management interventions

It was clear that participants wanted an upbeat and encouraging intervention that would motivate them. From an intervention design perspective this becomes a challenge when talking about complications and giving people reasons to change or improve self-management. Given that many people with type 2 diabetes are asymptomatic, especially early on in the illness, it requires careful consideration as to how information is presented so that the risks from diabetes are heeded to prevent future (potentially fatal) harm, without the site being perceived as threatening or pessimistic.

Most participants in this study were keen to engage in self-management but felt there were limits on how much time they were willing to spend on self-management and it was not necessarily their top priority. The impact of diabetes self-management on day to day life has been described as physically, intellectually, emotionally and socially demanding (Hinder et al. 2012). It can be hard work and enabled or constrained by economic, material and conditions with the family, workplace and community. The burden of treatment for chronic conditions has a negative impact on abilities of patients to collaborate in their care and the provision of healthcare should aim to be 'minimally disruptive' (May et al. 2009a). Even for participants in this study, who were engaged and interested in self-management, the amount of time and effort available for self-management activities was quite limited. Interventions promoting diabetes self-management need to minimise the demands they make on users, facilitate efforts to reduce the work of self-management, boost personal resources like confidence and problem-solving, provide access to supportive social (peer) networks and help users make use of healthcare resources.

Current national guidance for standards of diabetes care highlight the importance of patient-centred care (American Diabetes Association 2016; National Institute for Health and Care Excellence 2015). Improving self-management is also seen to be a crucial element of tackling the rising healthcare costs associated with the increased prevalence of chronic diseases like diabetes. However, many participants in this study reported difficulties in accessing the support they needed for successful self-management from

existing healthcare services. Digital interventions could help improve quality of care, patient satisfaction and promote patient-centred care. Features that could help meet some of the unmet needs described by participants in this study included being available 24/7, being minimally disruptive, having up-to-date evidence based guidance for patients, providing access to peer and professional advice and placing an emphasis on emotional management.

4.6.7 Implications for other long-term conditions

Most of the findings above could be relevant to most other long-term conditions. Clearly medical content needs to be tailored to the condition, but the other issues discussed around the nature of information provision and the overall holistic approach required to support self-management could be relevant to many other conditions like asthma, arthritis or chronic obstructive pulmonary disease. As many of these conditions are likely to be more symptomatic than diabetes, such interventions would require more symptom management – but the advantage for this would be opportunities to help make the intervention immediately relevant and useful so patients engage with the intervention quickly.

4.6.8 Implications for further research

As this was qualitative research, the findings are suitable for generating ideas and hypotheses, but their validity and generalisability would require testing through appropriately designed trials. Exploring professional opinions is also necessary as health professionals also have knowledge and experience that will describe healthcare needs and service provision requirements that patients may not be aware of. The process of synthesising the different perspectives to create an intervention requires further work. Different populations might have different health needs and exploring the impact of different cultures, health systems and varying health literacy would also be important. Finally understanding the acceptability and usefulness for people unfamiliar with digital interventions is an important element of understanding the potential for improvement in populations with an online self-management intervention.

4.7 Conclusion

This study identified a number of patient needs for self-management that are currently not being met and participants gave a clear description of the features they wanted from an online self-management intervention. Participants expressed a need for more accessible, patient-centred care with tailored information provision and more emphasis on emotional and social support. They wanted access to a wide range of practical information about living with type 2 diabetes. The OSMI needed to contain detailed but accessible information, maintain a supportive tone and provide access to professional and peer generated content. It would need to minimise the demands it made on users, reduce the work of self-management, boost personal resources like confidence and problem-solving, provide access to supportive social networks and help users make better use of healthcare resources. These findings are compared with the view of health-professionals in the next chapter and were used to develop the HeLP-Diabetes intervention as described in Chapter 6.

5. Health-professional preferences for an online self-management intervention for adults with type 2 diabetes

5.1 Chapter outline

In contrast to the previous chapter that focused on the patient perspective, this chapter has described the views of health professionals on the use of a digital self-management intervention to support adults with type 2 diabetes. It has described what health professionals thought about the challenges facing patients, how patients might benefit from an online self-management intervention and the potential obstacles to using and implementing such an intervention as part of routine diabetes care. As this was a qualitative study that built on the previous study, some of the methods and rationale were similar to those described in chapter 4. Where there were similarities, these have been dealt with briefly with reference to the previous chapter. The areas where there were differences have been described in the methods section of this chapter. The discussion has drawn together the findings of Chapters 4 and 5.

5.2 Introduction

5.2.1 *The challenge of engaging patients with digital interventions*

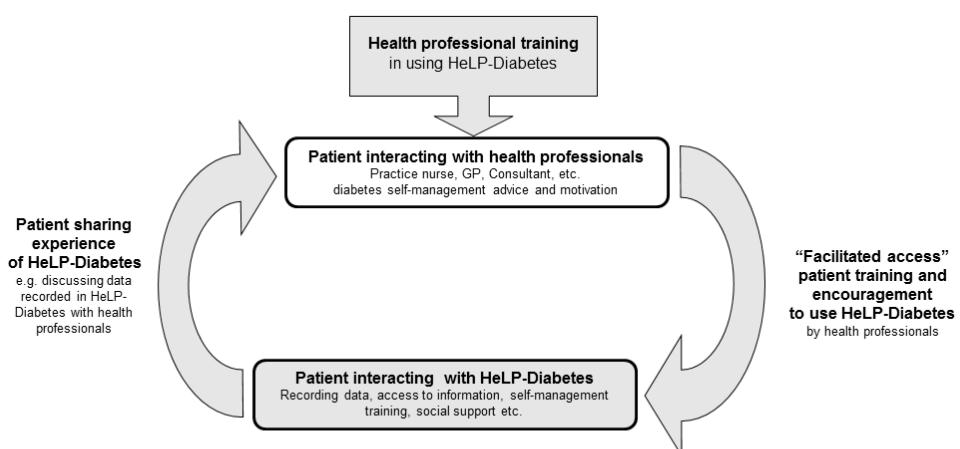
In Chapter 4, I discussed the issue of attrition and the problems of keeping users engaged with digital interventions. Disengagement with digital interventions is a significant concern as the usage of digital interventions has been correlated with their effectiveness (Couper et al. 2010;Donkin et al. 2011). The previous chapter also explored the design features of an intervention that might keep users engaged and technology-based prompts can help with this (Alkhaldi et al. 2016). However human input and support in using digital interventions by facilitators and peers have also been shown to increase exposure (Brouwer et al. 2011a). If health professionals or administrative staff in clinical settings were able to support patients with using digital interventions it could help increase engagement and effectiveness. Therefore exploring the role of health professionals in supporting the proposed intervention was the key area of interest for this study.

5.2.2 The role of health professionals in engaging patients

Physician communication has been shown to be a significant facilitator for improving patient engagement with treatment advice (Roter et al. 2009;Zolnierewk et al. 2009). Patient-centred clinician communication does not just improve medication adherence, but it has also been shown to improve other diabetes self-management behaviours (Heisler et al. 2002;Heisler et al. 2007). Educational and self-help programmes that are actively supported by clinicians can improve health outcomes for patients with long-term conditions (Coulter et al. 2007) and in patients with low health literacy the impact of written material is increased by verbal recommendations from professionals (Coulter 2012).

The interaction between patients and their health professionals around the intervention was seen to be a key element of the intervention and this is illustrated in Figure 5-1. We judged that the intervention was more likely to be used consistently over time by patients and therefore more likely to be effective if clinicians prompted regular use and expressed appreciation for the self-management efforts made by patients. Therefore embedding the intervention into routine care was an important factor for increasing use and impact of the intervention. Successfully supporting patient-centred care requires patient, professional and system-wide change (Graffy et al. 2009) so engaging patients and professionals, and integrating the intervention into routine primary care pathways were postulated to be key to maximising potential impact.

Figure 5-1 Important interactions for intervention use and implementation



5.2.3 Using Normalization Process Theory (NPT) to understand the work required in embedding the OSMI into routine care

As discussed in Chapter 2, NPT was used as a sensitising framework to analyse the work that health professionals thought would need to be done in implementing a new online self-management intervention for adults with type 2 diabetes. The use of a sensitising framework facilitates the process of identifying, categorising and understanding qualitative data (Bowen 2006). NPT has been applied to a number of different interventions and also used in systematic reviews to understand the process of implementation (Elwyn et al. 2008;Lloyd et al. 2013;Mair et al. 2012). These studies have used the four main constructs of the theory to analyse the work involved: Coherence, Cognitive participation, Collective action and Reflexive monitoring.

Coherence is the “sense-making” work that users do individually and collectively to develop their understanding of the problems they face when operationalizing a set of practices. This would require health professionals to understand key concepts like:

- how an OSMI would be different to existing DSME interventions
- the purpose of the OSMI
- the work required to implement an OSMI
- potential benefits of an OSMI for their work.

A previous study of implementing a shared decision support system found that normalizing the intervention required intensive work to ensure that teams had a shared understanding of the purpose (Lloyd et al. 2013). Ultimately over the duration of the study, the team only achieved partial implementation as, in the absence of good coherence, normalization was simply not possible. The study concluded that agreement among all team members to the simple question of “what is the work” was a vital step towards implementation. Normalizing the use of a new OSMI for type 2 diabetes into routine clinical practice would require similar work across a GP surgery involving doctors, nurses and admin staff. The work of implementation might require a combination of training staff, promoting the intervention with patients and possibly supporting registration or ongoing use. It is likely that the first and possibly most significant barrier to implementation would be achieving a shared understanding across the practice

of the work that would need to be done and getting individuals to develop a strong understanding of the work they must each do to achieve this.

Cognitive Participation is the relational work that people do to engage with or get “buy-in” to the innovation and build and sustain a community of practice around a new technology or complex intervention. This can involve processes like:

- key opinion leaders setting the agenda for local or national diabetes care promoting the OSMI
- health professionals wanting to support the aims of the OSMI and feeling that they are able to help support it
- practice or community diabetes teams making the organisational changes needed to support a OSMI.

Collective Action is the operational work that people do to implement a set of practices and explores the relationships between new and existing work.

Potentially important aspects of this construct are:

- doctors and nurses using a OSMI in consultations or encouraging patients to use one
- the OSMI not threatening existing roles for doctors or nurses
- the tasks needed to implement the OSMI are appropriately allocated to people with the right skill set – so administrative staff doing administrative tasks like registration, rather than clinical staff
- the implementation of the intervention is appropriately resourced.

Reflexive Monitoring is the appraisal work that people do to assess and understand the ways that a new set of practices affect them and others around them. This element can be supported by processes like:

- availability of data from trials, audits or informal feedback demonstrating benefits of the OSMI
- health professionals in GP surgeries or diabetes clinics believing the intervention is worthwhile
- doctors and nurses changing their working habits to facilitate uptake of a OSMI.

5.2.4 Challenges in changing health professional behaviour to implement a new OSMI for people with type 2 diabetes

Changing health professional behaviour to improve routine clinical practice has been shown to be extremely challenging (Grol et al. 2003). Clinicians often feel they have good reasons to be resistant to change, e.g. a physician survey

asking about the perceived barriers to implementing guidelines on diabetes care in the Netherlands cited problems with heavy physician workload, a lack of financial compensation, a lack of flexibility and a lack of time to implement the guidance (Dijkstra et al. 2000). Approaches to changing clinical practice need to be adapted to the specific features of the change proposal, the target group, the setting, and the likely barriers (Grol 1997). The majority of routine care for type 2 diabetes happens in primary care – e.g. diagnosis, referral for DSME, medication titration and annual reviews for people without advanced complications are all activities done by GPs and practice nurses, some of whom will have a special interest in diabetes. Care for more complex cases usually happens in community or hospital clinics with consultants or specialist nurses. Introducing a new digital SMI for patients into these settings would require changes in behaviour for doctors and nurses. They would need knowledge of the intervention and be willing to communicate the potential benefits of use to patients living with type 2 diabetes. Routine consultations or annual reviews for type 2 diabetes would represent opportunities to engage with patients and promote or encourage use of the intervention. Acknowledgement of the time and effort patients put into the intervention would reward patients for using the OSMI, and making the intervention part of the consultation could help integrate the intervention into routine practice. All of these activities are examples of work that could be important in implementing a new OSMI, but could prove challenging in a context where health professionals were concerned about workload, time pressures or expected incentives. Therefore understanding the health professional perspective on such issues would help inform the optimal strategy to communicate, engage and support relevant changes in clinical practice.

5.2.5 Patient access to Electronic Medical Records (EMR)

As highlighted in Chapter 4, digital interventions have the potential to interface with the electronic medical record. The policy brief had been made clear with the Department of Health issuing a mandate that stated that the Government expected by March 2015 everyone who wished would be able to get online access to their own health records held by their GP (Department of Health 2014). Improving access to online patient records has been part of the drive to

help patients take better control of their health and empower patients to improve their self-management (NHS England 2016). However while HeLP-Diabetes was being developed, such services were not widely available even though the evidence and data discussed in Chapter 4 suggested it could be beneficial and patients were broadly supportive of the concept. Exploring professional attitudes towards patient access to the EMR was important as it was a potential feature of the intervention and the barriers to implementation of this online service could be relevant to the implementation of a new OSMI. Therefore this topic was specifically addressed as part of this study.

5.3 Aims of the study

Primary objective

To determine health professional perspectives on the features of the intervention which would encourage uptake and use by patients and use by health professionals in routine diabetes care.

Secondary objective

To explore health professional views on patient access to electronic health records.

5.4 Methods

5.4.1 Design

This was a qualitative study using semi-structured interviews and focus groups with a convenience sample of health professionals working for NHS services in England.

5.4.2 Use of focus groups

The advantages of focus groups in using group discussions to help people explore and clarify their views were discussed in the previous chapter (Kitzinger 1995). The interplay between participants can allow for ideas to be generated, reflected on and debated (Ritchie et al. 2014); understanding the spectrum of responses to possible features provided data to support intervention design and prioritise development. Focus groups are particularly suited for exploring participants' attitudes and experience and we were particularly interested in

health professionals' attitude towards digital interventions and their experience of implementing new services. Most of the focus groups (3/4) were professionally homogenous and consisted of just nurses or doctors, some of whom worked together. This created a supportive environment that helped participants draw on shared experience and helped draw on contributions (McLafferty 2004). For example in one focus group, a nurse was asked about ways of increasing engagement with the intervention and at first she felt unable to answer. Her colleague took over, and talked about her workload and not having time to ring people, and the participant agreed with her and then suggested text messages as a more feasible engagement prompt.

5.4.3 *Use of interviews*

The biggest challenge with gathering health professionals' views was scheduling. Finding times and locations that would be convenient for multiple health professionals was anticipated to be challenging therefore participants were also offered individual interviews at locations convenient to them. The advantage of interviews is the in-depth exploration of views, experiences, beliefs and motivations of individuals (Britten 1995;DiCicco-Bloom et al. 2006;Gill et al. 2008). Being able to dedicate time and attention within the interview to explore one person's perspective allowed individuals to express their opinions in greater depth. Participants in the interviews were more likely to share personal stories and experience to illustrate where their opinions came from, allowing a deeper understanding and exploration of their perspectives. For example one participant shared her own experience of going to see a surgeon for a foot injury and she identified a sense of frustration and dis-empowerment when her agenda (to start running again) was completely ignored leading to her subsequent disengagement from the service she was attending.

The use of interviews and focus groups allowed data gathering to be in-depth and flexibly arranged for participants, but also used the benefits of group dynamics to encourage and elaborate on contributions from participants.

5.4.4 Ethics and research governance

The study was reviewed by the North West London Research and Ethics Committee and granted ethical and R&D approval on 10/11/2011. The REC reference number is 10/H0722/86. Ethical approval was granted together for the work described in this chapter, the work done in chapter 4 and development of the intervention. A copy of approval letter can be found in Appendix 5.

5.4.5 Participants, setting and eligibility criteria

Diabetes care is multi-disciplinary and involves primary care professionals (GPs and nurses), community care (diabetes specialist nurses and dieticians) and secondary care (endocrinologists, outpatient clinics and inpatient care). Participants in this study came from a range of professional backgrounds but they were all health professionals working for the NHS in England who had been involved in the care of people with type 2 diabetes (See section 5.5). The majority the doctors interviewed were clinical academics and worked part time in NHS practices. I was a participant in the first focus group, as was my supervisor EM.

Interviews and focus groups were held in a range of places – some were in the Department of Primary Care and Population Health at UCL, one focus group was held in the offices of the local GP research cluster, one interview was done at the 2011 meeting of the Society for Academic Primary Care and three other interviews were done where participants worked (Deanery, University outside London and a GP surgery in North West London).

5.4.6 Sampling strategy

Participants were chosen from a variety of professional backgrounds – GPs, Endocrinologists, Practice nurses, Specialist nurses and a dietitian based on a convenience sample generated through snowballing and professional contacts.

General Practitioners

GP partners would have experience of management and implementing change, and they would have a say in their surgeries taking up the intervention. Therefore it was important to explore their perspective. Salaried GPs provide much of the clinical doctor time in practices and would have multiple

opportunities for interactions with patients with type 2 diabetes. Younger GP trainees might be more enthusiastic or experienced with new technology so that perspective was sought for ideas on intervention design.

Endocrinologists

Although we envisaged the intervention to be used mostly in primary care, it was important to seek out the view of hospital consultants as well. Their knowledge and experience of the condition and supporting self-management was an important resource. They could also have links with community clinics or joint clinics with primary care where the intervention could be deployed. Recommendations from specialists would also carry weight within the profession so understanding the factors that would encourage consultants to recommend the intervention were also felt to be important.

Practice nurses

Practice nurses play an increasingly important role in the management of type 2 diabetes. They are often responsible for the practice annual diabetes review and they can often be key resources for patients for education and self-management support. Practice nurses had the potential to be key individuals in promoting the intervention or encouraging regular use, and their perspective was crucial.

Specialist nurses

Many nurses develop a special interest in diabetes and provide care for complex patients with more advanced disease and they are often actively involved in diabetes education. They were also likely to have knowledge of existing education resources and could provide valuable insight into design and content of the intervention. Specialist nurses are often involved in educational activities for health professionals as well and could have valuable experience of service development and improvement that could be relevant to implementation.

Dieticians

Although dieticians are not often part of primary care teams, they can work closely with community clinics and dietary changes are a key element of diabetes self-management. Therefore dietician input into the content of the intervention was an important consideration.

Gender, ethnicity and age

Gender was monitored but was not used as a criterion for purposive sampling. The nurses who participated were all female but this was balanced out by there being more male GPs interviewed than female GPs. There was one male and one female endocrinologist. Overall there were seven male participants and 11 female participants.

Ethnicity and age were also recorded but not used as criteria for purposive sampling. As the priority for this study was understanding the challenges to implementation in routine clinical practice across English health professionals, a mostly White British middle-aged sample was appropriately representative of the target population. The factors affecting implementation were anticipated to be more related to professional roles and norms, and much less to ethnicity or age.

5.4.7 *Recruitment*

Recruitment started with GPs in the eHealth unit at UCL. The first focus group involved GPs and an endocrinologist who were collaborators on the grant application. From there recruitment proceeded through snowballing and contacts were made with other GPs, nurses, dieticians and hospital doctors known to members of the research team, the local academic department and work colleagues. Advertisements were also put up at a conference for the Society of Academic Primary Care and a GP trainee participant was recruited from the conference. The main targets for recruitment were primary care staff involved in looking after patients with type 2 diabetes. Most routine care for diabetes in primary care is provided by GPs and practice nurses who were the primary target for recruitment. Dieticians and diabetes specialist nurses were also targeted through recommendations from participants. Recruitment continued until theoretical saturation was reached and there were no new data regarding intervention design, implementation or patient access to electronic

medical records. As the focus of this study was to inform the development of the intervention, the time and resources available for recruitment were limited. Therefore the majority of participants who worked in academic general practice settings and full-time clinicians had less representation, although efforts were made to broaden the range of participants and the sample included one non-academic GP and endocrinologist.

5.4.8 Data collection:

Demographic questionnaire: all participants were invited to complete a questionnaire to collect details of role, gender, ethnicity and age. This information was used to recruit a maximum variety sample based on the theoretical rationale described previously. A copy of the questionnaire can be found in Appendix 9.

Discussions were semi-structured with a list of topics to be covered (not necessarily in a defined order) during the session. The topic guide was piloted in an interview with a senior member of the eHealth unit by CD. The topic guide was revised and tested in the first focus group convened with co-applicants on the grant. Based on the data from these sessions, the topic guide was updated. An initial question about the use of the internet in consultations envisaged as an ice breaker had not yielded useful data and had caused long diversions so this was removed. The issue of electronic medical records had not naturally come up in consultations, so a specific question was added. Potential content and design features were not well described in the first interviews so a question was added about this. The final topic guide can be found in Appendix 8.

CD led two focus groups and did two interviews. I led one and co-facilitated one focus group and did five interviews.

Of the four focus groups, one was multi-disciplinary with one GP, one dietitian and one nurse. The benefits of a diverse group include the investigation of different perspectives as group discussions around divergent views can yield interesting data or make clear hierarchies and the nature of relationships that exist in clinical practice (Kitzinger 1995). However the risk of heterogenous

groups is that they suppress contributions from less confident participants, whereas homogenous groups can facilitate contributions from such participants as highlighted earlier in this chapter in a focus group with nurses and no doctor (Sim 1998). Looking at the structure of the data in the heterogeneous group there seemed to be fewer discussions between participants and there was a tendency for opinions to be expressed but not explored. The topic that generated the most interaction between participants was self-blood glucose monitoring with participants sharing experiences of patients who tested frequently with no evidence of benefits.

The remaining three groups were homogenous with one focus group of four doctors and two joint interviews with two nurses. Four to eight participants is seen as a good size for focus groups (Kitzinger 1995) so ideally the two nurse groups would have been run as a single focus group but due to health professional availability this was not possible. The sessions ran for 2 hours and were facilitated by two moderators. The second moderator took a more observational role and as discussed in Chapter 4, their main function was to ensure the main facilitator did not play too dominant a role in the discussions and helped to make sure all questions on the topic guide were covered during the session.

The interviews were done by either CD or me. They were around one hour long and were semi-structured using the topic guide described previously with open ended questions and specific prompts where needed. Five interviews were with GPs, one was with an endocrinologist and one was with a diabetes specialist nurse. Therefore we were able to collect in-depth data across a range of professional roles. While the focus groups were a good source of data regarding content and design, the interviews provided richer and more insightful data regarding the difficulties of implementation and reflections on health professional behaviour and motivation.

All focus groups and interviews were audio recorded and transcribed verbatim with personally identifiable information removed. Data were stored electronically in encrypted files in accordance with the Data Protection Act (1998). Paper

copies of consent forms and questionnaires were kept in locked filing cabinets in a locked office.

Atlas Ti was used to manage data retrieval, transcript coding and to make data analytic notes.

5.4.9 Data Analysis

Design and content

Data analysis was done through iterative cycles similar to the process described in Chapter 4. The first cycle of analysis was focused on informing the intervention development and needed to be completed quickly. It was done by the multidisciplinary team described in Chapter 4, consisting of an experienced medical sociologist (FS), a psychologist (CD), two fully qualified GPs (EM and me) and one GP trainee in the final year of her training (EG). As highlighted previously, this team represented a broad range of perspectives so the coding and analysis was sensitive to the clinical, sociological and psychological context of the data, and two of the participants had significant qualitative experience.

Transcripts were independently read by each researcher and important themes were extracted. The themes were descriptive and related to content and design issues (Miles et al. 2014). This generated simple descriptions that could be used to label features of an online self-management intervention for adults with type 2 diabetes. The content and design features suggested by health professionals are compared with patients in the discussion of this chapter.

The second cycle of analysis was a more in-depth analysis done by me. Transcripts were read and the data coded with a focus on data related to implementation and use of the electronic medical record. The coding structure was presented to EM and emerging themes were discussed. Thematic coding occurred iteratively and involved moving between transcripts, codes, research literature and the analysis. Once all the transcripts had been coded, the codes were grouped in a hierarchical structure with themes and sub-themes using Normalization Process Theory (NPT).

Use of NPT

In keeping with the aims of this study, the main analysis of the data focused on the implementability of the intervention and explored the factors influencing Coherence, Cognitive participation and Collective action in relevant staff. The aims of the intervention appeared to be well aligned with the goals of health professionals and there was a high level of coherence with their professional

work. The analysis below has described how clinicians interpreted the aims of the intervention and how they thought it might differ from existing practice. In terms of cognitive participation, the features that would help engage health professionals included content and design features, trustworthiness, evidence of benefits, champions and endorsements from respected bodies. Health professionals also expressed some reservations about the collective action that might be required to implement the intervention and how that would be resourced. There was no difference in the data between the factors that would engage health professionals with the intervention (Cognitive participation) and the criteria that they would use to appraise the impact of implementing the intervention (Reflexive monitoring). Therefore Reflexive monitoring has not been used as construct in the analysis below.

The final section of the analysis has explored health professionals' views on patient access to electronic medical records (EMR).

5.4.10 Reflexivity

As part of my analysis I have reflected on my roles and identities and how they have influenced my behaviour and interpretations of the data. My personal and professional experiences will have influenced my behaviour during interviews, interactions with participants and analytic decisions – when the data collection was done, I was a salaried academic GP with 3 years GP experience. I was a participant in the first focus group and my circumstances had an impact on my contribution. I felt that I was relatively inexperienced and as a researcher I was more interested in listening to the opinions of the other participants than expressing my own. To counteract this I made sure that I responded to cues to contribute as prompted by the main facilitator FS who was an experienced medical sociologist.

Two of the nurses who took part in this study work in the same GP surgery as I do. We discussed this as a team and decided it was better if I did not facilitate that focus group. While a pre-existing working relationship would have ensured a good rapport, the dynamics of a doctor-nurse relationship and perceived professional hierarchies could have inhibited their contributions.

I facilitated a focus group and did a joint interview with diabetes specialist nurses. As specialist nurses they would be used to working with doctors and would have more specialist knowledge than a GP. Therefore I would not expect them to be inhibited by professional hierarchies when talking to me.

As a doctor, I have received communications skills training and regularly reflect on my consultations skills. I believe this has helped me develop my ability to build a rapport quickly with strangers and use open-ended questions and active listening to help interviewees express themselves freely. However it is important to distinguish between clinical consultations skills which are designed to facilitate reaching a clinician-derived diagnosis, and research interviews that explore interviewee perspectives (Britten et al. 1995). Reflecting on my practice, I have found that a good rapport, curiosity and not seeking to pass judgement greatly facilitate the process of richer data collection.

Most of the interviews that I did were with doctors. I felt comfortable and the shared experiences appeared to contribute to a good rapport. There are risks and benefits of GP-GP interviews (Chew-Graham et al. 2002). When interviewed by another GP, GPs are more likely to make themselves available for interviews and tend to provide longer and less calculated responses. Interviewees may permit themselves a degree of vulnerability (if they feel safe) and provide richer and more intuitive responses. The risk of such interactions is shared conceptual blindness where my feelings and opinions would direct the conversation and interpretation, which has been explored below (Hamberg et al. 1994). Power differentials can exist if one person is felt to be more expert than the other and this may lead to perceived judgement or requests for validation (Chew-Graham et al. 2002). This was potentially an issue when interviewing the GP trainee, although I was aware of this and actively supported the participant in expressing her own views.

5.4.11 Reactivity

Clinical communication skills training has certainly improved my ability to stay neutral during interviews. I am able to maintain a rapport without sharing my opinions and feel comfortable using open-ended questions during interviews.

The main risk with interviewing health professionals was shared conceptual blindness. My own feelings or opinions might filter or evaluate what was being said. Pre-conceived ideas based on my own experience could prevent me probing or clarifying if I assumed I understood what was being said or lead me to misinterpret what was participants were sharing. To avoid this, my aim was to actively pay attention to what was being said and explicitly clarify any potentially ambiguous statements or any comments that would not be understood by a lay person.

5.4.12 Rigour

To maximise the rigour of this work, I have tried to be aware of my preconceptions and reflected on the credibility, dependability, confirmability and transferability of the study (Hamberg et al. 1994). In Chapters 1 and 2 I described the evidence, theoretical frameworks and models underpinning my understanding of the problems surrounding diabetes self-management and the assumptions guiding my approach to designing an OSMI to help.

To maximise credibility I have tried to ensure that the study design was appropriate, data were collected through well run interviews and focus-groups with appropriate participants and the analysis was reflexive and transparent. I believe the results are dependable and confirmable as the study has been described in detail with a documented rationale for the decisions made, it includes a reflexive account of my circumstances and the analysis has looked for divergent data. The context of the study, underlying assumptions and participants have been documented in detail and this should allow readers to make informed judgements about the relevance of the findings to other contexts.

5.4.13 Transparency

As mentioned above, the research process has been clearly documented. The theory and assumptions underpinning the study have been clearly described. All electronic and paper documents for the study have been securely stored, but with full access available for appropriate team members or for audits. The methods used for design, sampling and analysing the data have been described

above and the results include quotes with clearly labelled sources with participant numbers. Divergent views were sought in the analysis and presented where found. For example when looking at outcomes to judge the impact of an OSMI for type 2 diabetes, participants had quite different views. Some participants felt that biological outcomes (HbA1c) were the most important aspect, while others wanted patient feedback and evidence of use.

5.5 Results

5.5.1 User demographics

Data were collected from four focus groups and seven individual interviews. Details of the characteristics of participants have been summarised in Table 5-1 below. Health professionals included members of primary care, community care and secondary care teams. Eight participants were GPs, with most being salaried GPs - although two out of the five salaried GPs were ex-partners so had experience of both roles. Seven of the GPs recruited were actively involved in research or teaching. One GP was a full-time clinician. There was one GP trainee who had recent experience of both primary care and secondary care. There were six nurses – two worked in primary care, three were diabetes specialist nurses who worked as part of intermediate community care teams or in hospitals and there was one senior nurse consultant. There were two Endocrinologists working in secondary care settings and one dietitian. There was one Asian health professional while the remaining participants described themselves as White British. The average age of participants was 49 (with one participant declining to state their age).

Table 5-1 Summary of participants

| | Total |
|--------------------------------|--------------|
| Profession | N=18 |
| <i>Primary care</i> | |
| GP Partner | 3 |
| Salaried GP | 5 |
| Practice nurse | 2 |
| GP trainee | 1 |
| <i>Community diabetes team</i> | |
| Diabetes specialist nurse | 3 |
| Dietician | 1 |
| <i>Secondary care</i> | |
| Endocrinologist | 2 |
| Nurse consultant | 1 |
| Gender | |
| Male | 7 |
| Female | 11 |
| Age (in years) | |
| Mean | 49 |

Table 5-2 Health professional views on features needed for patient engagement

| | |
|-------------------|---|
| Desirable content | Information about type 2 diabetes Diet Physical activity Medication and side effects Healthy lifestyles Normal test values Myths and misconceptions Self blood glucose monitoring (SBGM) |
| Emotional support | Accepting diagnosis Emotional burden of diabetes |
| Design features | Simple Positive tone Secure Kept up-to-date |

Table 5-3 Main themes and sub-themes on the work of implementing an OSMI

| | | |
|---|--|--|
| Coherence <i>Why should I do the work?</i> | Reasons to engage | Empower patients Improve satisfaction for health professionals |
| | Reasons not to engage | Some patients do not want to take responsibility Risk of replacing face-to-face interventions Will not benefit patients Will exclude the most needy Just a website |
| Cognitive participation <i>What is needed for buy-in?</i> | Endorsements | RCGP, DoH, CCG or patient champions |
| | Evidence of benefits | Effectiveness (HbA1c) Cost-effectiveness Intervention use by patients Feedback from patients |
| | Concerns about impact on existing work | More to do in consultations Spend more time on computer |
| Collective action <i>How will the work get done?</i> | Suitable allocation of new work | Clinical staff have no time Admin staff should do engagement work Use IAPT model |
| | Possible resources to fund new work | Quality and Outcomes Framework (QOF), Directed Enhanced Services (DES) and Local Enhanced Services (LES) |

5.5.2 Health professional views on features needed for patient engagement

Desirable content

Participants felt that the content of the intervention needed to cover information about the disease, diet, physical activity, medication and side effects, healthy lifestyles and normal values of diabetes related tests. They also suggested that it should tackle common myths and misconceptions that patients might hold.

“I think accessing up to date advice on dietary issues, providing good quality written explanation of medications, helping people understand the potential for complications with diabetes.”

PB05 GP partner, Male

“Yes, I mean in practice, people are more concerned about the side-effects than they are actually of how the drugs are working ...But maybe you could explain better how it works and how to take it better and everything.”

PB09 Salaried GP, Female

“[PB13] Things like the myths of diabetes, because there's so many myths, isn't there?

[PB12] What somebody told them at the bus stop about their leg dropping off...

[PB13] ...that's so real for some people and it, sort of, completely dictates what they do and how they feel.”

PB12 Diabetes Nurse Consultant, Female

PB13 Diabetes Specialist Nurse, Female

A specific area of content need was around self-blood glucose monitoring (SBGM). Healthcare professionals were aware of the lack of evidence of improvements in outcome with SBGM and understood the reasoning why blood glucose test strips would be rationed. However nurses felt it could be a powerful motivating tool that could help patients understand how to improve blood glucose control if used correctly. The experience of healthcare professionals seemed to be that blood glucose monitoring did not reflect clinical needs, and in many cases blood glucose monitoring patterns were more reflective of patient personalities. Many health professionals had experience of patients with excellent control bringing in large volumes of meticulously recorded data – usually in patients with good control - and this was something that health

professionals dreaded. Conversely many patients with poor control who might have benefitted from blood glucose monitoring avoided checking their blood glucose levels as they knew it would be high and decided they would rather not know. Similar to the inverse care law, most activity was where the need was the lowest. Therefore education around appropriate SBGM was felt to be a potentially important task.

[PB12] Well we've got a bit of an issue to save moneythose who are on diet only or metformin only there's no provision for them to do that [self-blood glucose monitoring].

[PB13] Where previously we'd encouraged everyone to test because we felt it was empowerment and, you know, it...

[PB12] Motivating."

PB12 Diabetes Nurse Consultant, Female

PB13 Diabetes Specialist Nurse, Female

"The most obsessive person who ever did it, for me, used to produce, literally, one of these big round ring-binders, every three months... It had the average; it had the time series; ...all printed out in colour. ... you've got to look interested while you flip through page after page and you just think bloody hell; what am I going to have for supper tonight?"

PB10 Hospital Doctor, Male

"They check their blood sugar and it's awful, and therefore they won't do it again."

PB14 Diabetes Specialist Nurse, Female

Emotional support

Health professionals felt that including content about negative affective states (accepting the diagnosis and the emotional burden of living with diabetes) was important and one of the critical challenges that faced patients. Health professionals felt that support for these issues needed to be part of the intervention. Diabetes could be asymptomatic and patients might be otherwise healthy - so suddenly having to take on a lifelong label of a having a significant chronic condition could be a difficult transition. The quotes below also illustrate differences between two professionals' views about this process - one felt acceptance was a belief that patients had to "buy into"; another described it more as a change through "stages" that professionals could facilitate.

"I think, one of the key issues with patients with diabetes is actually the whole issue of the degree to which they buy into their diagnosis and understand the implications of it."

PB02 Salaried GP, Male

"It's a major life event for them if they've been previously healthy and they're suddenly being told they've got this very significant condition. So taking them through the stages that they may feel or at least making them aware is helpful."

PB09 Salaried GP, Female

"I mean, I think part of the problem is that they don't have symptoms, and don't appreciate how important control of their diabetes is. It is sometimes easier if they've got symptoms and you can treat it, or get them to change their diet, lifestyle, and they can see an improvement. It makes it much easier."

PB16 Practice Nurse, Female

Depression, self-blame and denial were common barriers to effective self-management encountered by health professionals. There could be self-blame from feeling responsible for bringing the disease upon oneself and shame and frustration from having to eat differently. Patients also had to deal with the stigmatising effects of being labelled as someone with diabetes. Professionals who highlighted the importance of emotional states on self-management often felt that it was difficult to see improvements in self-management without first dealing with emotional problems like low mood.

"Their mood is very important, and very often you have to manage that before you can do anything else... if that is possible."

PB14 Diabetes Specialist Nurse, Female

"Yes, because people are, I think they often feel that it's punitive, you know; it's something that they've done, brought it on themselves so they always come with this phrase, you know, I've been naughty or I've been bad, which is terribly punitive."

PB07 Diabetes Specialist Nurse, Female

"Helping people understand how to overcome stigma associated with diabetes, because there is an inevitable stigma associated with it, people... you know, there's the stigma of obesity, there's the stigma of... their having lives... their own lives restricted by this condition, so the whole... all the consequences of being labelled and what that means"

PB05 GP Partner, Male

Design features

Health professionals felt that simplicity and usefulness were the keys to successful intervention design. The intervention needed to be easy to use and

navigate round and be widely accessible. They suggested the use of simple language, videos and images to help with this.

"It'd have to be very easy"
PB14 Diabetes Specialist Nurse, Female

"I think it would have to be very basic"
PB12 Diabetes Nurse Consultant, Female

"I think something very visual would be most useful, the pictures and perhaps interactive... include video and vignettes for the patient."
PB07 Diabetes Specialist Nurse, Female

As previously described, health professionals felt that negative emotions formed a significant part of the burden on patients living with type 2 diabetes. Therefore they felt that the tone of the intervention was very important to counteract that. It needed to be supportive and encouraging and avoid victim blaming.

"You see I think if it's too negative they won't read it"
PB13 Diabetes Specialist Nurse, Female

"I think if there can be some sort of warmth coming out of a computer system and make it sort of as human as possible"
PB14 Diabetes Specialist Nurse, Female

There were two other features discussed by health professionals that were necessary for them to have faith in the intervention. These were security and the content of the intervention being kept up to date. Security was a concern voiced by many health professionals but it was tempered with a realisation that it needed to be balanced with usability. Health professionals had experience of systems that were very well protected but the security measures were onerous and very inconvenient. It was also important for the information to be kept up to date as sites that were not maintained or kept up to date were a source of frustration.

"...you've got to log in, you're going to need 16 passwords, and you just kind of think, I'd rather not bother... don't have a password with upper case and lower case and changes every three months."
PB06 GP Partner, Male

"I think if I knew the information was up to date, I think do get regularly updated, that will be useful... I think making sure it's up to date and I guess you would always have to adding things to the site."
PB11 Hospital Doctor, Female

“[talking about another website] ...I sometimes go to it and I get really frustrated because it’s out of date or what I’m looking for isn’t there”
PB12 Diabetes Nurse Consultant, Female

5.5.3 Health professional views on the work of implementing a new OSMI

5.5.3.1 Coherence

Reasons to engage with a new OSMI for type 2 diabetes

Empower patients: Patient-centred consultations driven by a shared agenda were felt to be the best approach to supporting self-management with the patient playing an active and engaged role in interactions. Amongst the professionals who participated in this study there was total agreement with this general aim of the intervention, even if this required culture change with professional resistance from some clinicians.

“Anything that I as a clinician will do is predicated on the other individual in the relationship actually playing their role, taking part, taking active control of their own lives. And the more information and understanding they have of what is going on, the more they’ll understand why I’m seeking to help them modify their behaviour.”

PB05 GP partner, Male

“And I think that if this instrument could change clinician behaviour ...the clinicians in general ought to be doing is improving self-care, improving shared decision making. All the evidence is that that improves quality and saves time ... It is a culture change...”

PB03 Salaried GP, Male

Improve satisfaction for health professionals: A significant motivation for supporting the intervention was the belief that patient-centred consultations would actually have benefits for health professionals and improve clinician satisfaction with consultations.

“The thing about improving the quality of the consultation for the clinician as well, that’s really important...”

PB04 Hospital Doctor, Female

Reasons not to engage with the OSMI

Some patients do not want to take responsibility: Participants noted that patient-centred consultations with engaged patients were not always the norm in many existing settings – in many consultations, communication was built on more traditional professional-centred models with healthcare professionals often

taking the role of a strict parent. One GP did point out that the disempowering dynamic was sometimes driven by patients themselves – especially older patients who sometimes expected to be told what to do.

“...a big problem, especially for elderly people ...who, perhaps, are more used to the, sort of, paternalistic model of medical health care, so, just being used to being told, being told what to do by the doctor.”

PB17 GP Partner, Male

Risk to face-to-face interventions: The health professionals in this study were concerned that there was a risk of computerised services replacing face-to-face services and this was seen as an unacceptable trade-off.

“As long as you don’t make it replace face-to-facing things because I know that’s a problem”

PB09 Salaried GP, Female

Concern about the lack of potential benefits of the intervention: Some health professionals were sceptical about the potential benefits of a new OSMI. One professional felt that the intervention could only provide limited advice that would become tiresome very quickly. Other professionals expressed their concerns of the risk of vulnerable patients being excluded from potential benefits due to the digital divide. Patients with the lowest health literacy and greatest needs often had the poorest access to health information, and this could be increased by a shift to online self-management support. Health professionals felt this particularly applied to patients from ethnic minorities where English was not a first language.

“...the information that you can get from your data is trivial, and it’s always the same. Eat less, exercise more, stop smoking. And so you’re never going to think whew, well, you know, I think I’ll log into supernet type2 diabetes to just see what the latest advice for me personally is, because it’ll just say do eat less and do more exercise, and stuff. That’s your problem”

PB10 Hospital Doctor, Male

“And so however one does it, and I’m not skilled enough or sophisticated enough to know how, but it’s important that actually this work doesn’t just become another piece of activity that, sort of, fits the inverse care law rather well.”

PB05 GP Partner, Male

“...so my question is how would you target the elderly Somali lady or the Bangladeshi woman whose HbA1c is always 12 and her daughter-in-law looks after her ...what would you do about her?”

PB14 Diabetes Specialist Nurse, Female

Just a website: One participant did not see an OSMI as conceptually different to a website. If professionals could not see the unique value of the intervention, NPT would predict they would be less likely to engage with it. However this participant felt that a good 'website' would still be a worthwhile intervention.

"But if you're referring people to a website that is... you know, that has got good information on it, that is correct, then I think that's a good thing."

PB11 Hospital Doctor, Female

5.5.3.2 *Cognitive participation*

To get buy-in from professionals, there were certain expectations that the intervention needed to fulfil. These included desirable content, emotional support, design features, endorsements from respected bodies and evidence of beneficial effects.

Endorsements from respected bodies.

Health professionals recognised the importance of having key individuals to champion the intervention, promote awareness and encourage use. It was possible that such advocates could be at the commissioning level or expert patients/patient champions. Endorsements from recognised professional bodies like the Royal College of GPs or the Department of Health were also felt to be important potential drivers for implementation.

"Critically, it will need to have the buy in of people who commission services, the people who are paying for services to be implemented will need to be addressed and will need to have the opportunity to think about this and say, gosh, this looks like it could be a really good value..."

...patients who can speak eloquently; that doesn't mean to say that they have posh accents, but who can speak convincingly about what it's done for them, both to clinicians and to patients."

PB02 Salaried GP, Male

"Patients that are the driver of changing clinicians..."
PB06 GP Partner, Male

"You probably want to get the Department of Health to say that everyone should commission it as part of their care package."
PB09 Salaried GP, Female

Evidence of benefits

The health professionals in this study thought it would be important to have evidence of the benefits of the intervention in order to engage clinicians in promoting the intervention. The criteria were based on evidence of effectiveness, cost-effectiveness, intervention use and patient feedback. When considering evidence of effectiveness, not all clinicians valued the same outcomes and some placed a higher value on clinical measures, others on quality of life indicators.

“I guess if you’re thinking about it being taken up by GPs …the cost, obviously, of it would… and evidence that it works”

PB14 Diabetes Specialist Nurse, Female

“Well, ideally, we’d like to have clinical data, did it improve the HbA1c?”

PB08 Diabetes Specialist Dietician, Female

“Getting good feedback from the patients, that’s going to make me recommend it… The amount of minutes they actually spent using it. And, yes, their feedback but it’s all very well them saying, oh yes, it’s great, and they’ve spent 10 minutes in it, and not gone back to it again.”

PB16 Practice Nurse, Female

Collective action

There were a number of concerns health professionals had about the potential impact of the intervention on their work. There were concerns about workload, effects on doctor-patient interactions and the availability of extra resources for new work. Suggestions to help with this included the use of administrative staff for engagement activities and using incentive schemes to pay practices for extra work.

Concerns about impact on existing work

Doctors felt quite strongly that the intervention would not be acceptable if implementing the intervention increased the workload on professionals – e.g. being sent large volumes of self-monitoring data.

“My huge anxiety about these things is being swamped. You know, what I don’t want to is, you know, arrive in my surgery and turn on and get, you know, 300 people who’ve suddenly their most recent blood sugars, you know, it would be unworkable…”

PB06 GP Partner, Male

“...if you introduce something that makes your life easier and improves the quality of what you’re doing, it will work. So that’s the challenge.”

PB02 Salaried GP, Male

The potentially detrimental impact of spending more time using a computer in a consultation, distracting the attention of the healthcare professional away from the patient, was also raised by participants.

“I think it’s really important, if possible, not to be fiddling on a computer when you’ve got a patient in front of you because it’s about human contact. I just think that’s really important.”

PB14 Diabetes Specialist Nurse, Female

Suitable allocation of new work

As discussed earlier in this chapter, the challenges with encouraging uptake and use of the proposed intervention meant that facilitating and encouraging use of the intervention through health services was envisioned as potentially an important element of the intervention. Unfortunately, any work that would need to be done by GP surgeries or diabetes services to encourage use of the intervention was felt to be a significant potential barrier to implementation as it was felt there was no capacity to allow for this.

“I’d say this is another... an additional activity un-resourced ...I can’t see clinicians spending a lot of resource and time - do you understand where I’m going?”

PB05 GP Partner, Male

“And don’t ask the poor practice nurse.”

PB08 Diabetes Specialist Dietician, Female

“It wouldn’t be fair to say, right, the practice can’t do it, then the diabetes service can do, because they can’t, that would be completely overwhelming. “

PB16 Practice Nurse, Female

“From the hospital perspective, I don’t know who would do it. Everyone would say they’re too busy.”

PB04 Hospital Doctor, Female

Two suggestions from participants raised the possibility that the skill sets required for facilitated access might be better suited to non-clinical staff. To facilitate the use of a new Information Technology (IT) tool into practice

workflows, one GP suggested making use of existing IT support staff within the practice. In terms of promoting engagement with the intervention, one participant suggested that the main skills needed were good communication skills that secretaries might have and this work might even be possible over the phone.

"I think most practices in today's world have IT managers who can help facilitate the process in terms of, sort of, embedding this within the practice and helping the practice understand how it could be utilised from a sort of technical perspective"

PB05 GP Partner, Male

"Oh, I see. I'm just thinking about our secretary here. It's something that initially a secretary could do, a secretary with a good manner"

PB14 Diabetes Specialist Nurse, Female

An alternative suggestion was to set up a dedicated facilitation service similar to the use of online tools facilitated by IAPT (increasing access to psychological therapy) for mental health problems.

"Well, obviously it's going to be set up like facilitated self-help for psychological problems where, I mean the health worker is employed to do it..."

PB09 Salaried GP, Female

Possible resources to fund new work

Health professionals also felt that any extra time spent on trying to engage users with the intervention would need to be reimbursed. Appropriate allocation of staff time and the availability of funding for such activities were felt to be important aspects of successful implementation. GPs were used to payment for activity through schemes like Quality and Outcomes Framework (QOF), Directed Enhanced Services (DES) and Local Enhanced Services (LES) schemes. Making use of such arrangements was felt to be potentially crucial for strategies for increasing uptake and use of the intervention in routine practice.

"...the problem is that generally you're not paying for extra time the nurses... the nurses don't have any extra time and, you know, you can't... it's not sufficient time to employ a whole extra person..."

PB09 Salaried GP, Female

"There are external drivers which are, sort of, QOF and those kind of things. There's certainly within QOF, and I know there are much more changes to patient-held records, patient information, self-

management, and those are the kind of external drives which will probably make something like this work."

PB06 GP Partner, Male

"Five... ten years ago... I would have said yes, that was the main professional driver for most of my GP colleagues, was to be giving good care. Since QOF, I have to say, all I ever hear from any of my GP colleagues is, is it QOFable, is incentivised? And if it's not incentivised, we don't do it..."

PB01 Salaried GP, Female

5.5.4 Health professional views on patient access to electronic medical records (EMR)

In the health professionals taking part in the study, there seemed to be some cross-professional polarisation of views about patient access to the electronic medical record (EMR). All the nurses in this study were uniformly supportive about patient's accessing their own records. They felt it could empower patients and the only concerns expressed were around security and data governance.

Doctors were much more circumspect in their assessment. They felt it could have benefits but they were much more likely to cite concerns about increased workload or medico-legal issues arising from patient access. They were worried that some patients would misinterpret what had been written and use that for the basis of litigation or become anxious about abnormal results. The main concern was that negative reactions in a small cohort of patients could greatly increase their workloads.

Nurses:

"Great... It's very empowering, isn't it, sort of sharing that record, I think, a personal health profile."

PB07 Diabetes Specialist Nurse, Female

"I don't personally have a problem with it, I just worry about confidentiality wise."

PB15 Practice Nurse, Female

Doctors:

"I think the trouble is you'd probably need to do it prospectively because, you know, a lot of records have been entered historically, not thinking that the you could read these, but these days, I mean anyone can request to see their records anyway, so, you know. But you still see things entered on record that you think is actually not going to be very helpful for a patient to see, particularly... ...But actually to just view them on their own at home, they may be

misinterpreting what's been put there, you know. I don't know. There are definitely pros and cons to that."

PB09 Salaried GP, Female

"And then if you say, well, all of this is going to go into a public record, then one of two things happens. One is that you stop writing down anything that's sensible on the basis that you can only say saw Mrs Smith, so that you get very brief notes. But then if they had very brief notes you clearly haven't been looked after, so the alternative is to write down every damn thing that happened in the consultation, which would just take you forever ...a sub-section of all the patients who will litigate against you for saying look at the standard of care that I've got... So I would stay a mile away from allowing you access to take my notes and make them available. Added to which, the security aspects of having a load of biochemical data available to patients is a nightmare... it'd have a huge impact on workload. If you divulge notes to patients, potentially medico-legally it ends up... it has huge medico-legal ramifications."

PB10 Hospital Doctor, Male

5.6 Discussion

5.6.1 *Summary of main findings*

Although based on a convenience sample, the data generated from the interviews and focus groups were useful and informative. Many of the health professionals involved had previous experience of developing or implementing new services and were therefore cognizant of the difficulties in implementing new interventions within the health service.

Overall the intervention appeared to fit with the values of the healthcare professionals and the type of care they wished to provide. Online self-management support was coherent with clinical practice and something professionals seemed to understand; it aligned with the desire to provide more patient-centred care in the context of a long-term condition like type 2 diabetes. Professionals felt that the main potential benefit of the intervention was improving the quality of consultations by facilitating shared agendas and better care-planning. However it was critically important that this could happen in a time-neutral way with no increase in workload.

5.6.2 *Intervention design*

There was also significant concordance between what health professionals and patients wanted from the design and content of the intervention. Health professionals wanted something with a positive tone, with simple and media-rich content that covered diabetes, diet, activity, medication, lifestyle change, normal test results and common diabetes myths. They felt the website needed to be kept up to date and have appropriate information governance.

These criteria are consistent with the standards that health professionals have used to judge websites in previous studies. Examples of professional criteria to judge the content of health-related websites include comparisons based on links with evidence based medicine (Griffiths et al. 2005); or a combination of technical criteria based on authorship, attribution, disclosure and currency with other features such as Accuracy, Completeness, Readability Level and Design (Eysenbach et al. 2002). However there was one area where the views of health professionals diverged from the views of patients described in Chapter 4. The main difference with patients was in the level of detail in the information

that might be provided by the intervention. Patients wanted something that was easy to use and provided access to very detailed information if they wanted. Health professionals wanted to maximise accessibility and were concerned about the digital divide, so they felt a simpler intervention would be better.

5.6.3 Health professional engagement

In terms of getting “buy-in” and cognitive participation in the work of implementation, it was felt that endorsements would be needed and accreditation by Diabetes UK, the RCGP or the Department of Health would improve health professional faith in the intervention. Health professionals thought that having champions or advocates promoting the intervention would be important and this could be either patients or commissioning bodies. The literature on implementation supports the concepts of patient champions and respected people driving forward change (Dixon-Woods et al. 2012; Mair et al. 2012). However, a recent review of reviews on implementation found that the impact of local opinion leaders was limited and higher profile leaders were required to help drive change (Lau et al. 2015).

Health professionals also wanted evidence of effectiveness prior to engaging with the work of implementation, and different professionals placed different emphasis on the relative importance of improvement in clinical markers like HbA1c, quality of life, patient feedback and evidence of intervention use. However it is unlikely that evidence alone would be sufficient to guarantee timely implementation as studies suggest that it takes around 17 years to translate evidence into routine clinical practice (Morris et al. 2011).

Minimising the work of the collective action needed to implement the intervention was a key concern. Making the intervention simple and quick to use and minimally disruptive to consultations was important. Doctors felt that the intervention would not be acceptable if it required them to review large volumes of self-monitoring data in consultations. Challenges with time, resources and integration with clinic workflows are common barriers faced by digital health interventions (Napoles et al. 2016). The concept of interventions being

minimally disruptive to patients was discussed in the previous chapter and it applied equally to health professionals and their consultations.

Clinical staff wanted administrative duties and intervention facilitation to be handled by non-clinical staff like IT managers or secretaries. There was a feeling that the extra work would need to be resourced with financial incentives (e.g. through the Quality and Outcomes Framework) or provision of extra staff time. The evidence in the literature supporting these views on the effectiveness of financial incentives is mixed – although they can influence practice, the best way to use financial incentives is not clear (Scott et al. 2011). They are more likely to be effective with larger payments for simple tasks and have the most impact on low performers (Lau et al. 2015).

It was also important to health professionals in this study that the intervention did not threaten the existing work done through face-to-face consultations. There was concern over replacement of face-to-face encounters by computers and the effects on the dynamics of the consultation. Previous studies into the impact of computers on consultations have suggested negative effects with the potential to reduce patient-centred consultations (Shachak et al. 2009). However more nuanced analysis suggests that computers can actually be empowering for patients, with use of the “third-party” (the computer) by patients to challenge or influence the behaviour of doctors (Pearce et al. 2011). Therefore the disruption caused by the use of a digital self-management intervention within consultations has the power to be an empowering change for patients.

5.6.4 Patient access to the electronic medical record

The contracts for GPs in England has recently stipulated that by March 2016 all surgeries would have to provide patients with online access to booking of appointments, repeat medication requests and access to coded data from the medical summary (NHS England 2016). However anticipated uptake appears to be low with the GP contract for 2016/2017 asking practices to aim for at least 10% of registered patients to be using one or more online service by 31 March 2017 (BMA 2016). Health professionals have been slow to engage and promote such services and professional ambivalence towards online patient services

could present challenges for online self-management programmes offering access to the EMR.

The doctors interviewed as part of this study had reservations about patient access to electronic medical records. They were worried about the possible increase in workload from dealing with patient complaints or having to spend longer documenting consultations and dealing with enquiries about results. In contrast, nursing staff did not express any reservations and were much more supportive and felt it was consistent with patient empowerment and supporting self-management. The evidence appears to support the views expressed by nursing staff and challenges the anxieties expressed by doctors. There have also been 2 systematic reviews on the impact of access to electronic medical records published in the past 2 years (de Lusignan et al. 2014; Mold et al. 2015). These reviews showed that patients using online services reported increased convenience and satisfaction and there were positive impacts on patient safety; professional concerns about privacy were unfounded and there was a slight increase in workload but not significantly so. While concerns by doctors about the negative consequences may be unfounded, if widely held such beliefs had the potential to be a significant barrier to implementing features supporting patient access to the electronic medical record.

5.6.5 Strengths of this study

There were a number of strengths of the study design. Health professionals were sampled across different settings - primary care, intermediate care and secondary care. Within each setting, professionals in different roles were involved – nurses and doctors in primary and secondary care and a dietitian working in intermediate care. As the intervention was aimed to be implemented through primary care, most of the clinicians were GPs. Many of the doctors interviewed had academic experience which meant they had experience of implementation and the challenges it can provide. The patient preferences data from Chapter 4 allows triangulation of some of the findings from this study and provided another source of evidence regarding their validity.

5.6.6 *Limitations*

The main limitation of the study lies in the degree of transferability of the findings. The majority of participants in this study had links to academic medicine and only one of the doctors involved was a full-time clinician. The fact that many of the participants had an academic background may have led to under-representation of non-academic perspectives. The predominant method of recruitment was snowballing and there may have been some degree of homogeneity of perspectives from familiarity or shared institutional values. Unlike the patient perspective study, the health professional interviews and focus groups had to be done mainly at the participants' place of work and therefore they could not be shown websites so all the discussions were based on "blue-sky" thinking about possible interventions. One way round this would have been to use vignettes and mock-ups or other prompts to help ground discussions in reality. Such discussion aids could have led to a higher yield of rich data regarding potential benefits of the intervention.

However all the professionals interviewed were practising clinicians with experience of looking after patients with type 2 diabetes using existing IT tools. The data reflected this and seemed to be grounded in contemporary clinical practice and did not seem to be skewed towards impossible or implausible theoretical possibilities. Two contextual factors that could not be anticipated were the rapid pace of change of the structural organisation of the NHS (the repercussions of the Health and Social Care act 2012) and the evolution of technology (e.g. the rapid growth of smartphones and tablets or the advent of 'App stores') and this could also limit the transferability of the findings to future contexts.

5.6.7 *Use of NPT*

Overall, it appeared that the intervention was highly acceptable to the sample of health professionals interviewed. The main challenges identified were felt to be defining the work required for implementing the intervention and then finding the capacity to do the work of implementation. The use of NPT facilitated a more coherent and logical organisation of the themes and a richer interpretation. Although not all of the NPT constructs were covered by the data, there were no data that could not be described using the constructs of the theory. However the

close fit of the analysis and the coding structure may reflect the familiarity of the team with NPT as it was the main implementation theory used to guide the initial application for funding this research.

5.6.8 Implications for an online diabetes self-management intervention

The health professionals who took part in this study felt that there are currently significant gaps in service provision for diabetes education like delays in being able to access education or a lack of emotional support. An online intervention would have the potential to bridge some of those gaps. It could be available immediately at diagnosis which would help reduce patient distress and frustration. Online CBT or other content developed for emotional problems would also be extremely valuable if they could be done effectively.

Online interventions could also help improve the quality of information provided to patients by providing tailored information or videos of patient stories. Online interventions have an advantage in having minimal per user costs (Murray 2012), so educating carers or family members would not significantly increase costs but could have significant benefits.

5.6.9 Implications for further research

A significant difference of opinion between professionals and patients was the amount of information that the intervention should have. Professionals were keen for the intervention to be simple whereas patients wanted more depth of information. It is possible that this reflects differences in the health literacy of the patients clinicians feel need the most help compared to the health literacy of patients who took part in the patient preference study. Linked to this were the concerns expressed by clinicians about the digital divide and accessibility of online interventions for disadvantaged groups. Such concerns have also been expressed in the literature (Eysenbach et al. 2006). However there is also evidence that patients with the greatest need benefit the most from health information (Gustafson et al. 2002); and with internet access improving across the population as described in Chapter 4, there is little reason to doubt that internet interventions can benefit those in greatest need. There is also evidence that information targeted at patients with low health literacy can have high levels of acceptability for all patients (Rowse et al. 2015). The optimal quantity of

information and level of detail that maximises patient benefits is not clear, however an advantage of digital interventions is that a small amount of text can be presented, with links to further info if wanted. Exploring any tension between the amount of information patients say they want and the amount of information that maximises the impact of an intervention is a potentially useful research area.

There were also concerns about online interventions being less motivating than those done face to face. It would be interesting to see if online interventions are less engaging or less effective than face to face and whether an IAPT type model where motivation can be encouraged by non-clinical staff remotely can recreate the human motivating factor with lower overheads.

5.7 Conclusions

Although based on a limited sample, this study provided some useful information regarding elements of the professional perspectives on developing an OSMI for diabetes self-management. Health professionals in this study were aware that patients face challenges with trying to self-manage at many levels. Many of these were explored in Chapter 4 and there appeared scope for online interventions to help improve self-management support in domains like tailored information provision, emotional support, supportive peer networks, care planning and practical help with accessing face-to-face healthcare services. Both health professionals and patients wanted a positive, easy to use intervention that could offer a wide range of content.

Such an intervention appeared to have high levels of acceptability to health professionals and was coherent with their values. The main barriers to implementation were a lack of understanding of the work needed for implementation, a lack of ownership and capacity for doing such work. If those barriers could be overcome, potential drivers of change could be evidence of benefits (more satisfying consultations, improvements in HbA1c, cost-effectiveness data, improvement in quality of life, and evidence of patient use), financial incentives and recommendations from Diabetes UK, the RCGP or the Department of Health.

6. Design of an online diabetes self-management intervention for adults with type 2 diabetes

6.1 Chapter outline

In the previous five chapters I have described the need for diabetes self-management education and the rationale for developing an online intervention to support this. I have described the findings of a systematic review of relevant literature, presented the theories most relevant to postulated mechanisms of action and described research on the views of key stakeholders – patients and health professionals.

This chapter focuses on the process of synthesising that data and the methodology used to guide the design of an online self-management intervention for adults with type 2 diabetes. This was done post-hoc after the intervention had been developed by the team and the main purpose is to describe the main processes used in the development and to characterise the intervention.

6.2 Introduction

The three main tasks of the development stage outlined by the MRC framework are:

1. Identifying the evidence base – this was done through the studies described in Chapters 3, 4, 5 and has been summarised below.
2. Identifying/developing theory – this was described in Chapter 2 and the main conclusions are summarised in Section 6.4.
3. Modelling process and outcomes – a description of the proposed mechanism of action of the intervention and the logic model used for this can also be found in Section 6.4.

6.2.1 *Integrating theory and data*

As part of the development stage outlined above, a significant body of quantitative and qualitative data was accumulated from the literature and the qualitative studies described in Chapters 4 and 5. Translating these data into a design specification for the final intervention required a process of synthesising

different types of data and theory. Due to time limitations it was not possible to do a systematic review of different models of intervention development during the study itself. A new comprehensive framework for developing behavioural interventions was published while the intervention was being developed - the Behaviour Change Wheel (BCW), described later in this chapter (Michie et al. 2014a). Elements of the BCW that predated publication of the full framework like a taxonomy of behaviour change techniques and the COM-B model of behaviour were already being used in the development of the intervention as discussed in Chapter 3. In this chapter, the final BCW will be used as a post-hoc applied structured framework to help analyse and describe the decisions and processes used to translate the design specification into an intervention to support self-management and behaviour change.

6.3 Aims and objectives of this chapter:

Aims:

1. To describe the process of development of a complex intervention for online self-management support for adults with type 2 diabetes informed by the 2008 MRC guidance on complex interventions.
2. To describe the final intervention to illustrate how the procedure was operationalised.

Objectives:

1. Describe the process of working with patients and programmers to develop the intervention
2. Illustrate with examples of the final intervention
3. Summarise the evidence base used to inform the development of the intervention
4. List the theoretical frameworks selected as part of the development process.
5. Highlight the proposed mechanism of action of the intervention
6. Demonstrate how data and theory were integrated and operationalized

6.3.1 Objective 1. Describe the process of working with patients and programmers to develop the intervention

There were two key principles that guided the process of designing the intervention and approach to software development: participatory design and agile development.

Participatory design

Participatory design is a socio-technical design approach that starts with a thorough examination of current work practice, and the end-users and other stakeholders are actively involved participants in the design process as work practice specialists (Lyng et al. 2011). An important aspect of participatory design is that users are treated as partners and have a role in decision making rather than merely being sources of information and test subjects (Sanders et al. 2008). Giving end-users a voice and making them a key part of design choices has many advantages (Kujala 2008). These include:

- Supporting user empowerment, validation and development of their expertise;
- Increasing chances of acceptance of the system by end-users;
- An opportunity to let users learn and use the system;
- Improving developer/researcher understanding of the users' work;
- Defining more accurate user requirements;
- Improving the quality of the system;
- Improving development efficiency;
- Increasing user and customer satisfaction.

For this intervention, the process of participatory design was operationalised through regular meetings with a group of patients with type 2 diabetes. The core group was purposively sampled to get a diverse group of eight patients based on gender, duration of diagnosis, ethnicity, treatment modality and self-rated computer skills. They were selected from the pool of patients who had participated in the qualitative study described in Chapter 4. Participants in that study were asked if they had an interest in working with the team after the qualitative study was over and those that were interested were invited to be part of the participatory design group. The demographics of the group can be found in **Error! Reference source not found..**

Table 6-1 Demographics of regular participatory design group

| N=8 | |
|-----------------------------------|----------------------|
| Mean age (years) | 55 |
| <i>Gender</i> | |
| Female | 3 |
| Male | 5 |
| Duration of diagnosis (range) | 3 months to 16 years |
| <i>Ethnicity</i> | |
| White | 5 |
| Black | 3 |
| <i>Treatment</i> | |
| Diet controlled | 5 |
| Tablets | 2 |
| Insulin | 1 |
| <i>Self-rated computer skills</i> | |
| Basic | 2 |
| Experienced | 3 |
| Expert | 3 |

A series of eight meetings were held with the group at two monthly intervals and the research team would prepare material for the group to review. The groups were facilitated and run similar to the focus groups described in Chapter 4 and audio recordings of the meetings were kept. The group were asked about content and design elements of the prototypes created during the development phase and decisions made by the user group were given the highest weighting when final decisions about the intervention were made.

As a way of trying to involve more people who had generously expressed an interest in helping us, we ran 4 groups with other volunteers from the pool of users described previously. This also allowed us to get a wider range of views on important aspects like the navigation and template for the website and beta-testing tools.

Agile development

Complementing the participatory design process with users was an agile development process of working with the software developers (Dingsoyr et al. 2012). Agile development relies on high levels of technical skills and simple designs to deliver working software to users at regular intervals. The development cycle was driven by four key principles –

- Valuing people and their input rather than processes
- Having a ‘lean’ mentality to minimise unnecessary work especially documentation
- Involving stakeholders to actively guide the evolution of the product
- Accepting that uncertainty is inherent in software development and pre-meditated attempts to anticipate or control variations will have minimal impact.

Using an agile methodology was crucial as it allowed the participatory design group to provide feedback on evolving prototypes that could be actioned to guide the direction of the intervention development. It was also important for the research team at UCL as we were not familiar with the content management system and the software company had never built an intervention on the proposed scale. The use of an iterative design process allowed opportunities for regular appraisals so progress could be monitored and problems identified early. Where there were difficulties making progress (e.g. interfacing with the electronic medical record), decisions were made quickly to suspend or terminate development of those features and resources were focused on aspects that were yielding better results (e.g. goal setting and action planning tools).

The strengths and weaknesses and learning points from the development process have been reviewed in Chapter 7.

6.3.2 Objective 2: Illustrate with examples the final intervention

Based on the data presented above, a website was created called Healthy Living for People with Diabetes (HeLP-Diabetes):

<https://www.help-diabetes.org.uk>

The intervention can be explored using the following login details:

Username: phd

Password: Examiner1

The intervention was developed in partnership with a commercial software company (Softforge) and developed using an open-source content management system called JOOMLA which is widely supported by a large community of developers. JOOMLA is well suited to running large sites with multimedia content and it has a large library of plug-ins that provides additional functionality. However the open source nature of the plug-ins can lead to compatibility problems if the original developer fails to keep the plug-in updated and this requires monitoring. The basic design templates on JOOMLA are also relatively limited so a web-designer was hired to improve the visual appeal. The server runs an open-source platform using Linux, Apache, MySQL, and PHP (LAMP-stack) which is an industry-standard, powerful but free to use combination of software. The intervention is hosted outside the NHS N3 network but runs on an encrypted ISO27001 certified hosting service.

Screenshot: Homepage

Whittington Health NHS **UCL**

HeLP Diabetes™

Healthy Living for People with type 2 Diabetes

Test User [View profile](#) [Logout](#)

Understanding diabetes **Staying healthy** **Treating diabetes** **Living & working with diabetes** **Managing my feelings** **My health record** **News & research** **Forum & help**

Zoom & language tools

Search... **Search**

Starting out:
[An interactive guide if you are new to HeLP Diabetes](#)

Popular links:

- [Common diabetes questions](#)
- [Food](#)
- [African and Caribbean diets](#)
- [My health tracker](#)
- [Physical activity](#)

NEWS: Can weight-loss surgery "cure" diabetes?

Diabetes self management programme

Even small changes in what you do can make a big difference to your health if you work them in to your daily life.

The choices you make have a much bigger effect on your type 2 diabetes than your healthcare team does.

Studies have shown that people who know more about diabetes develop fewer complications and have better control of their blood glucose levels.

Explaining Type 2 Diabetes

07:44 HD

Explore HeLP-Diabetes

Providing a consistent user experience

The key characteristics that unified the eight sections were the tone and core philosophy of the intervention. All of the content was required to be consistent with the following criteria:

1. Sustain a positive and encouraging tone
2. Provide a user-centred perspective that is holistic and compassionate i.e. understand that patient priorities reflect complex and interacting social, cultural, emotional and personal needs that may differ substantially from health professionally defined needs
3. Promote an enabling perspective that focused on what users could do to improve things e.g. sections on complications stressed the steps that could be taken to reduce the risks or manage existing complications
4. Have low barriers to accessibility and be as inclusive as possible by providing:
 - Content written with a target reading age of 12
 - Images on every page
 - Videos that summarise important information
 - Stories from real people living with type 2 diabetes
 - Content that addresses needs from different cultures and religions.

The website has eight sections that cover all three tasks of living with a chronic illness:

| | Self-management task |
|---|--|
| Section 1: Understanding diabetes | Medical management |
| Section 2: Staying healthy | Medical management |
| Section 3: Treating diabetes | Medical management |
| Section 4: Living and working with diabetes | Role management |
| Section 5: Managing my feelings | Emotional management |
| Section 6: My Health Record | Medical management |
| Section 7: News and research | Medical management |
| Section 8: Forum and help | Medical management, Emotional management and Role management |

In keeping with the principles of adult education and due to time constraints, the intervention was created as a website that users can browse as they wish. All the information and tools were made available from the start and all pages in the site linked to relevant content so users could find everything relevant to the issue for which they visited the website.

The eight sections that make up the intervention are described in more detail below and this description includes the potential active ingredients in the form of BCTs. The methodology for identifying BCTs is described here.

Methodology for characterising the intervention:

As discussed in chapters 1 and 3, interventions are often poorly described and the final intervention may not have effectively applied the theories considered during the design phase. The dissemination of knowledge and accumulation of evidence is greatly enhanced by accurate descriptions of the active ingredients of interventions. A taxonomy of 93 possible Behavior Change Techniques (BCTs) has been developed to assist the reporting and development of interventions (Michie et al. 2013a). This is the most comprehensive taxonomy for characterising behaviour change interventions that I had come across and I was familiar with its definitions and application as an earlier iteration of the taxonomy was used for the systematic review described in Chapter 3. Therefore I used this taxonomy to characterise HeLP-Diabetes and list the BCTs that were potential active ingredients of the intervention. I did this by reviewing the content of the whole website, section by section. The focus of this activity was to extract the BCTs used rather than identify behavioural antecedents to target. The content of the section was coded using the 93 item BCT taxonomy. This mapping exercise was done by me alone and it was not validated by another researcher due to limitations of resources.

Section 1: Understanding diabetes

This section has 2 main parts – ‘Common diabetes questions’ and ‘How diabetes affects my body’. This covers the aetiology and impact of type 2 diabetes and uses videos, images and text to make the information as accessible as possible. The text has been written with a reading age of 12 in

mind and uses simple language and short sentences. Medical terms are clearly explained to help facilitate communication with health professionals. Page titles are questions like 'What is type 2 diabetes?' in order to facilitate goal-orientated learning.

BCTs used: Information about health consequences, Credible source

Screenshot: Understanding diabetes



The screenshot shows a website layout for 'Understanding diabetes'. At the top, there's a green header bar with 'Zoom & language tools', 'Home', 'Understanding diabetes', 'Common diabetes questions', and a 'Print Page' button. Below the header, a search bar with 'Search...' and a 'Search' button is visible. The main content area has a title 'What is type 2 diabetes?' and a navigation bar with tabs: 'Overview' (which is active), 'Diagnosis', 'Glucose', 'Inside the body', 'The pancreas', and 'Insulin'. To the left, a sidebar titled 'COMMON DIABETES QUESTIONS' lists various topics with circular icons: 'What is type 2 diabetes?' (red), 'What is self-management?' (black), 'Why learn more about diabetes?' (black), 'What happens if I don't control my diabetes?' (black), 'What causes type 2 diabetes?' (black), 'What is pre-diabetes?' (black), 'Are there other types of diabetes?' (black), and 'Who gets type 2' (black). The main content area also contains a yellow box with an info icon and text: 'Type 2 diabetes is a long-term condition that can lead to serious health problems. You can reduce the risk of problems by controlling your blood pressure, blood glucose levels and cholesterol. Eating healthily, being physically active and not smoking are also important.' Below this, there's a video player for a 7-minute video titled 'Explaining Type 2 Diabetes'. The video player includes a play button, a timer (07:44), and an HD icon.

Section 2: Staying healthy

This section is the main behaviour change portion of the intervention. It covers five behaviours: healthy eating, physical activity, taking medication, avoiding excessive alcohol intake and smoking cessation. As mentioned previously, managing alcohol intake and smoking cessation are tackled by adaptations of other theoretically informed interventions – Down Your Drink (<https://www.help-diabetes.org.uk/staying-healthy/alcohol/cutting-down>) and StopAdvisor (<https://www.help-diabetes.org.uk/staying-healthy/smoking/stopadvisor>).

Therefore the description below will focus on the other behaviours which have the same basic structure. The basic structure of each of the behaviour change support sections contains information about the benefits of changing the behaviour, a quiz to help users do a self-assessment and tools to help users set

goals and action plans, and then review their progress. The action planning tool also encourages problem-solving by prompting users to anticipate barriers and propose possible solutions. Users can also set up text or email prompts to remind them about their plans. The physical activity section has videos that users can watch and build circuits to learn different exercises and then follow their own exercise routine. There are screenshots of the different tools supporting behaviour change taken from the physical activity section below.

BCTs used: Goal setting (behaviour), Problem solving, Action planning, Review behaviour goal, Prompts/cues, Demonstration of the behaviour, Feedback on behaviour, Self-monitoring of behaviour

Self-assessment quiz: (IPAQ physical activity questionnaire)

Activity quiz

During the last week, on how many days did you do vigorous physical activities like heavy lifting, digging, aerobics, or fast bicycling?
Please Select

How much time did you usually spend doing vigorous physical activities on one of those days?
1-600 Minutes per day or _____ Hours _____ Minutes

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?
Please Select

How much time did you usually spend doing moderate physical activities on one of those days?
1-600 Minutes per day or _____ Hours _____ Minutes

During the last week, on how many days did you do light physical activities like walking, dusting or weeding?
Please Select

How much time did you usually spend doing light physical activities on one of those days?
1-600 Minutes per day or _____ Hours _____ Minutes

Save

This is an interactive version of the IPAQ-SF questionnaire to assess self-reported levels of physical activity (Lee et al. 2011). Users enter data regarding their physical activity over the past 7 days. Based on the results, they are categorised into light, moderate or high physical activity levels. Users are given tailored advice based on their results.

Goal setting and action planning tool:

Zoom & language tools

Home | Staying healthy | Eating & drinking | Tools for changing what I eat [Print Page](#)

Search... **Search**

EATING & DRINKING

- How food choices can help
- Should I lose weight?
- Changing what I eat
- Keeping on track with my food
- **Tools for changing what I eat**
- My diet goals
- My diet goals - summary
- Set diet reminders
- View diet reminders
- Calorie requirement calculator
- Body mass index calculator
- My food tracker
- POWeR weight loss programme

My diet goals

Use this tool to set your own diet goals and make plans to achieve them.

My diet goals

Now that you have chosen to improve your diet you can use this tool to help you achieve it.

What goal do I want to achieve? [Ways to set your goals](#)

I will swap foods high in fat for lower fat or fat free alternatives [\(more info\)](#)

I will not eat any high carb/calorie snacks [\(more info\)](#)

I will increase the amount of fibre in my diet [\(more info\)](#)

[+ Add your own goal](#)

What are your reasons to achieve this goal? [Deciding your reasons](#)

Feel better about myself Be more confident

Feel better physically Improve my mood

Feel more comfortable in my own clothes Have better health

[+ Add your own reason](#)

How important is this goal to you?

Not Important  Very Important

0

[Next](#)

This is an interactive goal setting and action planning tool. There are specific ones for the main self-management behaviours: diet, physical activity, medicines and alcohol and a generic one that users can use to set their own type of goal.

For the specific behaviours the tool has built in examples to help users. They are supported with setting SMART goals (specific, measureable, achievable, relevant and time-bound) and encouraged to reflect on how important it is to them.

Users can then create an action plan with a review date.

Review goals and plans:



Haven't set any goals yet? Get some tips on [becoming more active](#) or set some goals and plans now using the [fitness goals and plans tool](#).



How am I doing?

Below are the goals and plans that you set for yourself.

Being realistic and honest with yourself, take a few moments to think about your progress towards improving your activity levels and fitness. How well have you achieved your goals so far? Use the table below to rate them.

| Plan | Rating | <input type="checkbox"/> | |
|---|---|--------------------------|--|
| Goal: I will try out a number of activities to find one I really enjoy (more info) Date added: 13/11/2015 | Start date: 13/11/2015 Review date: 20/11/2015 | | |
| ■ I will put together my very own 20 minute exercise circuit using the websites physical activity videos. | 0 | <input type="checkbox"/> | |

[Delete](#) [Add](#)

The review tool lets users self-rate their progress on the goals and action plans they have set for themselves. Goals can be deleted or edited as well as rated.

Set activity reminder:

Set activity reminders

Follow the steps below to send a message straight to your email account or phone.

These messages could be to help you remember your fitness plans (e.g. I will take the stairs this morning instead of the lift) or a motivational message (e.g. I will feel really good after my swim) for a time that you think might be difficult.

| | |
|--------------------------------------|--|
| Add reminders | |
| Add the text to send in your message | |
| Message | <input type="text"/> 140 Characters left |
| Message Choice | <input checked="" type="radio"/> Text <input type="radio"/> Email <input type="radio"/> Both |
| Time of day to be sent | |
| Hours | <input type="text"/> - <input type="button" value="▼"/> |
| Minutes | <input type="text"/> - <input type="button" value="▼"/> |
| Days of the week to be sent | <input type="checkbox"/> Mon <input type="checkbox"/> Tue <input type="checkbox"/> Wed <input type="checkbox"/> Thu <input type="checkbox"/> Fri <input type="checkbox"/> Sat <input type="checkbox"/> Sun |

The activity reminder allows users to set their own prompts as cues for their behaviour change goals and plans.

It can be used to send text messages or reminders.

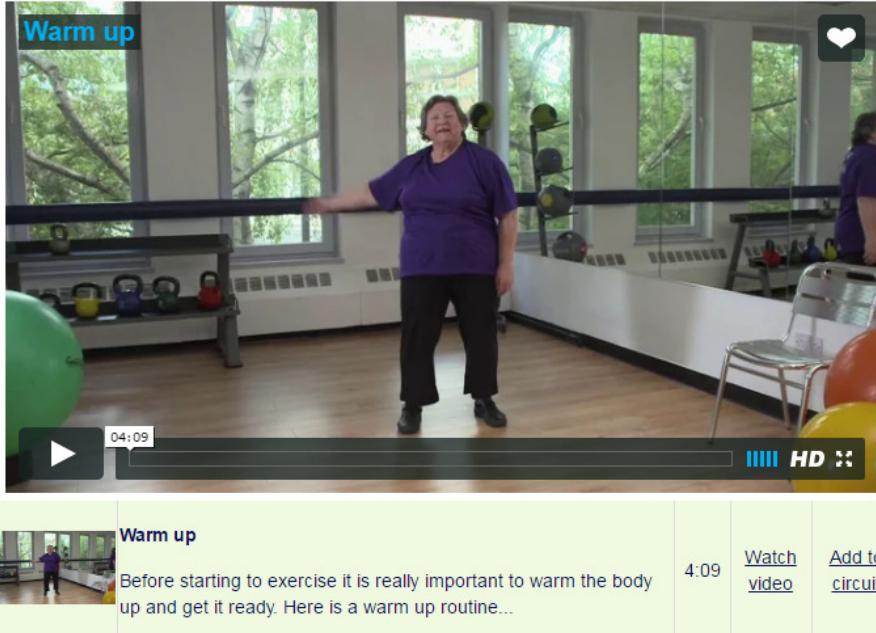
There is no cost to users.

Watch physical activity videos:

There are three important steps when exercising:

1. Warm up.
2. Do selected exercises.
3. Cool down.

To see a demonstration of an exercise, click on the [Watch video](#) link on the list below and then press play.



Warm up

04:09

HD

Warm up

Before starting to exercise it is really important to warm the body up and get it ready. Here is a warm up routine...

4:09

[Watch video](#)

[Add to circuit](#)

The physical activity videos have 3 levels – basic, intermediate and advanced.

Each level has a warm-up and cool down.

There is an introductory video with by a personal trainer with advice about increasing physical activity.

There are also clear guidelines about exercising safely with type 2 diabetes.

Users can build a circuit by joining videos of their choice together in a playlist.

For users with limited mobility there are links to exercise leaflets that demonstrate physical activity that can be done seated.

Section 3: Treating diabetes

This section is focused on enabling users to understand the rationale for medication and its effects (desirable and undesirable). It also covers alternative medicine, vaccinations, bariatric surgery and the common tests used as part of routine diabetes care.

BCTs used: Information about health consequences

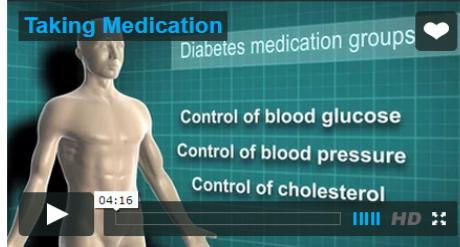
Screenshot: Treating diabetes

- Cholesterol tablets
- Glucose control
- Insulin: the basics
- Starting on Insulin
- Managing nerve pain
- Tablets for problems with sex
- Tablets to thin the blood
- Using medicines in special situations
- Weight loss
- Surgery
- Complementary medicine
- Vaccinations and immunisations
- How the NHS can help

Taking medicines 

You will need audio for these videos. To watch full screen move your cursor to the bottom right corner of the video and click the expand button .

In this 4-minute video, people with type 2 diabetes and doctors talk about some of the issues around having to take medicines to control the condition.



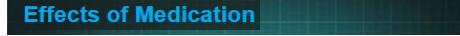
Taking Medication
Diabetes medication groups

Control of blood glucose
Control of blood pressure
Control of cholesterol

04:16  

Effects of medicines 

This 4-minute video explores the effects of medicines on people with type 2 diabetes.



Effects of Medication

RELATED TOPICS

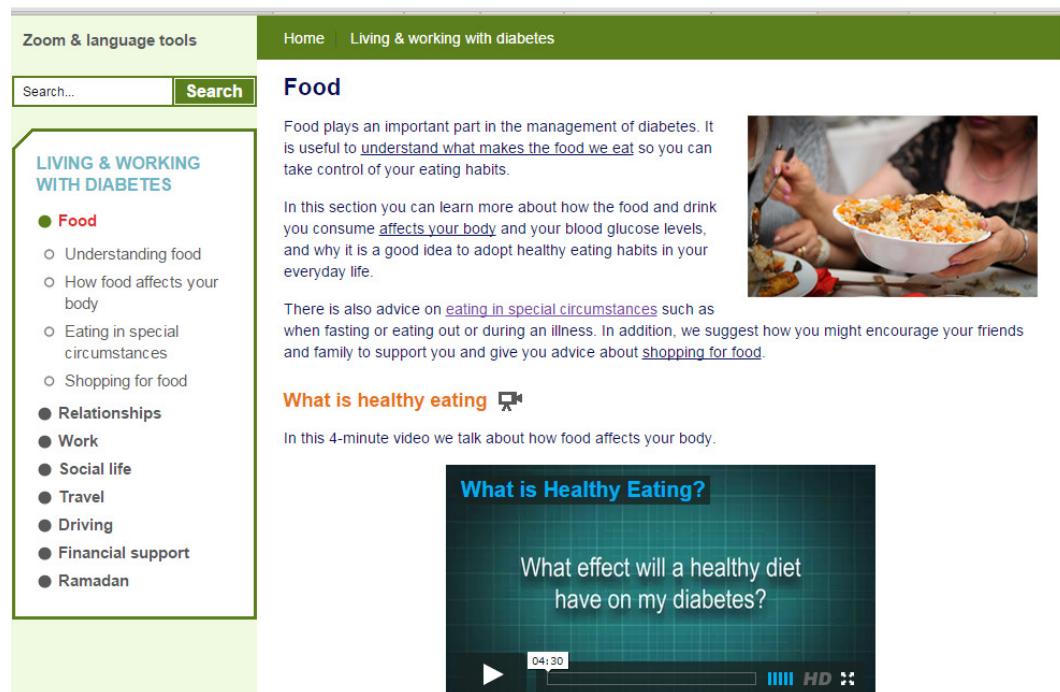
- How my body can be affected

Section 4: Living and working with diabetes

The focus of this section is role management and helping users understand how living with diabetes might affect them at work or at home. It covers food, relationships, work, social life, travel, driving, financial support and fasting in Ramadan.

BCTs used: Information about health consequences, Information about emotional consequences

Screenshot: Living and working with diabetes



The screenshot shows a website for managing diabetes. At the top, there are 'Zoom & language tools' and a search bar with a 'Search' button. The main navigation bar includes 'Home' and 'Living & working with diabetes'. The 'Food' section is currently selected. On the left, a sidebar titled 'LIVING & WORKING WITH DIABETES' lists categories: Food (selected), Relationships, Work, Social life, Travel, Driving, Financial support, and Ramadan. The main content area discusses the importance of food in diabetes management, mentioning understanding what makes food affect blood glucose levels, and provides advice for special circumstances like fasting. It also features a video thumbnail titled 'What is Healthy Eating?' with the subtitle 'What effect will a healthy diet have on my diabetes?' and a play button.

Section 5: Managing my feelings

There are 2 parts to this section. 'Understanding my moods' tackles negative emotions through videos and encouraging users to reflect and process unhelpful feelings. It also prompts users to think about positive steps they can take to improve their happiness.

'My mood tools' provides a self-assessment tool that allows users to fill out the Hospital Anxiety and Depression Scale (HADS) questionnaire to look for signs of anxiety or depression (Bjelland et al. 2002). If they score highly, users are signposted to help that includes a computerised CBT course (Living Life to the Full: <https://www.help-diabetes.org.uk/managing-my-feelings/my-mood-tools/>) that has been tailored for diabetes and provided through the intervention.

BCTs used: Reduce negative emotions Information about emotional consequences
Also: Computerised CBT

Screenshot: Managing my feelings

The screenshot shows a slide from a course module. At the top left is a search bar with 'Search...' and a 'Search' button. To the right is the title 'How to fix almost everything'. In the top right corner, it says 'Slide 1 of 16'. The main content area has a dark purple background with the title 'HOW TO FIX ALMOST EVERYTHING' in large, bold, white and yellow letters. Below the title, a small line of text reads 'Produced under Licence, © Dr Chris Williams. All rights reserved (2009) www.liveareas.com'. At the bottom of the slide are standard presentation controls: a double-headed arrow for navigation, a timer showing '00:00', a play/pause button, a volume icon, and a 'next' button with a right-pointing arrow. To the left of the main content, there is a sidebar with a light green border. It contains a heading 'LIVING LIFE TO THE FULL' and a list of eight modules: 'Introduction', 'Courses' (which is highlighted in red), 'Why do I feel so bad?', 'I can't be bothered doing anything', 'Why does everything always go wrong?', 'I'm not good enough', 'How to fix almost everything', 'The things you do that mess you up', 'Are you strong enough to keep your temper?', '10 things you can do to feel happier straight away', 'Get email support', and 'Worksheets'.

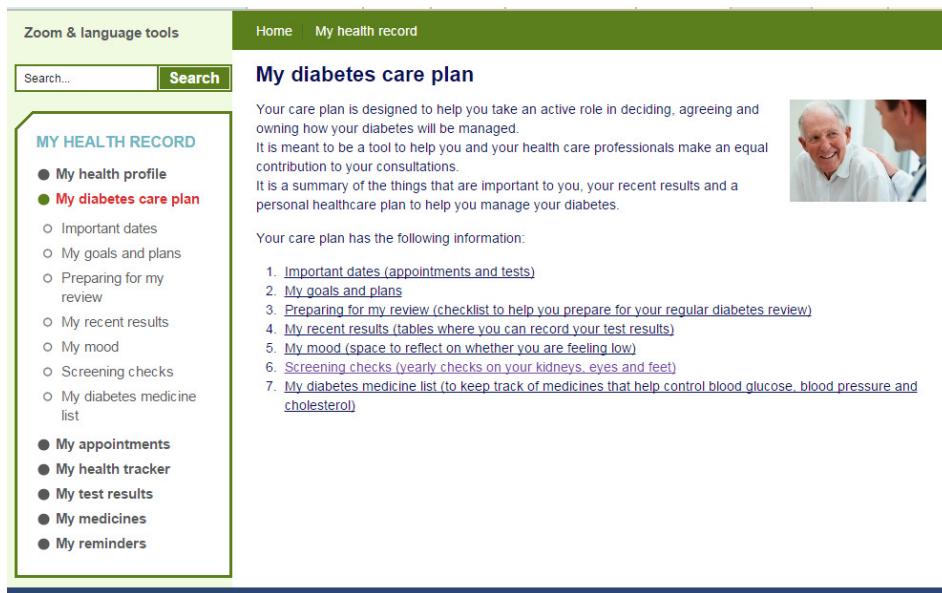
The screenshot above shows an example of a module from the cCBT course Living Life to the Full. It offers eight modules listed on the left. Each module offers a set of slides with audio and links to online workbooks.

Section 6: My Health Record

This part of the intervention supports self-monitoring. Users can track data about their blood glucose levels, weight, blood test results and blood pressure. They can manage a list of their medication and set up reminders for appointments. There is a care plan to help keep track of their diabetes care and support users to take responsibility for shared management.

BCTs used: Self-monitoring of behaviour, Self-monitoring of outcome(s) of behaviour, Monitoring of outcome(s) of behaviour without feedback

Screenshot: My Health Record



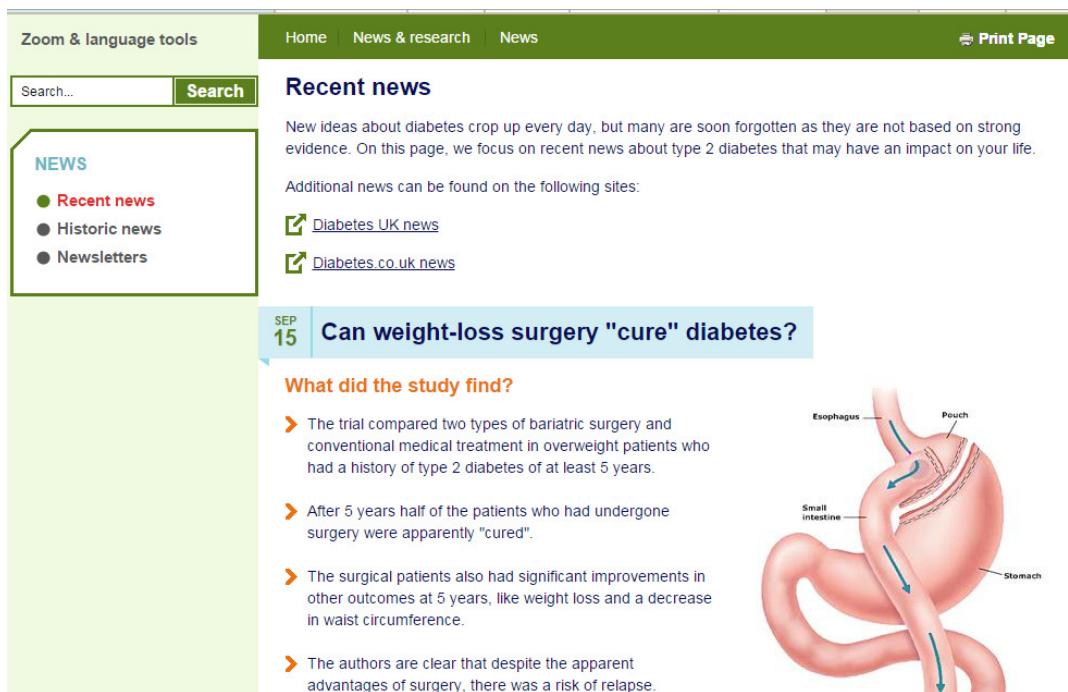
The screenshot shows the 'My diabetes care plan' section of the 'My health record' website. The left sidebar lists 'MY HEALTH RECORD' sections: 'My health profile' (selected), 'My diabetes care plan' (highlighted in red), 'Important dates', 'My goals and plans', 'Preparing for my review', 'My recent results', 'My mood', 'Screening checks', 'My diabetes medicine list', 'My appointments', 'My health tracker', 'My test results', 'My medicines', and 'My reminders'. The main content area is titled 'My diabetes care plan' and explains its purpose: to help users take an active role in managing their diabetes. It highlights that it's a tool for consultations, a summary of important things, and a personal healthcare plan. A sidebar image shows a doctor and a patient. Below the main text is a list of 7 items: 1. [Important dates \(appointments and tests\)](#), 2. [My goals and plans](#), 3. [Preparing for my review \(checklist to help you prepare for your regular diabetes review\)](#), 4. [My recent results \(tables where you can record your test results\)](#), 5. [My mood \(space to reflect on whether you are feeling low\)](#), 6. [Screening checks \(yearly checks on your kidneys, eyes and feet\)](#), and 7. [My diabetes medicine list \(to keep track of medicines that help control blood glucose, blood pressure and cholesterol\)](#).

Section 7: News and research

Since participants in the qualitative study were keen to stay in touch with new developments, we developed a part of the website to provide commentary on new research or news stories relevant to people with type 2 diabetes. It also has a summary of some of the important studies that provide the evidence for the main principles of treatment.

BCTs used: Information about health consequences

Screenshot: News and research



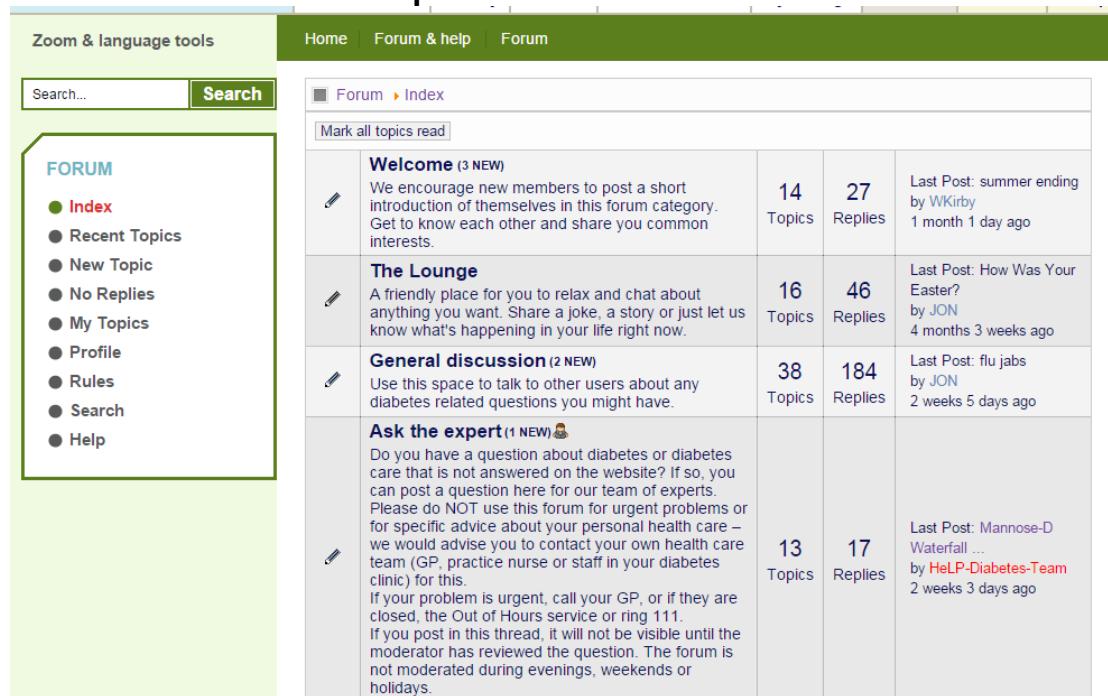
The screenshot shows the 'Recent news' section of the 'News & research' website. The left sidebar lists 'NEWS' sections: 'Recent news' (selected and highlighted in red), 'Historic news', and 'Newsletters'. The main content area is titled 'Recent news' and discusses new ideas about diabetes. It mentions that many ideas are soon forgotten as they are not based on strong evidence. It focuses on recent news about type 2 diabetes. A sidebar image shows a doctor and a patient. Below the main text is a list of news sources: [Diabetes UK news](#) and [Diabetes.co.uk news](#). A news article is highlighted: 'SEP 15 Can weight-loss surgery "cure" diabetes?'. The article title is 'Can weight-loss surgery "cure" diabetes?'. The article content is: 'What did the study find?'. The study found: 1. The trial compared two types of bariatric surgery and conventional medical treatment in overweight patients who had a history of type 2 diabetes of at least 5 years. 2. After 5 years half of the patients who had undergone surgery were apparently "cured". 3. The surgical patients also had significant improvements in other outcomes at 5 years, like weight loss and a decrease in waist circumference. 4. The authors are clear that despite the apparent advantages of surgery, there was a risk of relapse. To the right of the article is a diagram of a bariatric surgery procedure, specifically a Roux-en-Y gastric bypass. The diagram shows the stomach being divided into a small upper pouch and a larger lower pouch. The small intestine is then reconnected to the pouch, creating a bypass around the majority of the stomach and upper intestine. Labels include: Esophagus, Pouch, Small intestine, and Stomach.

Section 8: Forum and help

This section helps users with social support. It has a forum to allow peer support and interactions between users, and a facility for users to submit general diabetes related questions for a health professional response. It also has videos from Health Talk Online, which shows people with type 2 diabetes talking about different aspects of their lives like accepting the diagnosis, taking medicines and working with healthcare professionals.

BCTs used: Social support (unspecified), Credible source

Screenshot: Forum and help



The screenshot shows a forum interface with a green header bar. The header contains the text 'Zoom & language tools', 'Home', 'Forum & help', and 'Forum'. Below the header is a search bar with a 'Search' button. On the left, there is a sidebar titled 'FORUM' with a list of links: 'Index' (highlighted in red), 'Recent Topics', 'New Topic', 'No Replies', 'My Topics', 'Profile', 'Rules', 'Search', and 'Help'. The main content area shows a list of forum topics:

| Forum | | | | |
|-----------------------------------|---|-----------|-------------|---|
| Index | | | | |
| Welcome (3 NEW) | We encourage new members to post a short introduction of themselves in this forum category. Get to know each other and share your common interests. | 14 Topics | 27 Replies | Last Post: summer ending by WKirby 1 month 1 day ago |
| The Lounge | A friendly place for you to relax and chat about anything you want. Share a joke, a story or just let us know what's happening in your life right now. | 16 Topics | 46 Replies | Last Post: How Was Your Easter? by JON 4 months 3 weeks ago |
| General discussion (2 NEW) | Use this space to talk to other users about any diabetes related questions you might have. | 38 Topics | 184 Replies | Last Post: flu jabs by JON 2 weeks 5 days ago |
| Ask the expert (1 NEW) | Do you have a question about diabetes or diabetes care that is not answered on the website? If so, you can post a question here for our team of experts. Please do NOT use this forum for urgent problems or for specific advice about your personal health care – we would advise you to contact your own health care team (GP, practice nurse or staff in your diabetes clinic) for this. If your problem is urgent, call your GP, or if they are closed, the Out of Hours service or ring 111. If you post in this thread, it will not be visible until the moderator has reviewed the question. The forum is not moderated during evenings, weekends or holidays. | 13 Topics | 17 Replies | Last Post: Mannose-D Waterfall ... by HelP-Diabetes-Team 2 weeks 3 days ago |

6.4 Post-hoc description of the work done to achieve the objectives

6.4.1 Objective: 3. Summarise the evidence base used to inform the development of the intervention

There were three main sources of data used as an evidence base for the development of the intervention. They were the systematic review and synthesis of RCTs of digital interventions described in Chapter 3, the qualitative work with patients described in Chapter 4 and the exploration of health professional perspectives described in Chapter 5. The findings from these studies have been summarised in tables 6.1-6.3 below.

Table 6-2 Summary of results from the Cochrane systematic review of digital self-management interventions for adults with type 2 diabetes

| | |
|---|---|
| Participants | 3578 |
| Study type | 16 RCTs |
| Pooled effect on HbA1c from 11 RCTs in meta-analysis | -2.3 mmol/mol or -0.2% (95% confidence interval (CI) -0.4 to -0.1; P = 0.009) |
| Effect on HbA1c in mobile phone subgroup | -5.5 mmol/mol or -0.5% (95% CI -0.7 to -0.3); P < 0.00001 |
| Other effects | Studies did not show adequate evidence for improving depression, health-related quality of life or weight. Four (out of 10) interventions showed beneficial effects on lipid profile. |
| BCTs commonly used by effective interventions | Prompting self-monitoring of behavioural outcomes Providing feedback on performance |
| BCTs commonly used by interventions with no impact on HbA1c | Providing information on the consequences of behaviour Goal setting Barrier identification/problem solving |

Table 6-3 Summary of design features desired by patients and professionals

| | Patient preferences | Health professional preferences |
|------------------------------|--|---|
| Design and navigation | Easy to use Clear, concise, consistent Minimise scrolling Use videos Pages can be printed Have interactive features like quizzes Provide self-monitoring tools Webinars with medical professionals Ask the expert functions Act as a central hub for all diabetes related queries with links to other resources | Simple Media-rich Easy and quick to login |
| Language and tone | Accessible Use medical terminology where needed so users can become comfortable with terms used by professionals, but include accessible definitions of terms used Be encouraging and supportive Not shy away from difficult truths Have a sense of humour | Positive and supportive Avoid victim-blaming |
| Trust and engagement | Thorough proofreading Have no advertising Working links to/from good websites Use trusted brands | Evidence of effectiveness Evidence of use by patients Endorsements from patients Endorsements from professional bodies |
| Avoid these irritants | Poor design Not relevant/ localised Out of date Boring/ static | Large volumes of self-management data Complex log-in |

Table 6-4 Content requested by patients and health professionals

| | |
|---|--|
| Medical information | Medication Side effects Hypoglycaemia News and research |
| Dietary advice | Controlling blood glucose Weight loss Controlling cholesterol Understanding food Recipe ideas |
| Physical activity | Benefits of exercise Advice about weight loss Self-monitoring tools Easy to do physical activities Resources for group activities |
| Alternative medicine | Relaxation therapy and stress reduction Complementary therapies |
| Peer support | Advice from peers Emotional support Social comparisons Role models Not much enthusiasm for social media |
| Pregnancy <i>[excluded as advised by ethics and funding body]</i> | Safe conception and what to do if pregnant |
| Practical advice about living with type 2 diabetes | Travel Insurance Financial advice e.g. benefits Advice about work e.g. shift work Managing families Managing social situations and eating out |
| Information about health services | Services that patients should have access to Local support groups Telephone support lines |
| Test results | Normal values |
| Other | Tackle common myths |

6.4.2 Objective 4. List the theoretical frameworks selected as part of the development process.

As stated in Chapter 2, theory was used to help guide three elements of the intervention design process:

- The overall scope of the intervention (Corbin and Strauss)
- Support behaviour change (COM-B model)
- Anticipate challenges to implementation into clinical settings (NPT)

The scope of the intervention was to help users with the work of living with a chronic condition, as described by Corbin and Strauss i.e.

1. **Illness work (medical/behavioural management):** learning about diabetes, healthy eating, increasing physical activity, taking medication, smoking cessation, moderating alcohol intake, keeping appointments and working with health professionals.
2. **Life work (emotional management and day to day duties):** managing diabetes related distress from negative emotions like denial, sadness, anger, fear or frustration and treating depression.
3. **Biographical work (role management):** changing, maintaining or creating new meaningful roles at home or work.

Medical/behavioural management

To support the medical management of diabetes, the two main functions of the intervention were to help patients with i. increasing diabetes related knowledge and ii. supporting behaviour change (healthy eating, increasing physical activity, taking medication, smoking cessation, moderating alcohol intake, engaging with professionals and attending appointments).

To support increasing diabetes related knowledge, the education provision elements of the site were written with the principles of adult education in mind (Collins 2004), i.e. based on the assumptions that users:

1. Have accumulated a foundation of experience and knowledge
2. Are autonomous and self-directed

3. Benefit from clear goals
4. Are practical and relevancy-orientated
5. Need to be respected
6. Can be motivated by intrinsic factors (cognitive interest, escape/stimulation, personal advancement, social welfare) and extrinsic factors (social relationships and external expectations)
7. Learn best when participating actively
8. Have different ways of learning
9. Learn more effectively when given timely and appropriate feedback
10. Prefer an environment that is informal and personal

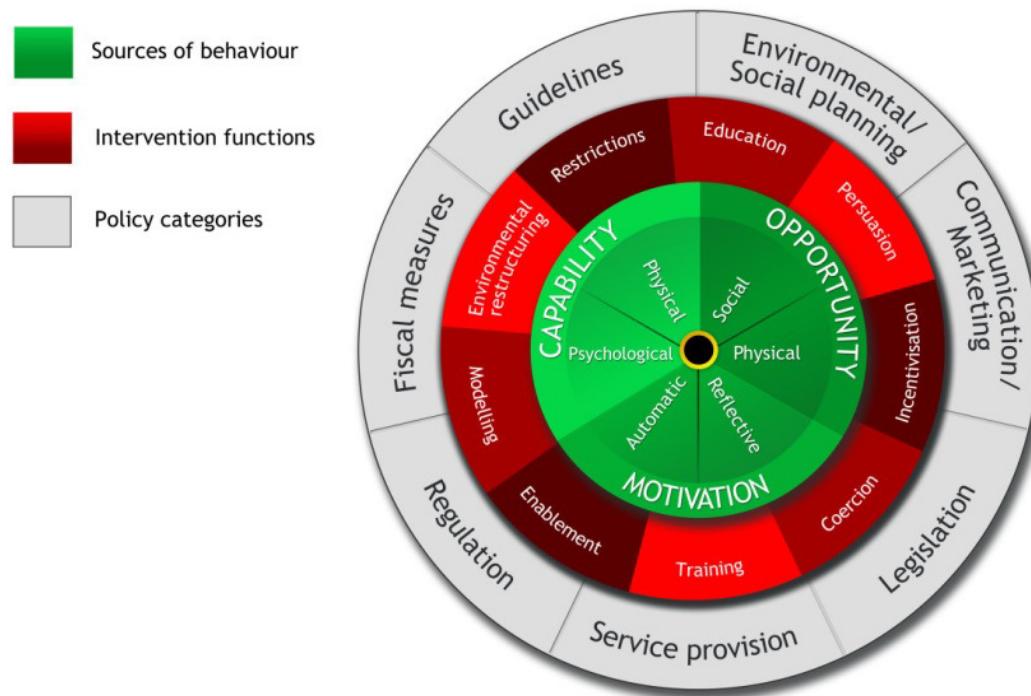
The theory behind the behaviour change elements of the intervention has been described in Chapter 2. For this intervention, it was important to target multiple behaviours and the complexity of motivation, including both 'reflective' (Type 1) processing and automatic (Type 2) processing (Strack et al. 2004).

Therefore, the behaviour change elements needed to be supported by a framework that could be used to analyse multiple behaviours and identify the important motivational and other factors that drive those behaviours, and then match suitable target factors with appropriate techniques to change that behaviour. An example of such a framework is the Behaviour Change Wheel (BCW) which was developed through a rigorous process of reviewing existing frameworks to develop an integrative framework, linked to the COM-B model of behaviour (Michie and others 2011). The BCW and COM-B framework can be used to make a 'behavioural diagnosis' of the target behaviour as a basis for identifying behaviour change techniques likely to be effective.

There were a number of reasons for using the BCW for the post-hoc analysis of the intervention design process. As discussed in chapters 1 and 3, the process of implementing theory in intervention design is often done poorly and this is partly because theories of behaviour change usually highlight potential antecedents of behaviour but they do not cover the process of selecting intervention ingredients to influence those antecedents. The BCW has been designed to support the design of behaviour change interventions and provide a link between the analysis and understanding of the drivers of behaviour (based on theoretical models like COM-B) and the design of interventions to influence

those antecedents. Therefore it describes nine intervention functions and seven policy categories relevant to intervention design as shown in Figure 6-1 below. This provided a list of potential functions that the intervention could use to target the determinants of behaviour as identified by the COM-B model. The COM-B model provided a comprehensive framework to systematically analyse potential antecedents driving the behaviours and outcomes of interest. The BCW provided a similar framework to analyse and describe the functions of the intervention and link this to how we thought these would affect potential antecedents identified in the COM-B analysis.

Figure 6-1 The Behaviour Change Wheel - reproduced from (Michie and others 2011c)



The nine different intervention functions target different components of behaviour.

An online intervention can help to educate and persuade users and facilitate enablement. By providing videos and tools to support establishing healthy behaviours it can also help to facilitate training. It can prompt users to restructure their environment and help enable users to perform tasks

successfully. The mapping of COM-B components to intervention functions and BCTs is dealt with in more detail in Objective 4.

Behaviours associated with addiction like excessive alcohol intake and smoking are characterised by a failure of self-regulation and harm from maladaptive behaviour and the theories accounting for these behaviours have a different emphasis (Webb et al. 2010;West et al. 2013). Online tools specifically designed for managing alcohol intake and smoking cessation were incorporated into the intervention for these behaviours.

For alcohol, the content of an evidence based intervention to reduce alcohol consumption (DownYourDrink) was incorporated into an alcohol section of HeLP-Diabetes (Linke et al. 2004). DownYourDrink is a theoretically informed intervention that has been evaluated through an RCT (Wallace et al. 2011). Participants in the RCT given access to DownYourDrink reduced their weekly alcohol consumption by an average of 20 units per week.

For smoking cessation, the StopAdvisor intervention was offered as an optional module in the smoking section of the website (Brown et al. 2014;Michie et al. 2012b). StopAdvisor is a theoretically informed intervention also evaluated through an RCT. StopAdvisor has been shown to be more effective than information only websites in helping patients of low socio-economic status quit smoking.

Emotional and role management

Denial and non-expression of emotions may be a useful short-term coping strategy to cope with the stress surrounding the diagnosis of a chronic illness, but in the longer term, unresolved emotions could have negative effects through chronic raised sympathetic arousal (stress), delayed help seeking, rumination and poor communication with health-care providers (Wiebe et al. 2003). Conversely, there are several potential benefits if emotions are expressed and processed (Austenfeld et al. 2004;de Ridder et al. 2008). Thinking, talking or writing about negative emotions can make the experience less intensive and invasive (habituation), increase insight into why emotions are experienced and

how their impact can be reduced (cognitive reappraisal), decrease emotional distress and create opportunities for social support and enhanced closeness with others and improve self-regulation.

Encouraging people to think about past experiences in a neutral way (as if observed by an outsider) helps to reduce the negative arousal that typically occurs when people experience and engage with negative emotions, allowing them to process their experiences more reflectively (Kross et al. 2005). This approach is consistent with mindfulness and meditation and it is reflected in therapeutic techniques that encourage people to consider negative feelings and experiences from diverse perspectives (Teasdale et al. 2000). Therefore a mindfulness based approach to encourage reflective processing of negative emotions was used to help patients with emotional management.

Information provision was planned to provide practical advice to support adjustments to changes in family life and working roles in people living with type 2 diabetes.

Specific plans were made for tackling low mood. The risk of depression can double in people living with type 2 diabetes and the prevalence in high risk populations can reach 30% (Anderson et al. 2001). Depression appears to have prognostic and diagnostic implications in diabetes: it is associated with poor control and increased rates of complications (de Groot et al. 2001; Lustman et al. 2000); in prospective studies, depression doubles the likelihood of being diagnosed with diabetes (Eaton et al. 1996; Kawakami et al. 1999). Success in goal attainment has been positively related to subjective well-being or the absence of depressive symptoms, therefore actively improving mood could prove valuable to self-management interventions (Scholz et al. 2006). Computerised Cognitive Behavioural Therapy (CCBT) has been shown to be an effective intervention for treating depression, so this was judged to be a practical and useful addition to the intervention (Kaltenthaler et al. 2004).

The CCBT programme chosen for HeLP-Diabetes was a version of Living Life to the Full (LLTF) that was adapted for people living with type 2 diabetes. LLTF is a CCBT programme that is freely available online (<http://www.lltf.com/index.php>). It is an online version of an evidence-based

CBT approach for negative emotions like depression, anxiety, anger, guilt and shame (Garland et al. 2002; Williams et al. 2002). Although LLTF itself had not been evaluated as part of an RCT, it was a stable and widely available online intervention that has been extensively tested and used by people in the UK and abroad. It was practical and feasible to offer a version of this programme through HeLP-Diabetes and therefore this was chosen as the basis for the CCBT element of the intervention.

Operationalisation in the intervention

Emotional management was a consideration in writing all the content of the website and steps were taken to ensure the tone was supportive and encouraging throughout, with a focus on positive changes that users could make to improve outcomes e.g. all pages talking about the complications of living with type 2 diabetes were written with advice on the steps that users could take to try and avoid developing those problems and the options available to manage complications for those who had already developed them.

Theory guiding implementation of the intervention

As described in Chapters 2 and 5, Normalization Process Theory was used to help anticipate and plan to mitigate the possible challenges that would be faced when trying to implement a new online self-management intervention into routine primary care.

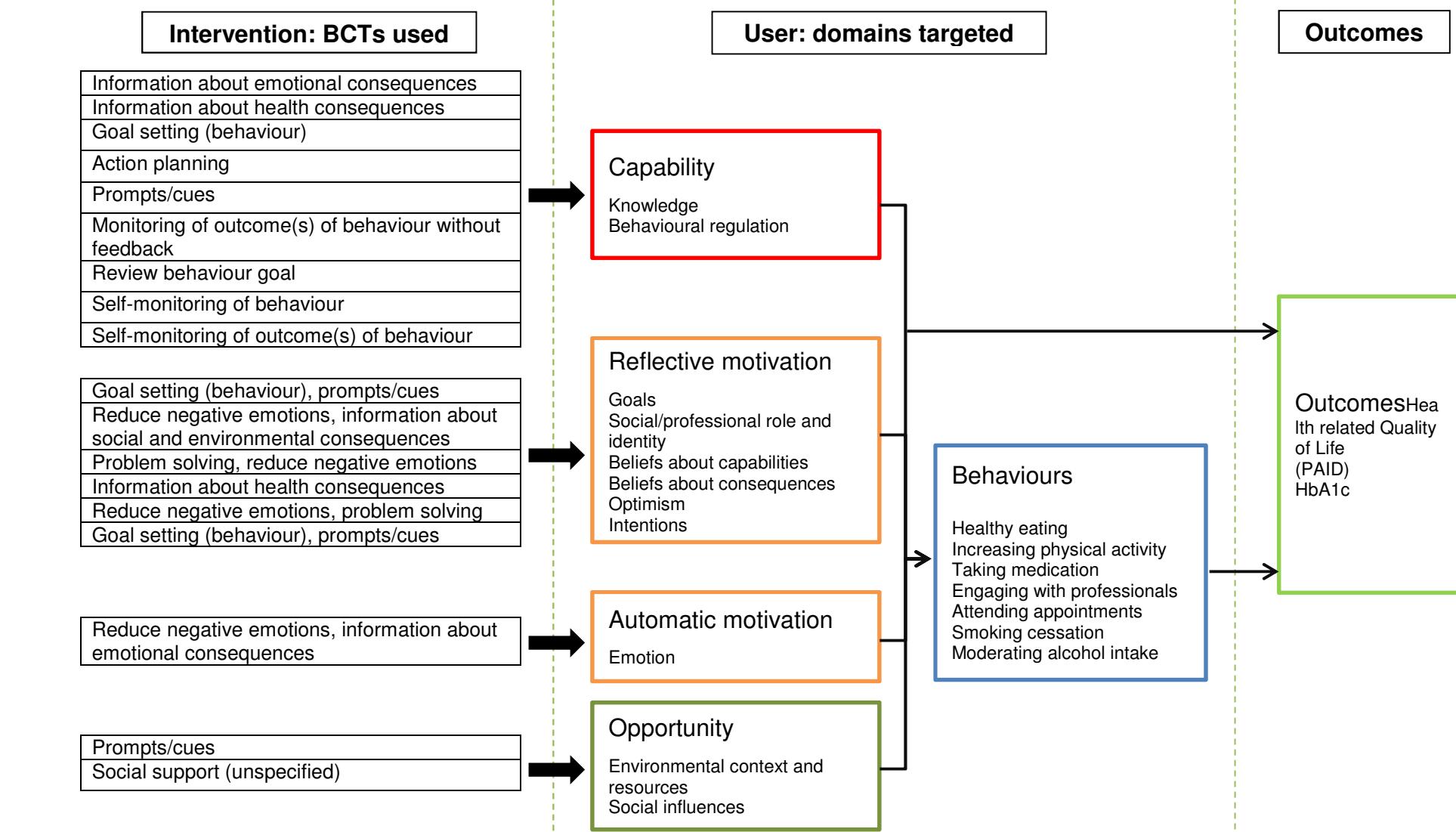
6.4.3 Objective 5. Highlight the proposed mechanism of action of the intervention

Logic models are intervention-specific representations of the proposed mechanism of action of the intervention (Conrad et al. 1999). They are often graphical, limited to one page and usually have four elements:

- (1) context
- (2) theory and assumptions
- (3) intervention
- (4) outcomes

Logic models are a good way of communicating the main proposed mechanism of action for the purposes of dissemination or implementation. However the creation of the model needs to be theory or evidence based and the process should be explicit and justified. The rationale for the logic model for this intervention was described in Chapter 2 and it has been reproduced in Figure 6-2 below.

Figure 6-2 Logic model demonstrating possible mechanism of action and outcomes to be measured



Theories of behaviour change used:

Control Theory
Social Cognitive Theory
Operant Learning Theory

Intervention context:

Patient interacting with intervention at home
Patient discussing intervention use with health professionals

6.4.4 Objective 6. Demonstrate how the data and theory were integrated and operationalized: a post-hoc application of the Behaviour Change Wheel

Using the BCW as described previously to design interventions is a three stage process with eight steps in total (Michie et al. 2014a). The three stages are: 'Understanding the behaviour', 'Identify intervention options' and 'Identify content and implementation options', as described below:

Stage 1: Understand the behaviour

1. *Define the problem in behavioural terms*
2. *Select the target behaviour*
3. *Specify the target behaviour*
4. *Identify what needs to change*

Stage 2: Identify intervention options

5. *Identify intervention functions*
6. *Identify policy categories*

Stage 3: Identify content and implementation options

7. *Identify behaviour change techniques*
8. *Identify mode of delivery*

As illustrated in Figure 6-2, the behaviours targeted for diabetes self-management were spread across different areas that included eating, physical activity, medicine management, smoking cessation, alcohol intake and interacting with health professionals. As smoking cessation and alcohol intake were targeted through specialised interventions, they will not be discussed. The application of the BCW to the remaining four areas is described below.

Step 1 – Define the problem in behavioural terms

Defining a problem in behavioural terms requires designers to be specific about the behaviour and the individuals or groups or individuals being targeted by the intervention that need to be changed to solve the problem(s). This is illustrated in Table 6-5below:

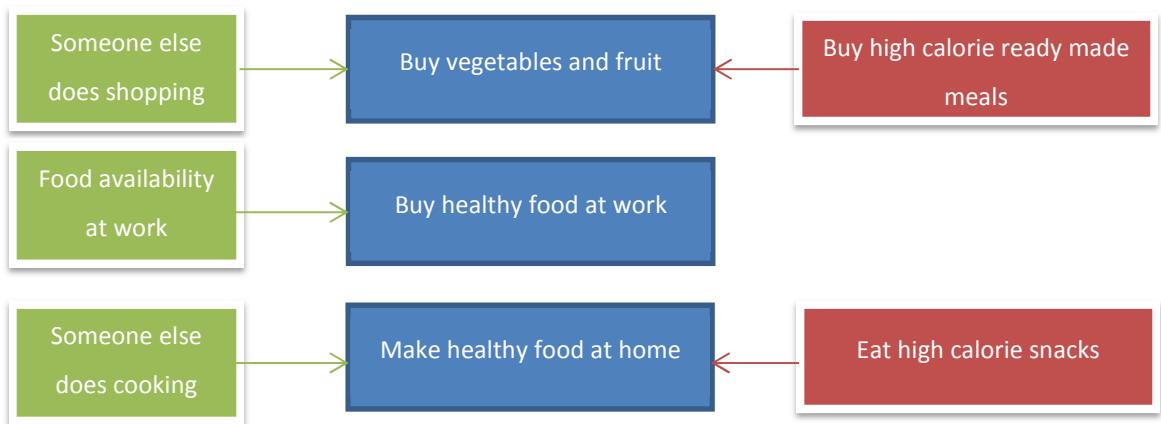
Table 6-5 Behavioural definition of good self-management for type 2 diabetes

| | Location for behaviour | People involved |
|---|--|-------------------------------|
| Eating: | | |
| Reduce calorie intake to levels appropriate for weight loss targets | At home and work | User and family or carers |
| Reduce the amount of high GI food in the diet | At home and work | User and family or carers |
| | | |
| Physical activity: | | |
| Increase physical activity levels to recommended levels | At home and on commute | User and family or carers |
| | | |
| Medicine management: | | |
| Take medicine regularly and as prescribed | At home | User and carers |
| | | |
| Interactions with health professionals: | | |
| Attend regular screening checks and annual review | Hospital, community clinics and GP surgery | User and health professionals |
| Create own agenda for consultations with health professionals | Home | User and health professionals |

Step 2 - Select the target behaviour

Behaviours cannot exist in isolation and in their real life contexts they interact and compete with many other behaviours performed by the individuals and those around them. An example of the competing behaviours within individuals and their environment can be seen in Figure 6-3 below.

Figure 6-3 Example of a behavioural system around healthy eating [adapted from (Michie and others 2014a)]



This step would normally involve creating a ‘long list’ of potentially relevant behaviours. This list can then be turned into a shorter more focused list of potential targets based on a systematic evaluation of the behaviours considering four criteria:

1. The impact of behaviour change on the desired outcome
2. The likelihood that the behaviour can be changed
3. The potential impact on related behaviours
4. The ease of measuring the behaviour.

Based on these criteria, behaviours can be categorised as very promising, quite promising, unpromising but worth considering or not acceptable.

However creating such long-lists for every possible behaviour for every area and then systematically analysing them was not feasible in the time scales available for this project. Target behaviours were selected based on (non-systematic) reviews of evidence, best practice guidance and suitability for change through an online intervention.

Based on the analysis feasible for the study design, the list of target behaviours selected can be found in Table 6-6.

Table 6-6 Target behaviours for the intervention

| |
|--|
| Eating: |
| Swap foods high in fat for lower fat or fat free alternatives |
| Not eat high carbohydrate or high-calorie snacks |
| Increase the amount of fibre in diet |
| |
| Physical activity: |
| Reduce the amount of time spent inactive for more than 15 minutes |
| Find ways to get more active while doing everyday tasks and errands |
| Try out a number of activities to find one users really enjoy |
| Achieve recommended levels of moderate physical activity a week if feasible for user |
| |
| Medicine management: |
| Simplify medicine routine |
| Remember to take medicines everyday |
| |
| Interactions with health professionals: |
| Increase attendance for screening health checks and annual reviews |
| Take an active part in care planning and creating personal agendas for consultations with health professionals |

Step 3 - Specify the target behaviour

Once target behaviours are identified, it is important to specify the context and detail of the behaviour. There are six elements of each behaviour that can be described in more detail and these are:

- i. Who needs to perform the behaviour?
- ii. What does the person need to do differently to achieve the desired change?
- iii. When will they do it?
- iv. Where will they do it?
- v. How often will they do it?
- vi. With whom will they do it?

An example of this process applied to the target behaviours for this intervention can be found in Table 6-7 – 6-9.

Table 6-7 Specification for diet behaviours

| Dietary behaviours | What | Who | Where | When |
|---|---|--|---------------------------------------|-------|
| Swap foods high in fat for lower fat or fat free alternatives | Use low fat food, reduce oil in cooking and reduce saturated and hydrogenated fat intake | User or person responsible for cooking or shopping | At home, when shopping and at work | Daily |
| Not eat any high carbohydrate/calorie snacks | Use low fat, low calorie and low GI food in small portions between meals | User | At home, social occasions and at work | Daily |
| Increase the amount of fibre in diet | Use wholemeal or granary bread, brown rice and pasta, wholegrain breakfast cereals, beans, lentils, nuts and seeds, vegetables and fruits in meals and snacks | User or person responsible for cooking or shopping | At home, when shopping and at work | Daily |

Table 6-8 Specification for physical activity

| Physical activity | What | Who | Where | When |
|--|--|------|-------------------------------------|------------------|
| Reduce the amount of time spent inactive for more than 30 minutes | Limit sedentary activities to no more than 30 minutes at a time and walk where possible | User | At home, at work or while commuting | Daily |
| Find ways to get more active while doing everyday tasks and errands | Increase the duration of regular physical activities and try to walk where possible | User | At home, at work or while commuting | Daily |
| Try out a number of activities to find one users really enjoy | Use the intervention, exercise classes or new hobbies to become more active | User | Home, gym or with friends | 3-5 times a week |
| Achieve recommended levels of moderate physical activity a week if feasible for user | Build on experience of increasing physical activity to reach 150 minutes of activity vigorous enough to make user sweat every week | User | Home, gym or with friends | 5-7 times a week |

Table 6-9 Specification for medication adherence

| Adherence related behaviour | What | Who | Where | When |
|-------------------------------------|---|------|------------------------|-----------|
| Simplify medicine routine | Use the intervention or reviews with doctor or pharmacist to reduce complexity of medication regime | User | GP surgery or Pharmacy | 6 monthly |
| Remember to take medicines everyday | Use intervention to prompt use or plan for common circumstances for missed medication | User | Home | As needed |

Table 6-10 Specification for interactions with health professionals

| Interaction with health professional | What | Who | Where | When |
|--|---|------|----------------------------------|-----------|
| Increase attendance for screening health checks and annual reviews | Attend yearly diabetes review and complete 9 essential diabetes checks | User | GP surgery and community clinics | Yearly |
| Take an active part in care planning and creating personal agendas for consultations with health professionals | Use Diabetes Year of Care type templates for care planning and use intervention to set personal agendas for consultations | User | Home and GP surgery | As needed |

Step 4 - Identify what needs to change

Understanding the behaviours in as much detail as possible can help maximise the impact of an intervention by ensuring that effort is targeted at important drivers of the behaviour and assumptions, about what is important do not lead to potentially important drivers being left out. This can be done using the COM-B model described previously, in the context of data from as many sources as possible via multiple methods as most individuals have poor insight into why they behave in the way that they do (Wilson et al. 1991; Wilson et al. 2004). Information can be collected via focus groups, interviews or questionnaires from patients, health professionals, managers or other stakeholders bearing in mind limitations of insight, social desirability and professional identity biases (Michie et al. 2014a). It is also important to consider both desirable and conflicting behaviours.

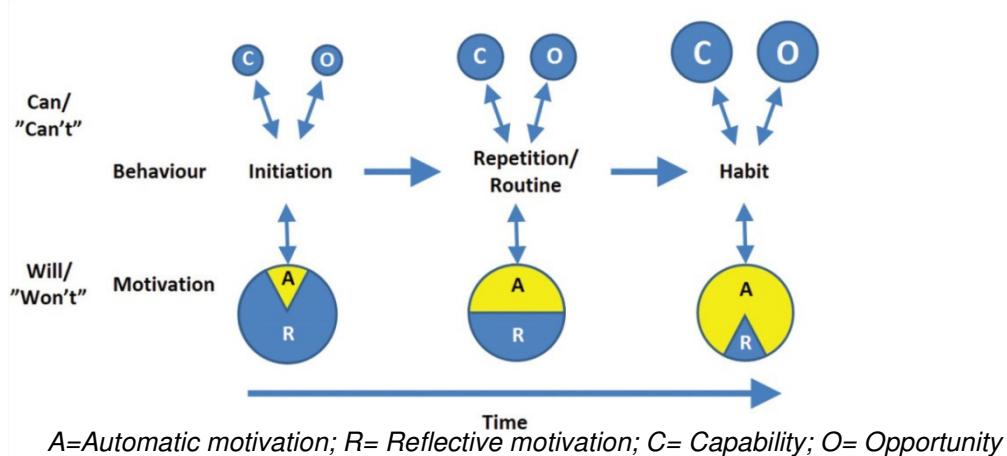
The depth of data gathering and therefore analysis may be constrained by resources. For this intervention the analysis constraints of time and funding meant that the analysis was limited to multi-disciplinary team discussions between health professionals. There are two elements of the behaviour change wheel framework that are particularly helpful for guiding intervention development even when resources only allow such limited analyses. The first is illustrated in Table 6-11. The Theoretical Domains Framework (Michie et al. 2005) expands on the components of capability, motivation and opportunity and maps them onto 14 theoretical domains which facilitates a systematic and comprehensive analysis of all antecedents of behaviour and is accessible for a broad spectrum of professionals (Cane et al. 2012; French et al. 2012).

Table 6-11 Links between the COM-B components and theoretical domains

| COM-B | Theoretical domain |
|--------------------------|--|
| Psychological capability | Knowledge Skills (cognitive and interpersonal) Memory attention and decision process Behavioural regulation |
| Physical capability | Skills (physical) |
| Reflective motivation | Social/professional role and identity Beliefs about capabilities Optimism Beliefs about consequences Goals Intentions |
| Automatic motivation | Reinforcement Emotion |
| Physical environment | Environmental context and resources |
| Social environment | Social influences |

The second useful element is a model illustrating how interactions between COM-B components evolve during the formation of the regular, automatic habits needed to sustain behaviour change (see Figure 6-4).

Figure 6-4 Model illustrating how interactions between COM-B components evolve during formation of the regular behaviours (Michie and others 2014a)



Step 5 – Identify intervention functions

The first four steps help describe what needs to be changed for the desired behaviour; step five identifies what intervention functions can be used to effect this change. The nine ways that interventions can be used to affect behaviour are listed below with their definitions.

- i. Education = increasing knowledge or understanding.
- ii. Persuasion = using communication to induce positive or negative feelings or stimulate action.
- iii. Incentivisation = creating an expectation of reward.
- iv. Coercion = creating an expectation of punishment or cost.
- v. Training = imparting skills.
- vi. Enablement = increasing means/reducing barriers to increase capability (beyond education and training) or opportunity (beyond environmental restructuring).
- vii. Modelling = providing an example for people to aspire to or imitate.
- viii. Environmental restructuring = changing the physical or social context.
- ix. Restriction = using rules to reduce the opportunity to engage in the target behaviour (or to increase the target behaviour by reducing the opportunity to engage in competing behaviours).

To help select the intervention functions likely to be most appropriate for the specific context, and therefore most likely to be implemented, it is helpful to consider a range of issues. A useful set of criteria for guiding this is the APEASE criteria: affordability, practicability, effectiveness/cost effectiveness, acceptability, safety, equity. The intervention functions judged, using these criteria, to be relevant to an online diabetes self-management intervention are listed below in Table 6-12, along with their hypothesised impact on COM-B components.

Table 6-12 Suitable intervention functions for an online diabetes self-management intervention and their impact on components of behaviour

| Intervention function | <i>Capability</i> | | <i>Motivation</i> | | <i>Opportunity</i> | |
|------------------------------------|-------------------|----------------------|-------------------|------------------|--------------------|---------------|
| | <i>Physical</i> | <i>Psychological</i> | <i>Reflective</i> | <i>Automatic</i> | <i>Physical</i> | <i>Social</i> |
| Education | | Yes | Yes | | | |
| Persuasion | | | Yes | Yes | | |
| Incentivisation | | | Yes | Yes | | |
| Training | Yes | Yes | | | | |
| Environmental restructuring | | | | Yes | Yes | Yes |
| Enablement | Yes | Yes | | Yes | Yes | Yes |

Step 6 - Identify policy categories

As this research project did not have access to policy making, this step was not relevant to the intervention design.

Step 7 - Identify behaviour change techniques

The penultimate step identifies the behaviour change techniques (BCTs) that are the active content of the intervention designed to change behaviour. The BCT taxonomy currently identifies 93 items organised into 16 groupings (Michie et al. 2013b).

The BCTs selected to achieve each intervention function are listed in Table 6-13. Details about the content delivered through the BCTs can be found under Objective 5.

Table 6-13 BCTs used to achieve the intervention functions for an online self-management programme for adults with type 2 diabetes

| Intervention function | BCTs used |
|-----------------------------|---|
| Education | Information about health consequences Self-monitoring of behaviour Self-monitoring of outcome(s) of behaviour |
| Persuasion | Credible source Information about emotional consequences |
| Incentivisation | Monitoring of outcome(s) of behaviour without feedback Self-monitoring of behaviour |
| Training | Demonstration of the behaviour Self-monitoring of behaviour |
| Environmental restructuring | Prompts/cues |
| Enablement | Action planning Goal setting (behaviour) Problem solving Reduce negative emotions Review behaviour goal Self-monitoring of behaviour Self-monitoring of outcome(s) of behaviour Social support (unspecified) |

Step 8 - Identify mode of delivery

The mode of delivery was defined within the original research proposal and would fall under the BCW category of “digital media-based internet delivered intervention”.

Although mobile phones apps were also considered as a possible delivery medium, when the project was started mobile internet had limited penetration and the time and cost required to optimise the intervention for mobile phones was not justifiable. However, a plan was made to update the template for the intervention and make it “responsive” i.e. usable with smaller screens of different size and resolution, and the technology delivering the videos were made to be compatible with Apple’s IOS platform. The intervention also had the capability to send text messages to mobile phones. Therefore although not designed as an intervention for use with mobile phones, compatibility with mobile phones and tablets was factored into the design where possible.

6.5 Discussion

Summary of main results

This chapter has described the experience of applying the MRC complex intervention framework to developing an online self-management tool for adults with type 2 diabetes called HeLP-Diabetes (Healthy Living for People with type 2 diabetes). The process was informed by a systematic review of the evidence and qualitative work conducted specifically for the intervention to determine patient and health professional defined needs and wants. The scope of the intervention was defined by Corbin and Strauss' model of living with a chronic illness and the COM-B model was used to understand the core behaviours relevant to diabetes self-management i.e. relating to diet, activity, and taking medication. Alcohol intake, depression and smoking cessation were tackled by more specialist interventions imported into the programme. The process of understanding and planning implementation was guided by the Normalization Process theory. The Behaviour Change Wheel was used as a post-hoc framework to summarise the process by which the data were synthesised and used to create the intervention and the intervention was described in terms of BCTs.

Strengths

There were a number of elements of good practice that guided the development of the intervention. The process was grounded in evidence that included a systematic review of quantitative data and a qualitative review of the needs of users and health professionals. This ensured that the content was relevant to users and it fitted in with the context of health service provision. The proposed mechanism of action was guided by theory and the active ingredients of the intervention have been explicitly described in terms of 15 BCTs delivered through 8 sections of the website. The platform used to develop the intervention is a widely supported open-source content management system (JOOMLA) and it is flexible and relatively inexpensive to maintain and update with new content or features; it has the potential be scaled up easily and provide a service on an NHS wide basis or adapted to be used with other conditions.

Limitations

Although the systematic review was able to provide some evidence, the overall evidence base was limited. There were not enough data to reach a definitive conclusion about the most effective BCTs that should be used, and interventions in general were poorly described which hampered attempts to learn from previous studies. However data from other interventions targeting similar behaviours was used to help inform the intervention design.

Another challenge faced during development was the rapid pace of change in technology. Between the start of development and the end of the research project, the devices people use to go online have changed significantly with tablets and mobile phones being widely used. Standard industry practice now suggests online content need to be ‘mobile-first’ i.e. work with small and narrow screens but with content that can be scaled up to fit larger laptop or desktop displays. Retrospective adaptations to make the content mobile friendly through the use of “responsive” templates that adapt to different size screens have been made.

The complexity of the condition and the breadth of behaviour change required for successful self-management of type 2 diabetes restricted the amount of development time that could be invested in tailoring content to the particular behaviours or different population subgroups. However the intervention design allows for content to be easily updated and newer content for specific scenarios like fasting in Ramadan or Afro-Caribbean diets could be added over time. Adding new content like this over time has one advantage as it serves as a way of engaging users and can encourage visits back to the site.

With such large and complex intervention some decisions about content and descriptions will have been made that rely on researcher judgement and may not have been explicitly documented (Michie et al. 2012a). However the use of theoretical frameworks has hopefully allowed for the development process and intervention content to be described in sufficient detail to help inform current and future research for related interventions.

Implications for future work

The HeLP-Diabetes website is currently being evaluated. The evaluation consists of two studies running in parallel. The first is a two-arm Randomized Control Trial (RCT) comparing outcomes in patients using HeLP-Diabetes with patients given access to a basic information provision website. As the intervention was funded by a grant for applied research, the outcomes for the trial are focused on clinical measures, quality of life scores and cost-effectiveness: the primary outcomes are HbA1c and Problem areas in diabetes (PAID) scores. Changes in behaviours or mediators are not being measured as part of the RCT. The second study is an implementation study looking at uptake and usage of the intervention when deployed through primary and secondary care services as part of routine care and outside the procedures that exist to support the clinical trial.

Beyond these studies, process evaluations targeting fewer behaviours but with a more detailed analysis and measurement of changes in behaviour could provide richer information on mechanism, context and implementation and help to distinguish between the effects of the intervention on mediators and the effect of mediators on outcomes. Such studies might benefit from methodologies better tailored to testing digital interventions that are alternatives to traditional RCTs, like n of 1 trials or Multiphase Optimization Strategy (MOST) (Collins et al. 2007).

6.6 Conclusions

This chapter has summarised the experience of using the MRC complex intervention framework to develop an online self-management intervention for adults with type 2 diabetes. I have summarised the relevant quantitative and qualitative evidence gathered to inform the development of the intervention and the process used to translate that knowledge into a functional intervention. The scope of the intervention was defined by Corbin and Strauss' model of living with a chronic illness and the COM-B model was used to understand the core behaviours relevant to diabetes self-management. Implementation was guided by the Normalization Process Theory and the Behaviour Change Wheel was

used as a post-hoc framework to summarise the process by which the data was synthesised and used to create the intervention and the active components of the intervention have been described in terms of Behaviour Change Techniques.

7. Discussion

7.1 Chapter summary

In this chapter I have started with a very brief overview of the work I did for this thesis. I then put this work into context by comparing this work to other programmes to develop complex interventions for diabetes and other long-term conditions. This description has been followed by a section highlighting what this body of work adds to the literature and the examples of good practice that can be shared. I have also described the main lessons learnt over the course of this work and what could be done differently by similar programmes in the future. The main messages have been summarised in the conclusion and this was followed by a section on personal reflections highlighting the significant personal development that has been enabled by the work described in the thesis.

7.2 Review of what has been achieved in this thesis

This thesis describes the research work that I have done as part of a five year NIHR Programme Grant for Applied Research to develop, evaluate and implement an online self-management tool for adults with type 2 diabetes. This work involved a systematic review of digital self-management interventions for adults with type 2 diabetes, qualitative work to explore the view of patients and health professionals and a review of relevant literature to inform the development of a theoretically informed and evidence based complex intervention. The data were used in conjunction with the MRC complex interventions framework to support the development of a new online self-management website called HeLP-Diabetes (www.help-diabetes.org.uk). The website supports patients with their key aims of feeling empowered, eating healthily and managing their medication burden. It also provides access to comprehensive information about type 2 diabetes, emotional support, information about NHS services and access to online support from peers. HeLP-Diabetes incorporates the design features that patients wanted and are easy to use with an encouraging tone; there has been significant effort invested in proof-reading and editing so that the information is accessible, accurate and well written; the site is free from advertisements and uses branding from trusted

NHS providers; and finally the content is kept up to date and tailored to patients living in England. New material is added regularly to keep users interested and regular newsletters and emails are used to prompt users to re-visit the site. The website uses 14 behaviour change techniques embedded in eight different sections to support users with diabetes self-management and the Normalization Process Theory has been used to help guide the implementation plans to embed the intervention into routine clinical care.

7.3 Knowledge generated through the research

In Chapter 3 I have described the results of a Cochrane systematic review of OSMIs for adults with type 2 diabetes. This review showed that these interventions can improve HbA1c, although the impact is small (-0.2%). If delivered at scale at low costs, this could potentially be important and interventions delivered through mobile phones have the potential to be even more effective as the reduction in HbA1c in this subgroup was larger (-0.5%). The use of theory to develop such interventions was patchy, but supporting self-regulation and the use of Control Theory to combine BCTs showed potential to help maximise effectiveness.

Chapter 4 described the results of qualitative work with patients living with type 2 diabetes. This study highlighted patient needs for self-management that were currently not being met. Participants expressed a need for more accessible, patient-centred care with tailored information provision and more emphasis on emotional and social support. They wanted access to a wide range of practical information about living with type 2 diabetes. The OSMI needed to contain detailed but accessible information, maintain a supportive tone and provide access to professional and peer generated content. It would need to minimise the demands it made on users, reduce the work of self-management, boost personal resources like confidence and problem-solving, provide access to supportive social networks and help users make better use of healthcare resources.

In Chapter 5, I have described the work done with some health professionals to inform the development of HeLP-Diabetes. The professionals we spoke to were aware that patients often struggled with self-management and they felt that there was scope for online interventions to help improve self-management

support in domains like tailored information provision, emotional support, supportive peer networks, care planning and practical help with accessing face-to-face healthcare services. Both health professionals and patients wanted a positive, easy to use intervention that could offer a wide range of content. Such an intervention appeared to have high levels of acceptability to health professionals and was coherent with their values. The main barriers to implementation were a lack of understanding of the work needed for implementation, a lack of ownership and the capacity for doing such work. If those barriers could be overcome, potential drivers of change could be evidence of benefits (more satisfying consultations, improvements in HbA1c, cost-effectiveness data, improvement in quality of life, and evidence of patient use), financial incentives and recommendations from Diabetes UK, the RCGP or the Department of Health.

HeLP-Diabetes was described in detail in Chapter 6. A number of theoretical frameworks were used to inform five key elements of the design process i)understanding user needs ii) identifying suitable antecedents for behaviour change and relevant behaviour change theories to inform intervention development iii) identifying barriers and facilitators of implementation iv) agile development and participatory design v) describing the active ingredients of the intervention in terms of BCTs. The scope of the intervention was defined by Corbin and Strauss' model of living with a chronic illness and the COM-B model was used to understand the core behaviours relevant to diabetes self-management. Our implementation plan was guided by the Normalization Process Theory and the Behaviour Change Wheel was used as a post-hoc framework to summarise the process by which the data was synthesised and used to create the intervention. The development process was iterative and driven by a participatory design process where users were involved at every stage of development and shared the responsibility of decision making. The active components of the intervention have been described in terms of 15 Behaviour Change Techniques which were:

1. Action planning
2. Credible source
3. Demonstration of the behaviour
4. Feedback on behaviour
5. Goal setting (behaviour)

6. Information about emotional consequences
7. Information about health consequences
8. Monitoring of outcome(s) of behavior without feedback
9. Problem solving
10. Prompts/cues
11. Reduce negative emotions
12. Review behaviour goal
13. Self-monitoring of behaviour
14. Self-monitoring of outcome(s) of behaviour
15. Social support (unspecified)

7.4 Combining research with agile development

The plan for designing HeLP-Diabetes was based on academic good practice and informed by the MRC complex interventions framework. However there were considerable tensions trying to reconcile this with an agile and iterative design approach. This starts with the process of reviewing the literature – the MRC guidance advocates a systematic review of the literature. While this produces a very high quality academic paper, the time taken to complete this process is not compatible with development cycles (e.g. it took 4 years to get the Cochrane Review published – we only had 2 years to develop the whole intervention before the RCT). Systematic reviews often tend to favour methodologically robust evidence from RCTs – however the time taken to complete and publish such data means that it is likely to be focused on old technology which may be of very limited use to inform contemporary intervention design (e.g. the need for data on Apps while RCTs of online or SMS based interventions are still ongoing). Agile development also requires constant iterative testing and feedback – which does not fit in with the traditional RCT model – for the programme grant we were given 2 years to develop HeLP-Diabetes and then had 3 years to run the RCT - but with an increasingly out of date product. Academic rigour, culture and methodology might better be suited to evaluating digital interventions rather than creating them – however even this might require flexibility and a shift away from time consuming RCTs to more adaptive trial designs like N of 1 trials or a multi-phase optimisation strategy (Evaluating digital health interventions, Murray et al 2016). The lack of flexibility and standardisation required by RCTs means that context is often de-emphasised and under-reported. However for real world success and uptake of

digital interventions, context is critical and it is an essential consideration for agile development.

The use of theory to guide development is important for the science of intervention design as it makes the process transparent, systematic, reproducible and facilitates the sharing of knowledge. However for individual researchers, the benefits are less clear cut. The sheer volume of theories (80+ theories of behaviour change, 60+ theories of implementation) can be overwhelming. No single theory or framework covers all aspects of development – so using multiple theories across multiple disciplines is necessary and it is unlikely small teams or research associates will have the knowledge or skills to do this well. And even after a comprehensive theoretical analysis, there may be considerable judgement required in the selection, design and implementation of active ingredients like BCTs.

7.5 How this work fits with existing research

Since the systematic review of the literature described in Chapter 2, a number of studies in this area have been published. However recent reviews have highlighted a paucity of high quality evidence from randomized controlled trials (Cotter et al. 2014; Pereira et al. 2015). There has been a recent shift in focus with mobile phone based applications (mHealth) becoming a key area of interest; however even though there are more than 1000 publically available smartphone apps for diabetes, a recent review found only 20 peer-reviewed evaluations of these apps (Garabedian et al. 2015). Text messaging is a cheap and widely available technology that can be used in most parts of the world and is another popular area of research (Bin-Abbas et al. 2014; Capozza et al. 2015).

A recurrent theme in the literature was that interventions were often described without much detail and it was difficult to determine the precise functions and therefore possible mechanisms of action for these complex interventions. In Chapter 2, I have discussed the importance of having an explicit theory base for the intervention to allow a better understanding of how interventions might work, facilitating the accumulation of knowledge and considering a full range of antecedents of a behaviour. Many of the interventions did not report on an

explicit theoretical basis for the intervention (Carter et al. 2011; McIlhenny et al. 2011; Noh et al. 2010). There were also limited descriptions of the methods used to develop the interventions. Having an explicitly described methodology for the process used to develop the interventions would allow a better understanding of those interventions and their development, facilitate the accumulation of knowledge about the process of effective intervention design and the sharing of experience about of the range of technology and features available. The multi-disciplinary team contributing to the development of HeLP-Diabetes enabled a systematic and robust theoretical and methodological basis for creating the intervention that has been reported and reviewed in more detail in the next section of this discussion chapter.

Many studies and reviews reported positive effects of interventions on knowledge and some showed improvements in HbA1c, at least in the short term (Costa et al. 2009; Cotter et al. 2014; Jackson et al. 2006; Pereira et al. 2015). However, generally the evidence for sustained improvements in self-care behaviour was poor. Part of this might be explained by findings from face to face interventions. A recent review examined face to face behavioural programs for type 2 diabetes mellitus and included some with a technological component. It found that when it came to supporting behavioural changes, education programmes offering ongoing support beyond education (usually 11 or more contact hours) were more effective and people with poor glycaemic control benefitted the most (Pillay et al. 2015). Studies of online interventions often report problems with attrition and people of lower socio-economic status tended to be under-represented. As healthcare needs tend to be higher in people at a socio-economic disadvantage, there is a risk that current interventions might not be targeting those who could benefit the most and may not be engaging them for long enough to bring about sustained changes in behaviour. The issue of engagement was a key line of enquiry in the development of HeLP-Diabetes and there was a significant focus on generating ideas from both patients and health professionals about maintaining user interest in the intervention.

Emotional management was often not a focus of online self-management interventions. However an exception was the OnTrack intervention that targeted

diabetes self-management and dysphoria and described the intervention in significant detail in a protocol paper (Cassimatis et al. 2015). The theory base for emotional management was focused on Social Cognitive Theory and Elaborated Intrusion Theory and it incorporated motivational videos, mindfulness and relaxation audios. Outcome data for this intervention is currently not published so the impact of these components is unknown; we therefore do not yet know whether these techniques add value to the intervention and are more effective at dealing with diabetes-related distress than the more general approach taken by HeLP-Diabetes that is critiqued later in this chapter.

7.6 The strengths of this work

Using the MRC complex intervention guidance provided a clear overarching framework and defined the aims of the development of the intervention as articulated in Chapter 6. One of the strengths of the way in which this was applied to the development of HeLP-Diabetes was the use of a multi-disciplinary team which drew on expertise from a wide range of academic fields and the degree of patient involvement in the project. Patient and public involvement (PPI) was a key element of the programme, informing decisions at every stage. PPI representatives were part of the design starting with the inception of the research and were co-applicants on the original research grant proposal. Patient views were explored in detail through qualitative research which helped define the scope of the intervention, and patients helped to define the look and feel of the intervention through the ongoing use of participatory design. The patients who helped with that process have also continued to work with us and continue to review content and updates, moderate the forum and provide advice on future research projects. Their ongoing involvement through the forum also enriches the intervention by providing ongoing peer support as a core component of the intervention.

The second element of good practice mentioned above was the use of mixed methods drawn from different disciplines. The research department has significant expertise and experience in medical sociology (FS is a senior lecturer in medical sociology and EM significant expertise as a senior clinical

academic with many qualitative publications) and under their supervision I have learned and applied qualitative methodology to gain a deeper understanding of the patient perspective and what self-management means for patients. This was crucial in setting the tone of the intervention and deciding the patient-defined priorities for the intervention and creating the first drafts of content and designs for the intervention. Co-applicants for the programme grant also drew on experience in health psychology (SM is a leading expert in behaviour change) and implementation science (CM is a sociologist who created the NPT) and this helped inform the creation of theoretically informed active components and the plan for implementing the intervention in real clinical environments.

Another element of good practice was the application of a an iterative and incremental development model to the creation of the intervention (Larman et al. 2003). Software development models broadly fall into 2 categories – plan-driven sequential models, e.g. the classic Waterfall method (Royce 1970); and dynamic models characterized by iterative cycles and active involvement of all stakeholders – e.g. agile methods (Nerur et al. 2007). Software development is a complex undertaking in itself – sometimes referred to as a “wicked problem” – a challenge that is difficult to formulate with evolving solutions that change as understanding of the problem deepens (Rittel et al. 1973). Agile approaches emphasise the importance of people, communication and flexibility with iterative and incremental changes rather than process driven progress through defined stages. The evolving scope of the intervention as defined through user input and the process of integrating the expertise of clinicians, psychologists, sociologists, programmers and designers required a degree of flexibility that could not succeed with a rigid progression through product stages as the dialogue between all of those parties resulted in an ongoing process of better understanding the problem and potential solutions. Articulating the problems in ways meaningful to different stakeholders led to improving definitions of the specific challenges being faced and their relative importance to different parties; and an improving understanding of the technology allowed better anticipation of the resources required for different solutions and a more informed choice of direction of development.

The principle of flexibility also applied to the structure of the intervention. The intervention was designed in a modular way with different sections that covered a comprehensive and holistic agenda that dealt with all three aspects of living with a chronic condition (medical and behavioural management, emotional management and role management) as described by Corbin and Strauss. The modular nature of the information and functionality of the intervention created a resource that was relevant to patients registering at any stage of their diabetes journey, but was designed to remain relevant as their condition changed over time.

The use of Normalization Process Theory to focus on implementation early on in the design process was another strength of the design methodology. Working with local health professionals to promote the intervention had the potential to help engage patients with the intervention and reduce the problems with attrition that I have discussed previously. Increasing health professional familiarity with the intervention facilitates the process of signposting relevant content triggered by changes in the patient's condition. A tool that can be used by both patients and health professionals can help to become a shared focal point and the use of the care planning tool could promote patient-centred care that could increase patient engagement and health professional satisfaction.

The methodological and theoretical approach for general intervention development was the foundation used to create a website that was designed to be engaging, effective, usable and widely implemented.

Mitigating risks for implementation and future viability

For interventions like HeLP-Diabetes, there are significant challenges to ensuring the viability of the intervention beyond the original funding grant. In order to remain relevant it requires significant ongoing work to keep the technology up to date, the content in line with evolving evidence and care pathways and the look and feel fresh and engaging. Going forward we will require a successful business model to sustain investment in the intervention so that the time, effort and resources invested by the team and funding bodies can bear fruit. The eHealth Unit has worked with UCL and UCL Business to set up a

Community Interest Company to manage the business model and explore ongoing viability. This is another example of good practice that supports implementation and potential real-world benefits from resources invested in research activity.

7.7 Limitations of this work

The multi-disciplinary nature of the development process of the complex intervention had many benefits, but many of the methods were new to the members of the team or being used in new contexts for diabetes self-management education. As a result there were a number of lessons learned about the process of intervention development and the content of the intervention that are described below.

7.7.1 Limitations of resources

As a research grant funded intervention, there were specific limitations on the time available to develop the intervention and the resources available to do so. We had two years to plan and develop an intervention ready to evaluate through a randomized controlled trial. To maximise the value for money we elected to use an open source content management system to develop the intervention (Joomla) which had a number of flexible add-ons to create additional functionality. The technology had particular implications for the use of behaviour change techniques: as discussed in Chapters 3 and 6, Control Theory predicts that self-monitoring of behaviour and providing feedback on behaviour would increase intervention efficacy but it was not possible to build tools to support this due to limitations of time and technical feasibility. As would be expected, where software components already existed to provide functionality, implementation and optimisation was straightforward; where bespoke software needed to be written from scratch, creating usable software was much more difficult. The final technological barrier was related to problems interfacing with Electronic Medical Records (EMR). The original grant application specified that the intervention would interface with the primary care electronic medical record and we had a partnership with a third party developer that had technology ready to deploy that would have enabled this. Unfortunately the software company responsible for the EMR in question decided on a cost

structure that made it impossible to incorporate this functionality into the intervention.

7.7.2 Limitations of development process

Usability testing

To keep costs down, the usability testing was done internally by the HeLP-Diabetes team. The team did seek advice from web-designers and also followed up with recommended reading to further improve skills. However none of the team had prior experience of running usability testing. Towards the end of the project we were able to compare the results of our testing with that done by others with more Human Computer Interface (HCI) experience. EM was able to secure input from the HCI team at UCL as HeLP-Diabetes was used as a test product for MSc students. As might be expected, comparing the data generated from our internal testing with the data from people with HCI expertise revealed deeper insights, a more extensive list of problems and sensible solutions from those with more expertise. One reason for this could be due to the fact that the skills drawn upon in the usability testing done by our team were based on our training in qualitative research with focus groups and interviews. This tended to focus on verbal reports rather than observational data. This limited the insights gained as people are not generally consciously aware of the drivers of automatic behaviour: being overly reliant on verbal data may lead to a focus on features that users think are important, which turn out to be of little consequence when applied in practice (Yardley et al. 2015). For example, the qualitative work discussed in Chapter 4 suggested users wanted to have access to a broad and professional-level depth of information. However provisional data from piloting the intervention suggests that such detailed information may not be something that users actually access very much. Therefore for future projects, earlier involvement of people with HCI expertise or seeking access to better training would be an important learning point.

Involving professionals with more human-computer interaction (HCI) expertise early would have helped with the usability testing and participatory design. This would not involve replacing user-testing with expert heuristic evaluations as expert heuristic reviews have numerous potential pitfalls (Jeffries et al. 1992). A

heuristic review by a single expert is the weakest way of picking up problems as it is at high risk of bias and can be skewed by personal preferences. Expert reviews by 3-5 different experts can pick up as many problems as user-testing, however it is dependent on expertise – highly skilled ‘experts’ with domain specific expertise pick up the most problems. Another issue is the difference between problems noticed by users and experts. Experts are more likely to generate long lists of minor problems while users tend to focus on major issues. Expert heuristic evaluations can lead to long lists of bugs for programmers to fix that may not include the most important problems and can potentially drive up costs without corresponding improvements in usability. Therefore there were good reasons for choosing usability-testing as we did for HeLP-Diabetes rather than expert heuristic evaluations.

Working with developers

As mentioned above, one of the strengths of the development cycle was the use of agile design. While our software programmers were familiar with agile development, the research team had not had prior experience of working with this methodology. Successful grant applications require careful planning over a number of years and have more in common with the waterfall method previously described rather than an agile development methodology. Some of the differences between planned and agile methodologies are highlighted in Table 7-1 below.

Table 7-1 Differences between planned and agile design (adapted from Nerur and Balijepally 2007)

| | Planned (traditional) design | Agile design |
|---|--|--|
| Design process | Deliberate and formal, linear sequence of steps, separate formulation and implementation, rule-driven | Emergent, iterative and exploratory, knowing and action inseparable, beyond formal rules |
| Goal | Optimization | Adaptation, flexibility, responsiveness |
| Problem-solving approach | Selection of best means to accomplish a given end through well-planned, formalized activities | Learning through experimentation and introspection, constantly reframing the problem and its solution |
| View of the environment | Stable, predictable | Turbulent, difficult to predict |
| Key characteristics | Control and direction Avoids conflict Formalizes innovation Manager is controller Design precedes implementation | Collaboration and communication – integrates worldviews Embraces conflict and dialectics Encourages exploration and creativity, and is opportunistic Manager is facilitator Design and implementation are inseparable and evolve iteratively |
| Rationality | Technical/functional | Substantial |
| Theoretical and/or philosophical roots | Logical positivism, scientific method | Action learning theory, Dewey's pragmatism, phenomenology |

A purely agile methodology has limitations as agile development is focused on creating software that is useful, but does not necessarily create software that is usable - there is evidence that initial design efforts are needed to provide a consistent and cohesive user interface and navigation structure as designers need that to work with from the beginning (Brhel et al. 2015). Brhel et al propose a methodology that combines the strength of both approaches that could be used in the future. It is called User-Centred Agile Development (UCAD) and advocates the following five principles:

1. Separate product design and product creation: The initial “cycle zero” starts the process with product design work – using stakeholder input and web-designers to have a clear design concept for the first iteration prior to starting the “agile” software development.
2. Using iterative and incremental design and development: create intermediate solutions to development problems as steps to creating the complete and desirable solution for end-users.
3. Design and development should proceed in parallel interwoven tracks: it is necessary to conduct user research and prepare designs for the upcoming development cycle at least one iteration ahead of the development team.
4. Continuous stakeholder involvement: Stakeholders should be actively involved in user-centred agile approaches early on and should remain involved throughout the entire development process to collect input and feedback.
5. Use artefact mediated communication: In user-centred agile approaches, tangible and up-to-date prototypes or examples should be used to document and communicate product and design concepts, and should be accessible to all involved stakeholders.

Using UCAD also helps deal with another issue encountered during the development phase – distinguishing user input for design from user testing. In Chapter 6 I described the process of participatory design we used so PPI representatives were involved in making decisions about the evolution of the intervention. However as the project progressed the users became very familiar and invested in the intervention, therefore they became relative “experts” in using the intervention and the feedback used to develop the intervention reflected the views of a small group of very committed stakeholders. This increases the risk of development being skewed towards creating an intervention that meets the needs of a small user group and the intervention might not be targeted at the common needs shared by the wider population (which could be a relatively simple and accessible intervention). There was also a blurring between usability testing and participatory design with discussions getting bogged down in circular arguments about preferences for minor details like colours and fonts rather than focusing on wider strategic decisions. Future projects may benefit from formally separating the roles of guiding design and usability testing so that committed patient stakeholders who understand and are able to clearly articulate patient values can be involved in the more complex tasks of strategic planning and design specifications, while usability testing can be carried out on a wider pool of users. The wider pool of usability testers could reflect the demographics of typical users and not necessarily be limited to those with type 2 diabetes, (which could make it easier to recruit people for this task).

However discussions with our web-designers have suggested that people living with the condition are more motivated and their information needs reflect that of the target population so where possible they make for better usability testing subjects.

From a theoretical perspective, the work described in this thesis explored in significant detail some of the models and frameworks described in the literature to support education and behaviour change. The weakest element was the lack of a comprehensive framework or good explanatory model for tackling poor psychological adjustment and diabetes related distress. Elements contributing to this like negative emotions, a lack of problem solving and a lack of support have been described and targeted through the tone of the intervention and certain components, but the approach is fragmented and not as systematic as the Behaviour Change Wheel. Having a structured framework to articulate a more comprehensive and coherent model for tackling adjustment and disease related distress may have improved the impact of the intervention on this aspect of self-management and could have facilitated a more significant contribution to the literature in this area.

7.7.3 Missing skills

Another difficulty with an agile type development cycle is the need for good communication between stakeholders. Because of the limitations of resources, we were working with a small company with two programmers. As mentioned above, the web-designer came in for the last half of the development cycle. However, what was missing was expertise in expressing the needs of stakeholders as programming tasks and an understanding of the feasibility of requests. One example would be building a calorie calculator – when discussed with the programmers, they felt the task was relatively simple. And writing the code to do the calculations was relatively straightforward. However translating that functionality into a tool that was intuitive and useful was actually a large task. What was missing from the discussions was an understanding of the skills not present – HCI expertise (for optimising the look and feel of the tool) and systems analysis (i.e. breaking down the task into a detailed series of tasks that would have identified the need for a database with the nutritional content of all

commonly eaten food and portions sizes that would make sense to typical users).

One of the limitations of not understanding the technology at the start of project was a heavy reliance on the programmers for support with systems analysis. At the point of tendering for the work, the programming company felt confident that they would be able to undertake this task and during the selection process they demonstrated a good understanding of the project needs and were able to develop prototypes very quickly that reflected our specifications. We therefore listened to their advice when it came to making decisions about using the technology and generally they were helpful and gave us good guidance. However there are two elements of the advice we were given that I would now disagree with. The first was advice to work with a web designer for the last half of the development cycle. While this gave us sufficient time to refine the intervention design and make it much more user-friendly, by that stage a lot of development had taken place and we were committed to the basic structure of the intervention. Had we brought a designer in at an earlier stage, the final intervention may have looked very different and potentially more time to work on HCI elements may have enhanced usability. The second element that I disagree with was their judgement that there was more freedom and security afforded by an open-source platform and this reduced the risks to long-term viability as the Joomla content management system was supported by hundreds of software companies. While there are many companies supporting Joomla as a platform, the degree of customisation required for the website meant that another small software company could not simply pick up where our current programmers left off. Small agile developers tend to be light on documentation so contingency planning for a potential handover to another company if needed has required significant planning and resources that we had not originally anticipated.

Over the course of the work, I developed a good understanding of the technology and was able to anticipate the programming implications of our design decisions and communication with the programmers improved significantly: development became much smoother as our requirements were

expressed in ways that were more specific and feasible and iterations were developed on time and closer to expectations. I was also better at anticipating where design input was needed and defining tasks for our web designer. However the learning curve on this process was steep and resulted in significant frustration in the first half of the development cycle.

7.7.4 Competing priorities

The scope of the intervention defined in the grant application was quite ambitious. The difficulties with development meant that there was constant tension between the aspirations of what we wanted to create and feasibility of what could be delivered on time. There were five different behavioural areas to support, a large amount of information content needed to be written and tools needed to be created for emotional management, social support and self-monitoring. In order to achieve this, certain compromises were necessary – possible support for interfacing with the electronic medical records was dropped and for alcohol, smoking cessation and CCBT, pre-existing interventions were incorporated into the intervention. This allowed the intervention to deliver the range of services specified in the funding grant application, but the price was a user experience that was slightly disjointed in specific areas.

There were also tensions from the different needs of funders and researchers. Current funding models and grant structures are not ideal for developing eHealth interventions. Creation of an engaging computer based intervention using UCAD methodology requires multiple prototyping and rapid iteration and optimization through implementation. The traditional model of a relatively short development cycle followed by a relatively long randomized control trial with minimal evolution of the intervention results in interventions being tested before they have reached their full potential and interventions are at risk of being out of date by the end of the trial. Future models that support smaller scale feasibility trials and optimization prior to committing to RCTs (e.g. using full or fractional factorial experiments as part of a multi-phase optimisation strategy) might make more efficient use of resources (Evaluating digital health interventions, Murray et al 2016).

7.8 Conclusions

The work presented in this thesis has contributed to the development of a new online self-management service for adults with type 2 diabetes. It was developed from a strong evidence base with explicitly described theoretical foundations, behaviour change techniques and development methodology, significant and ongoing PPI input and planning for implementation integrated into the design process. The synthesis of expertise from multiple academic disciplines with substantial lay input creates a unique intervention that can hopefully help to bridge the gaps between research and service delivery, health professionals and patients, lay experts and patients not currently engaged in their own care.

7.8.1 *Implications for practice*

Overall HeLP-Diabetes is a unique creation that is accessible yet comprehensive. It is simple to use but helps users deal with complex multimorbidity. It has the potential to be a very useful supporting resource for people living with type 2 diabetes and encourage more engaged and empowered patients and patient-centred consultations. If HeLP-Diabetes can provide mass education at lower per-user costs, it may free up resources to allow more intensive interventions for those with higher health care needs who might not be suitable for online education.

As described in Chapter 4, there are many patient needs for diabetes self-management that are currently not well met. Services should look to develop more flexible, tailored, patient-centred approaches to supporting the physical, emotional and social needs of people living with type 2 diabetes. While technology offers some potential solutions to help meet this challenge, there may be significant professional barriers that will need to be overcome to drive this change forward. The health professionals with links to academia interviewed in Chapter 5 were very supportive of the idea of using technology to support self-management, but they had a number of reservations about the practicalities. Technology was seen as a “disruptive” force that could result in change – the ability of technology to inform and empower patients was seen as a potential benefit, while the costs, workload implications and concerns about access were potential pitfalls. Introducing a new OSMI into routine clinical

practice will require evidence that the intervention is effective and used by a wide demographic of users with minimal impact on clinical workloads, supported by adequate resources for training and implementation and endorsed by users, local leaders and national bodies.

7.8.2 Implications for policy

Creating practical and implementable eHealth interventions and delivering them within the timescale of a grant is feasible and can be achieved on budget. However, to maximise the impact of limited resources it may be better to invest in multiple smaller feasibility trials and encourage optimisation prior to committing to a trial. Ideally anything that could be done on an organisational level to reduce the risks to small research groups from having to manage development of new software could also be sensible. This could involve common open source frameworks and sharing of technology, consultancy services to help identify gaps in skill sets or pooling of expertise within or across institutions to ensure all projects have access to adequate expertise in HCI, web design, systems analysis and programming. Finally, encouraging early work on potential implementation and exploring the human and contextual factors affecting deployment in real world settings are crucial to ensuring impact and a return on the investment made by funding bodies.

Given the potential for digital interventions, it would be important for funding bodies to support the right kind of environment that helps them to flourish. This might require a change in what gets funded and how. Ideally policy would support rapid, iterative studies using routine or longitudinal data collection across multiple pilots with projects encouraged to “fail fast”. Such studies would be explicitly context-sensitive and focus on user involvement and implementation from the beginning of development. The interventions would need to be flexible and responsive to their environments and focus on iterating based on the minimum intervention needed to bring about change.

7.8.3 Future research

HeLP-Diabetes is being evaluated through an RCT and an implementation study that are ongoing. However there are a number of potential research questions that were not part of their design.

Process evaluation: To minimise the questionnaire burden and reduce the potential therapeutic impact of detailed monitoring, the RCT planned for the intervention will not do a process evaluation. However new MRC guidance encourages the use of process evaluations to assess fidelity and quality of implementation, clarify causal mechanisms and identify contextual factors associated with variation in outcomes of studies of complex interventions (Moore et al. 2015). For HeLP-Diabetes it would be good to be able to do a process evaluation to see how GP practices promoted and used the intervention. It might also be helpful to carry out an exploration of the views of users and non-users to understand facilitators and barriers to use and study potential mediators of impacts, for example, changes in knowledge and behaviours. Assessing the implementation of HeLP-Diabetes in routine clinical practice would be important in understanding how the intervention was achieving any impact and what the critically important components might be (Hardeman et al. 2014).

Structured education: As described in Chapter 6, HeLP-Diabetes was created as a website that could be used as patients wanted. However, high levels of engagement with such an approach requires users to be intrinsically motivated and relies on patients actively seeking information or support needed to improve self-management. For users where such motivation is not strong or they do not yet have sufficient knowledge or insight to be aware of their own healthcare needs and how they could benefit, a more structured and supported intervention may provide added benefits. Non-users might be more likely to be those with poor health literacy or those on the wrong side of the digital divide and a purely user directed journey may not have the desired impact on reducing health inequalities. Although it was not possible to create such a structured journey through HeLP-Diabetes in the timescale of the original programme grant, we have been working on creating such an intervention for future work although

this has required the use of a second content management system (Moodle) in conjunction with the original one (Joomla) to allow the creation of structured content.

Tailored interventions: A less rigid approach to structured education would be a tailored intervention where content could be matched to specific patient needs. Such an approach requires algorithms for assessing needs and matching needs to content and it represents significant additional work on top of the work to create HeLP-Diabetes. However, this is likely to maximise the impact of the intervention and increase engagement as users would receive content more relevant to their specific situation.

Models for tackling diabetes-related distress: One of the theoretically weakest elements of the work described in this thesis is the lack of a systematic theoretical framework for tackling emotional management in diabetes. Future work to explore the literature on this and update the intervention to improve the way this is tackled could increase benefits to the psychological and physical health of users.

Ethnic minorities: Diabetes is common in many ethnic minority groups; where this is combined with lower socio-economic groups, the burden of morbidity and mortality from diabetes is disproportionately large. Such users may have specific needs for interventions due to differences in health literacy and cultural norms and there may be unique barriers to self-management education based on spoken language, ability to read or write, health beliefs, diets, religious customs etc. It is not possible for a website with a significant amount of content written in English like HeLP-Diabetes to be the ideal intervention for these populations, but simpler modified versions could be created that are better placed to suit their needs.

8. Personal reflections

This doctoral programme was done part time over five years in a very supportive academic environment and provided a fantastic opportunity for personal development. Some of the most significant areas of personal growth have been described below.

8.1 Knowledge and intellectual abilities

Knowledge base: One of the most interesting aspects of this doctoral work was the multi-disciplinary nature of the work spanning clinical medicine, medical sociology, health psychology and software development. Initially this was a huge challenge. But over the course of the five years, the terminology and ways of thinking in the different subjects has become more familiar and it has been easier to think across disciplines. The subjects that came more naturally were clinical medicine, psychology and software development. Medical sociology felt more alien but exploring areas that were outside my comfort zone and thereby learning to think in different ways were the most rewarding elements of the work. Attending a lecture on the epistemological basis for qualitative research was the single most useful learning opportunity of the last 5 years. Reflecting on the differences between constructivism and positivism was immensely helpful in developing a holistic approach to medicine and being able to make sense of mixed methods research. Before this, “good” research for me had very much been about a logical or quantitative model that explained things with clear links between cause and effect or quantified associations or risks. Having an alternative approach that supported an intellectually rigorous but flexible methodology for understanding how people make sense of the world around them in their own terms was crucial to adding a humanising element to all research work and valuing the things that make research meaningful to patients.

Research methods (theoretical knowledge and practical application): The main opportunities for learning have been in doing systematic reviews, doing focus groups and interviews and analysis of qualitative data. I have also been involved in the randomized control trial and gained experience of trials and trial

management. Future areas for development would be to focus on quantitative analysis and learning more about statistical methods.

Academic literacy and numeracy: This has been a very important area for personal development. I have always enjoyed writing but more as a creative exercise in self-expression rather than a structured vehicle for presenting reasoned discourse and argument. The discipline required to write in the forms and quantities required for creating a doctoral thesis has provided an excellent opportunity to develop a writing style better suited to academic literature. Creating HeLP-Diabetes has also provided opportunities for improving writing in another different style designed to make material simple and accessible for lay readers. I attended a 1 day workshop on writing for the web and this was very useful in developing my editing and technical skills to write simply and concisely in a way that would be effective online. I am also due to attend a 1 day workshop on producing informatics to create images for visual representations that make statistics more accessible and engaging.

8.2 Self-management

Preparation and prioritisation: This was a significant weakness at the start of my research work. It was related to problems with time management and feeling that my knowledge and skills were not adequate to sustain a programme of doctoral research. Constantly striving for the “perfect” piece of work was self-defeating as perfection is impossible and used up large amounts of time for exponentially diminishing returns, whilst simultaneous making it less likely that the work would be of a quality I could be satisfied with; as in agile software development, the most significant improvements come from rapid iteration based on external feedback from supervisors or peers. Taking too long chasing lost causes in search of “perfection” meant deadlines were missed, colleagues were inconvenienced and feedback was compromised: an unhelpful vicious circle that reduced the time taken to properly prepare and prioritise tasks. Eventually I learnt that I was more likely to get closer to “perfection” by embracing imperfection and focusing on creating drafts quicker and sharing those even if I was not happy with the quality. This freed up time for planning,

prioritisation and preparation that greatly improved the quality and quantity of the final output.

Time management: I eventually worked out the key to time management was planning, planning and more planning. However I also learnt that time management is a misnomer. It is not time that I needed to manage, but workload. Time management was actually about active work management – deciding what to take on, how much time to spend on it, the best way to get it done, getting help when needed etc.

8.3 Working with others

Team working: The process of creating HeLP-Diabetes provided valuable opportunities for reflection and self-improvement. Managing a shared creative activity was challenging as there were no “right” answers and opinions were often based on subjective interpretations, intuitive assessments and personal preferences that could vary hugely between team members. In this context effective team work required a degree of reflexivity and self-awareness, respect and good communication skills – simply being polite or trying to be nice to people was not enough. Reflecting on the principles of constructivism and realism were helpful for me in accommodating different opinions and approaches to problems where there was no ‘right’ answer. This process was also supported by improving self-management as trust was an important element of working relationships and being able to deliver good work in a reasonable time helped increase faith and respect for each other’s work and opinions. And while being driven and motivated are good qualities and essential for sustaining the commitment required to complete a five year programme of research, it was also equally important to be flexible and know when to let things go. Judgement, leadership and working in a team facing multiple “wicked” problems were the most challenging skills to work on but like many other difficult problems, they provided the most useful and interesting areas for self-development.

8.4 Advice for others

Overall this PhD provided a wonderful opportunity for learning about behaviour, behaviour change and intervention design. However like many important life lessons, such learning was a result of trial and error, and there are some mistakes that future researchers might wish to avoid.

The first mistake was my assumption that it was better to invent new ideas and learn from own mistakes. Although at the start, the PhD seemed like an interminably long period of study, the time passed quickly and in the end, I made most progress when I found the relevant literature on what other people had thought, tried and failed to do. The highest yield was from the novel application of existing ideas and technology.

But one of the challenges in understanding existing ideas and technology was the vastness of the literature that covers multi-disciplinary intervention design and development. Particularly the sheer volume of theories of behaviour change theories was utterly overwhelming. Therefore input from supervisors and collaborators with relevant experience and expertise was priceless. It has taken me the duration of my PhD to get to the point where I understand enough about theory to effectively inform intervention design. Which is where I would have liked to have been at the start....

And my final mistake was to aim for the biggest intervention possible to deliver the maximum possible change, rather than the minimum intervention needed to facilitate change. All complex interventions are works in progress that may or may not have opportunity to evolve into effective or useful products. A more realistic aim for a PhD would have been to describe a useful stage of evolution in an ongoing iterative process of intervention design and agile learning, rather than pursue a definitive final product.

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Appendix 1 Search terms and databases

Unless otherwise stated, search terms are free text terms.

Abbreviations:

'\$': stands for any character; '?': substitutes one or no character; adj: adjacent (i.e. number of words within range of search term); exp: exploded MeSH; MeSH:

medical subject heading (MEDLINE medical index term); pt: publication type; sh: MeSH; tw: text word.

The Cochrane Library

#1 MeSH descriptor Diabetes mellitus explode all trees
#2 diabet* in All Text
#3 (IDDM in All Text or NIDDM in All Text or MODY in All Text or T1DM in All Text or T2DM in All Text or T1D in All Text or T2D in All Text)
#4 ((non in All Text and insulin* in All Text and depend* in All Text) or (noninsulin* in All Text and depend* in All Text) or (non in All Text and insulin?depend* in All Text) or noninsulin?depend* in All Text)
#5 ((insulin* in All Text and depend* in All Text) or insulin?depend* in All Text)
#6 (#1 or #2 or #3 or #4 or #5)
#7 MeSH descriptor Diabetes insipidus explode all trees
#8 (diabet* in All Text and insipidus in All Text)
#9 (#7 or #8)
#10 (#6 and not #9)
#11 MeSH descriptor Computer systems explode all trees
#12 MeSH descriptor Computers explode all trees
#13 MeSH descriptor Medical informatics explode all trees
#14 MeSH descriptor Multimedia explode all trees
#15 MeSH descriptor Therapy, computer-assisted explode all trees
#16 MeSH descriptor Image Processing, computer-assisted explode all trees
#17 MeSH descriptor Biomedical Technology explode all trees
#18 MeSH descriptor Computer-Assisted Instruction explode all trees
#19 MeSH descriptor Computer communication networks explode all trees
#20 MeSH descriptor Software explode all trees
#21 MeSH descriptor Internet explode all trees
#22 MeSH descriptor Hypermedia explode all trees
#23 MeSH descriptor Telemedicine explode all trees
#24 MeSH descriptor Video recording explode all trees
#25 MeSH descriptor Drug therapy, computer-assisted explode all trees
#26 MeSH descriptor User-computer interface explode all trees
#27 MeSH descriptor Medical records systems, computerized explode all trees
#28 MeSH descriptor Cellular phone explode all trees
#29 MeSH descriptor Remote consultation explode all trees
#30 (#11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29)
#31 (computer-assist* in All Text near/6 therap* in All Text)
#32 (computer-assist* in All Text near/6 treatment* in All Text)
#33 (computer-assist* in All Text near/6 education* in All Text)
#34 (digital in All Text near/6 therap* in All Text)
#35 (digital in All Text near/6 treatment* in All Text)
#36 (digital in All Text near/6 education* in All Text)
#37 (web-based in All Text near/6 therap* in All Text)
#38 (web-based in All Text near/6 treatment* in All Text)
#39 (web-based in All Text near/6 education* in All Text)
#40 (computer* in All Text or Internet in All Text or hypermedia* in All Text or telecommunication* in All Text)
#41 (interactive in All Text or online in All Text or on-line in All Text or telemedicin* in All Text or tele-medicin* in All Text or (video in All Text and record* in All Text)
or (cellular in All Text and phon* in All Text) or (mobil* in All Text and phon* in All Text))
#42 (multimedia* in All Text or multi-media* in All Text)
#43 (cd-rom in All Text or compact-disc* in All Text)
#44 ((world in All Text and wide in All Text and web in All Text) or (worldwide in All Text and web in All Text) or website* in All Text)
#45 (electronic in All Text and health* in All Text)
#46 (#30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or #38 or #39 or #40 or #41 or #42 or #43 or #44 or #45)
#47 (#10 and #46)

MEDLINE

1. exp Diabetes Mellitus/
2. diabet\$.tw,ot.
3. (IDDM or NIDDM or MODY or T1DM or T2DM or T1D or T2D).tw,ot.
4. (non insulin\$.depend\$ or noninsulin\$.depend\$ or non insulin?depend\$ or noninsulin?depend\$).tw,ot.
5. (insulin\$.depend\$ or insulin?depend\$).tw,ot.
6. exp Diabetes Insipidus/
7. diabet\$.insipidus.tw,ot.
8. or/1-5

9. 6 or 7
 10. 8 not 9
 11. exp Computer systems/
 12. exp Computer/
 13. exp Medical Informatics/
 14. exp Multimedia/
 15. exp Therapy, Computer-Assisted/
 16. exp Image Processing, Computer-Assisted/
 17. exp Biomedical Technology/
 18. exp Computer-Assisted Instruction/
 19. exp Computer communication networks/
 20. exp Software/
 21. exp Internet/
 22. exp Hypermedia/
 23. exp Telemedicine/
 24. exp Video recording/
 25. exp Drug Therapy, Computer-Assisted/
 26. exp User-Computer Interface/
 27. exp Medical Records Systems, Computerized/
 28. exp Cellular phone/
 29. exp Remote consultation/
 30. ((computer-assist* or digital or web-based) adj6 (therap* or treatment* or education*).tw,ot.
 31. (computer* or Internet or hypermedia* or telecommunication*).tw,ot.
 32. (interactive or online or on-line or telemedicin* or video record* or cellular phon* or mobil* phon*).tw,ot.
 33. (multi-media or multimedia).tw,ot.
 34. (cd-rom or compact-disc*).tw,ot.
 35. (world wide web or worldwide web or website*).tw,ot.
 36. electronic health*.tw,ot.
 37. or/11-36
 38. randomised controlled trial.pt.
 39. controlled clinical trial.pt.
 40. randomi?ed.ab.
 41. placebo.ab.
 42. drug therapy.fs.
 43. randomly.ab.
 44. trial.ab.
 45. groups.ab.
 46. or/38-45
 47. Meta-analysis.pt.
 48. exp Technology Assessment, Biomedical/
 49. exp Meta-analysis/
 50. exp Meta-analysis as topic/
 51. hta.tw,ot.
 52. (health technology adj6 assessment\$).tw,ot.
 53. (meta analy\$ or metaanaly\$ or meta?analy\$).tw,ot.
 54. ((review\$ or search\$) adj10 (literature\$ or medical database\$ or medline or pubmed or embase or cochrane or cinahl or psycinfo or psyclit
 or healthstar or biosis or current content\$ or systemat\$)).tw,ot.
 55. or/47-54
 56. (comment or editorial or historical-article).pt.
 57. 55 not 56
 58. 46 or 57
 59. 10 and 37 and 58
EMBASE
 1. exp Diabetes Mellitus/
 2. diabet\$.tw,ot.
 3. (non insulin* depend* or noninsulin* depend* or non insulin?depend* or noninsulin?depend*).tw,ot.
 4. (insulin* depend* or insulin?depend*).tw,ot.
 5. (IDDM or NIDDM or MODY or T1DM or T2DM or T1d or T2D).tw,ot.
 6. or/1-5
 7. exp Diabetes Insipidus/
 8. diabet* insipidus.tw,ot.
 9. 7 or 8
 10. 6 not 9
 11. exp computer/
 12. exp medical informatics/
 13. exp multimedia/
 14. exp computer assisted therapy/
 15. exp image processing/
 16. exp medical technology/
 17. exp teaching/
 18. exp information processing/
 19. exp telemedicine/
 20. exp videorecording/
 21. exp computer interface/
 22. exp medical record/
 23. exp mobile phone/

24. exp teleconsultation/
 25. ((computer-assist* or digital or web-based) adj6 (therap* or treatment* or education*).tw,ot.
 26. (computer* or Internet or hypermedia* or telecommunication*).tw,ot.
 27. (interactive or online or on-line or telemedicin* or video record* or cellular phon* or mobil* phon*).tw,ot.
 28. (multi-media* or multimedia*).tw,ot.
 29. (cd-rom or compact-disc*).tw,ot.
 30. (world wide web or worldwide web or website*).tw,ot.
 31. electronic health*.tw,ot.
 32. or/11-31
 33. 10 and 32
 34. exp Randomized Controlled Trial/
 35. exp Controlled Clinical Trial/
 36. exp Drug comparison/
 37. exp Randomization/
 38. exp Crossover procedure/
 39. exp Double blind procedure/
 40. exp Single blind procedure/
 41. exp Prospective Study/
 42. (random\$ adj6 (allocat\$ or assign\$ or basis or order\$)).ab,ti.
 43. ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj6 (blind\$ or mask\$)).ab,ti.
 44. (cross over or crossover).ab,ti.
 45. or/34-44
 46. exp meta analysis/
 47. (metaanaly\$ or meta analy\$ or meta?analy\$).ab,ti,ot.
 48. ((review\$ or search\$) adj10 (literature\$ or medical database\$ or medline or pubmed or embase or cochrane or cinahl or psycinfo or psyclit
 or healthstar or biosis or current content\$ or systematic\$)).ab,ti,ot.
 49. exp Literature/
 50. exp Biomedical Technology Assessment/
 51. hta.tw,ot.
 52. (health technology adj6 assessment\$).tw,ot.
 53. or/46-52
 54. 45 or 53
 55. 33 and 54
 56. limit 55 to human
 57. (comment or editorial or historical-article).pt.
 58. 56 not 57

PsycINFO

exp Diabetes Mellitus/
 diabet\$.tw,ot.
 (IDDM or NIDDM or MODY or T1DM or T2DM or T1D or T2D).tw,ot.
 (non insulin\$ depend\$ or noninsulin\$ depend\$ or non insulin?depend\$ or noninsulin?depend\$).tw,ot.
 (insulin\$ depend\$ or insulin?depend\$).tw,ot.
 exp Diabetes Insipidus/
 diabet\$ insipidus.tw,ot.
 or/1-5
 6 or 7
 8 not 9
 exp Multimedia/
 exp Computer-Assisted Instruction/
 exp Internet/
 exp Hypermedia/
 exp Telemedicine/
 exp Cellular phone/
 ((computer-assist* or digital or web-based) adj6 (therap* or treatment* or education*).tw,ot.
 (computer* or Internet or hypermedia* or telecommunication*).tw,ot.
 (interactive or online or on-line or telemedicin* or video record* or cellular phon* or mobil* phon*).tw,ot.
 (multi-media or multimedia).tw,ot.
 (cd-rom or compact-disc*).tw,ot.
 (world wide web or worldwide web or website*).tw,ot.
 electronic health*.tw,ot.
 or/11-23
 randomi?ed.ab.
 placebo.ab.
 randomly.ab.
 trial.ti.
 or/25-28
 exp Meta-analysis/
 hta.tw,ot.
 (health technology adj6 assessment\$).tw,ot.
 (meta analy\$ or metaanaly\$ or meta?analy\$).tw,ot.
 ((review\$ or search\$) adj10 (literature\$ or medical database\$ or medline or pubmed or embase or cochrane or cinahl or psycinfo or psyclit
 or healthstar or biosis or current content\$ or systematic\$)).tw,ot.
 or/30-34

29 or 35
10 and 24 and 36

Web-of-Science
#1 Title=(diabet*) OR Title=(insulin* depend*) OR Title=(non insulin* depend*) OR Title=(IDDM) OR Title=(NIDDM)
OR Title=(T1DM) OR Title=(T2DM)
AND Topic=(T1D) AND Topic=(T2D)
#2 Topic=(computer*) OR Topic=(multimedia) OR Topic=(web-based) OR Topic=(Internet) OR
Topic=(telecommunication*) OR Topic=(electronic-health)
OR Topic=(hypermedia*) OR Topic=(website*) OR Topic=(interactiv*) OR Topic=(online) OR Topic=(cellular phon*)
#3 #2 AND #1
#4 Topic=(random*) OR Topic=(controlled clinical trial) OR Topic=(random*) OR Topic=(clinical trial*) OR
Topic=(meta-analys*) OR Topic=(hta)
#5 #4 AND #3
CINAHL
exp DIABETES MELLITUS/
diabet*.af
(IDDM OR NIDDM OR MODY OR T1DM OR T2DM OR T1D OR T2D).ti,ab
("non insulin* depend*" OR "noninsulin* depend*" OR "non insulin* depend*" OR "noninsulin* depend*").ti,ab
("insulin* depend*").ti,ab
exp DIABETES INSIPIDUS/
("diabet* insipidus").ti,ab
1 OR 2 OR 3 OR 4 OR 5
6 OR 7
8 not 9
exp COMPUTER SYSTEMS/
exp MEDICAL INFORMATICS/
exp MULTIMEDIA/
exp THERAPY, COMPUTER ASSISTED/
exp IMAGE PROCESSING, COMPUTER ASSISTED/
exp COMPUTER ASSISTED INSTRUCTION/
exp COMPUTER COMMUNICATION NETWORKS/
exp SOFTWARE/
exp INTERNET/
exp HYPERMEDIA/
exp TELEMEDICINE/
exp VIDEORECORDING/
exp DRUG THERAPY, COMPUTER ASSISTED/
exp USER-COMPUTER INTERFACE/
exp COMPUTERIZED PATIENT RECORD/
exp REMOTE CONSULTATION/
(computer* OR Internet OR hypermedia* OR telecommunication).ti,ab
(interactive OR online OR on-line OR telemedicin* OR video OR record* OR "cellular phon*" OR "mobil* phon*").ti,ab
(multi-media OR multimedia).ti,ab
(cd-rom OR compact-disc*).ti,ab
("world wide web" OR "worldwide web" OR "website*").ti,ab
("electronic health*").ti,ab
11 OR 12 OR 13 OR 14 OR 15 OR 16 OR 17 OR 18 OR 19 OR 20 OR 21 OR 22 OR 23 OR 24 OR 25 OR 26 OR 27
OR 28 OR 29 OR 30 OR 31 OR 32
"clinical trial".pt
random*.ti,ab
placebo.ti,ab
trial.ti,ab
34 OR 35 OR 36 OR 37
"technology assessment".ti,ab
exp META ANALYSIS/
hta.ti,ab
("health technology assessment*").ti,ab
("meta analy*" OR metaanaly*).ti,ab
((review* OR search*) AND (literature* OR medical database* OR medline OR pubmed OR embase OR cochrane OR
cinahl OR psycinfo OR psyclit
OR healthstar OR biosis OR current content* OR systemat*).ti,ab
39 OR 40 OR 41 OR 42 OR 43 OR 44
("editorial" OR "historical material" OR "commentary").pt
45 not 46
38 OR 47
10 AND 33 AND 48

Appendix 2 Risk of bias in included studies

Christian 2008

Risk of bias table

| Bias | Authors' judgement | Support for judgement |
|--|--------------------|--|
| Random sequence generation (selection bias) | Low risk | "Assignments to 1 of these 2 groups were based on a computer-generated random number sequence" |
| Allocation concealment (selection bias) | Low risk | "Assignment was concealed to the RA by a padded envelope that also contained a kit of baseline enrollment materials." |
| Blinding (performance bias and detection bias) | Unclear risk | "Neither physicians nor patients could be blinded to the intervention assignment." No information provided about blinding of assessors. |
| Incomplete outcome data (attrition bias) | Low risk | "Analyses were tied to a priori hypotheses. We conducted intention-to-treat analyses using a "last-record-carried-forward" method in which the last available data from dropouts were used when analyzing 12-month data." |
| Selective reporting (reporting bias) | Unclear risk | Insufficient information to permit judgement |
| Other bias | Unclear risk | "Ninety-eight percent of patients were taking anti-hyperglycemic medications, and 51% of patients had changes in their medication regimen during the study. We were not able to determine the independent effects of changes in medication regimens on HbA1c levels. However, there was a significantly greater reduction in HbA1c level for control patients who had their dosage of anti-hyperglycemic drugs increased or the type of medication changed—a 0.9% reduction in HbA1c level vs a 0.04% reduction for intervention patients who also had changes in their anti-diabetes drug regimen" Comment: The effect of the intervention on HbA1c is likely to be smaller than the effects of changes in anti-hyperglycemic medication |

Glasgow 1997

Risk of bias table

| Bias | Authors' judgement | Support for judgement |
|--|---------------------------|---|
| Random sequence generation (selection bias) | Low risk | "Two hundred and six patients were randomized within physician practice, using a table of random numbers, to either Usual Care or to Brief Intervention." |
| Allocation concealment (selection bias) | Unclear risk | Insufficient evidence to permit judgement |
| Blinding (performance bias and detection bias) | Unclear risk | Insufficient evidence to permit judgement. No comment on blinding of outcome assessors. |
| Incomplete outcome data (attrition bias) | Unclear risk | "Sixteen percent of participants could not be contacted for the one year follow-up. Attrition was not differential across condition (16.7% vs 15.3% for intervention vs. control)." No reasons for missing data |
| Selective reporting (reporting bias) | Unclear risk | Insufficient evidence to permit judgement |
| Other bias | Unclear risk | |

Risk of bias table

| Bias | Authors' judgement | Support for judgement |
|--|---------------------------|---|
| Random sequence generation (selection bias) | Unclear risk | Insufficient evidence to permit judgement |
| Allocation concealment (selection bias) | Unclear risk | Insufficient evidence to permit judgement |
| Blinding (performance bias and detection bias) | Unclear risk | Insufficient evidence to permit judgement |
| Incomplete outcome data (attrition bias) | Unclear risk | Insufficient evidence to permit judgement |
| Selective reporting (reporting bias) | Unclear risk | Insufficient evidence to permit judgement |
| Other bias | Unclear risk | Control arm received automated dietary change goals |

Glasgow 2005

Risk of bias table

| Bias | Authors' judgement | Support for judgement |
|--|--------------------|--|
| Random sequence generation (selection bias) | Unclear risk | "Randomization was conducted by the project statistician." No details about method of randomization were provided |
| Allocation concealment (selection bias) | High risk | "Randomization was conducted by the project statistician, who then notified research staff of condition assignment." |
| Blinding (performance bias and detection bias) | Unclear risk | Insufficient evidence to permit judgement |
| Incomplete outcome data (attrition bias) | Unclear risk | Insufficient evidence to permit judgement |
| Selective reporting (reporting bias) | Unclear risk | Insufficient evidence to permit judgement |
| Other bias | Unclear risk | |

Glasgow 2006

Risk of bias table

| Bias | Authors' judgement | Support for judgement |
|--|--------------------|--|
| Random sequence generation (selection bias) | Unclear risk | Insufficient evidence to permit judgement |
| Allocation concealment (selection bias) | Unclear risk | Insufficient evidence to permit judgement |
| Blinding (performance bias and detection bias) | Unclear risk | Insufficient evidence to permit judgement |
| Incomplete outcome data (attrition bias) | Low risk | "Attrition was modest (10%) by the 2-month assessment, and not different across conditions. Because of this low attrition rate, we used complete-case analyses in the present investigation, but intention-to-treat analyses with baseline values substituted for missing cases produced identical conclusions." |
| Selective reporting (reporting bias) | Unclear risk | Insufficient evidence to permit judgement |
| Other bias | Unclear risk | Physicians had the option of excluding patients for whom they felt the intervention would not be appropriate. |

Glasgow 2010

Risk of bias table

| Bias | Authors' judgement | Support for judgement |
|--|--------------------|---|
| Random sequence generation (selection bias) | Low risk | "Participants were individually randomized via a computer program developed by our computer programmer and statistician." |
| Allocation concealment (selection bias) | Unclear risk | Insufficient evidence to permit judgement |
| Blinding (performance bias and detection bias) | Unclear risk | Insufficient evidence to permit judgement but the study design makes it unlikely that participants or staff were blinded |
| Incomplete outcome data (attrition bias) | Low risk | Intention to treat analysis done. 17.5% loss to follow up |
| Selective reporting (reporting bias) | Unclear risk | Insufficient evidence to permit judgement |
| Other bias | Unclear risk | |

Risk of bias table

| Bias | Authors' judgement | Support for judgement |
|--|--------------------|--|
| Random sequence generation (selection bias) | Low risk | "Prior to enrolment, an Excel spreadsheet was created that randomized 60 patients in groups of six. A stack of envelopes was created, containing the results of the randomization. The allocation sequence was generated by the investigator" |
| Allocation concealment (selection bias) | Low risk | "This collection of envelopes was randomly "cut" in the middle, and the envelopes were numbered from 1 to 60. The sequence was concealed until the interventions were assigned at enrolment." |
| Blinding (performance bias and detection bias) | High risk | "There was no blinding in the study due to the nature of the intervention." |
| Incomplete outcome data (attrition bias) | Unclear risk | Reporting of cases of attrition does not provide details about all the participants excluded in the results section |
| Selective reporting (reporting bias) | Unclear risk | Insufficient evidence to permit judgement |
| Other bias | Unclear risk | |

Risk of bias table

| Bias | Authors' judgement | Support for judgement |
|--|--------------------|--|
| Random sequence generation (selection bias) | Unclear risk | "Block randomization was used to assign each patient" No details given Insufficient evidence to permit judgement |
| Allocation concealment (selection bias) | Unclear risk | Insufficient evidence to permit judgement |
| Blinding (performance bias and detection bias) | Unclear risk | No blinding of participants possible with this study design. No information provided about blinding of assessors. Insufficient evidence to permit judgement |
| Incomplete outcome data (attrition bias) | Unclear risk | Insufficient evidence to permit judgement No imputation for missing data |
| Selective reporting (reporting bias) | Unclear risk | Insufficient evidence to permit judgement |
| Other bias | Low risk | |

Lo 1996**Risk of bias table**

| Bias | Authors' judgement | Support for judgement |
|--|---------------------------|--|
| Random sequence generation (selection bias) | Unclear risk | "Participants were randomly assigned" No details given Insufficient evidence to permit judgement |
| Allocation concealment (selection bias) | Unclear risk | Insufficient evidence to permit judgement |
| Blinding (performance bias and detection bias) | Unclear risk | No blinding of participants possible with this study design. No information provided about blinding of assessors. Insufficient evidence to permit judgement |
| Incomplete outcome data (attrition bias) | Unclear risk | Insufficient evidence to permit judgement No details provided about participants who did not complete the study. All patients who dropped out were from the control arm |
| Selective reporting (reporting bias) | Unclear risk | Insufficient evidence to permit judgement |
| Other bias | Unclear risk | |

Risk of bias table

| Bias | Authors' judgement | Support for judgement |
|--|--------------------|--|
| Random sequence generation (selection bias) | Low risk | Random numbers table |
| Allocation concealment (selection bias) | Unclear risk | Insufficient evidence to permit judgement |
| Blinding (performance bias and detection bias) | Unclear risk | It would not be possible to blind participants in this study design. Collection of data was self-reported so blinding of "assessors" was not necessary; however patients were not blinded and were responsible for data collection so the risk of bias cannot be described as low. |
| Incomplete outcome data (attrition bias) | Low risk | "When intent-to-treat analyses were used, PAM and self-efficacy remained significant, while the P value for A1C increased to 0.060." Intention to treat analysis used |
| Selective reporting (reporting bias) | Unclear risk | Insufficient evidence to permit judgement |
| Other bias | Unclear risk | |

Quinn 2008

Risk of bias table

| Bias | Authors' judgement | Support for judgement |
|--|--------------------|--|
| Random sequence generation (selection bias) | Unclear risk | "Eligible patients gave consent and were randomized to either the control or intervention group." Insufficient evidence to permit judgement |
| Allocation concealment (selection bias) | Unclear risk | Insufficient evidence to permit judgement |
| Blinding (performance bias and detection bias) | High risk | "This study was a non-blinded, randomized controlled trial (RCT)" |
| Incomplete outcome data (attrition bias) | Unclear risk | "Characteristics for drop-out subjects were not different from the remaining study subjects." No details given about reasons for dropping out of study. Insufficient evidence to permit judgement |
| Selective reporting (reporting bias) | Unclear risk | Insufficient evidence to permit judgement |
| Other bias | Unclear risk | "A convenience sample of 30 patients with type 2 diabetes was recruited" Small convenience sample - insufficient detail about local population to determine the consequences of this Control group were expected to be quite pro-active: "They were asked to fax or call in their BG logbooks every 2 weeks to their HCPs until their BG levels were stabilized in the target ranges or until their HCPs changed testing frequency." |

Risk of bias table

| Bias | Authors' judgement | Support for judgement |
|--|--------------------|--|
| Random sequence generation (selection bias) | Unclear risk | "We randomized at the physician practice level in order to prevent potential contamination of the study intervention, i.e., all participating physicians at a practice site were randomized to the same study group. When a physician practice is contacted, agreement of individual physicians within the practice is sought, and they are added to the study physician group. " Insufficient evidence to permit judgement |
| Allocation concealment (selection bias) | Unclear risk | Insufficient evidence to permit judgement |
| Blinding (performance bias and detection bias) | High risk | Patients and providers were not blinded |
| Incomplete outcome data (attrition bias) | Low risk | Sensitivity analysis using weighted estimating equations (WEE) to address any residual bias from missing data |
| Selective reporting (reporting bias) | Low risk | Protocol for the trial published prior to study completion |
| Other bias | Unclear risk | The exclusion criteria meant that only patients with private insurance and access to the internet/ email took part in the trial. The characteristics of such patients might have influenced the efficacy of the intervention and its generalisability. |

Smith 2000**Risk of bias table**

| Bias | Authors' judgement | Support for judgement |
|--|---------------------------|---|
| Random sequence generation (selection bias) | Unclear risk | "The 30 women were randomized into two groups (computer Vs non-computer) of 15 each" Insufficient evidence to permit judgement |
| Allocation concealment (selection bias) | Unclear risk | No details provided Insufficient evidence to permit judgement |
| Blinding (performance bias and detection bias) | Unclear risk | Blinding of participants was not possible. No details about blinding of assessors. Insufficient evidence to permit judgement |
| Incomplete outcome data (attrition bias) | Unclear risk | Insufficient evidence to permit judgement |
| Selective reporting (reporting bias) | Unclear risk | Insufficient evidence to permit judgement |
| Other bias | Unclear risk | Small sample size |

Wise 1986

Risk of bias table

| Bias | Authors' judgement | Support for judgement |
|--|--------------------|--|
| Random sequence generation (selection bias) | High risk | "Assignment to test groups was randomized by year and month of birth" |
| Allocation concealment (selection bias) | Unclear risk | Insufficient evidence to permit judgement: no details of allocation concealment provided |
| Blinding (performance bias and detection bias) | Unclear risk | Insufficient evidence to permit judgement: control group "unaware of the study" and no details about blinding of assessors |
| Incomplete outcome data (attrition bias) | Unclear risk | Insufficient evidence to permit judgement: details of number of patients recruited at the start not reported |
| Selective reporting (reporting bias) | Unclear risk | Insufficient evidence to permit judgement |
| Other bias | Unclear risk | |

Risk of bias table

| Bias | Authors' judgement | Support for judgement |
|--|--------------------|--|
| Random sequence generation (selection bias) | Unclear risk | "We recruited patients for this open-label, randomized, controlled, prospective study from both a university hospital setting". No details provided of randomization procedures Insufficient evidence to permit judgement |
| Allocation concealment (selection bias) | Unclear risk | No details provided about allocation concealment Insufficient evidence to permit judgement |
| Blinding (performance bias and detection bias) | High risk | "open-label" study |
| Incomplete outcome data (attrition bias) | Unclear risk | "Five patients (8.1%) dropped out of the intervention group and seven (10%) out of the control group. The characteristics of patients who did and did not drop out were similar in both the intervention and control groups". No details provided about reasons for patients dropping out. No imputation of data or intention to treat analysis reported Insufficient evidence to permit judgement |
| Selective reporting (reporting bias) | Unclear risk | Insufficient evidence to permit judgement |
| Other bias | Unclear risk | |

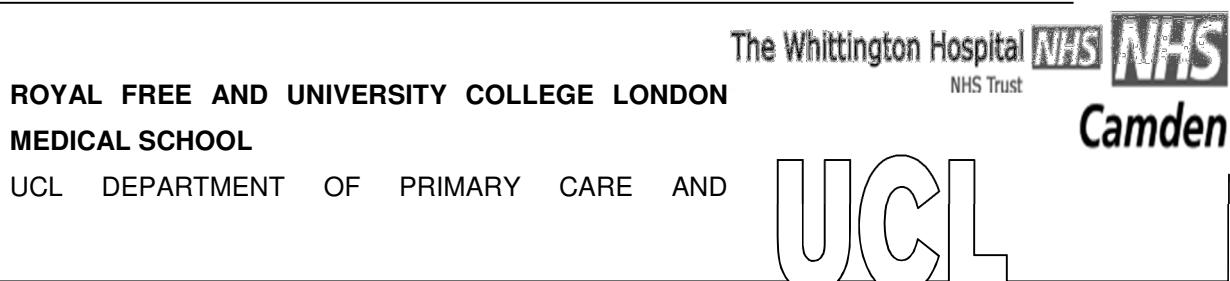
Risk of bias table

| Bias | Authors' judgement | Support for judgement |
|--|--------------------|---|
| Random sequence generation (selection bias) | Unclear risk | "150 patients are randomly allocated to two groups". Insufficient evidence to permit judgement |
| Allocation concealment (selection bias) | Unclear risk | Insufficient evidence to permit judgement |
| Blinding (performance bias and detection bias) | Unclear risk | Insufficient evidence to permit judgement |
| Incomplete outcome data (attrition bias) | Low risk | No missing data |
| Selective reporting (reporting bias) | Unclear risk | Insufficient evidence to permit judgement |
| Other bias | Unclear risk | |

Appendix 3 Summary of populations and interventions

| study ID | intervention | [n] screened | [n] randomised | [n] safety | [n] ITT | [n] finishing study | [%] of randomised participants finishing study | comments |
|----------------|--|---------------------------------|--------------------------------|--------------------------|-----------------------------|--|---|----------|
| Christian 2008 | Intervention: Computer Expert System (I) Control: Ususal Care (C) | Total: 322 | I: 155 C: 155 Total: 310 | I: 0 C: 3 Total: 3 | I: 14 C: 23 Total: 37 | I: 141 C: 132 Total: 273 | I: 91% C: 85% Total: 88% | |
| Glasgow 1997 | Intervention: Computerised Touchscreen Assessment (I) Control: Usual Care (C) | Not stated | I: 108 C: 98 Total: 206 | I:0 C:0 Total:0 | Not reported | I: details not reported C:details not reported Total:161 | I: details not reported C:details not reported Total: 78% | |
| Glasgow 2003 | Intervention: D-NET Peer support (I) D-NET TSM - not included in the review Control: Access to articles (C) | Not stated | I:80 C:80 Total:160 | I:0 C:0 Total:0 | Not reported | Not clear from report | I:? C:? Total:? | |
| Glasgow 2005 | Intervention: DPP (I) Control: Touchscreen assessment (C) | I: 621 C: 566 Total: 1187 | I: 469 C: 417 Total: 886 | I:0 C:0 Total:0 | I: 90 C:63 Total:153 | I: 379 C: 354 Total: 733 | I: 81% C: 85% Total: 83% | |
| Glasgow 2006 | Intervention: TSM (I) Control: Enhanced Usual Care (C) | I: n/a C: n/a Total: 2662 | I: 174 C:161 Total: 335 | I:0 C:0 Total:0 | I: 21 C: 13 Total: | I:153 C:148 Total:302 | I: 88% C: 92% Total: 90% | |
| Glasgow 2010 | Intervention: CASM (I) Control: Enhanced Usual Care (C) | I: n/a C: n/a Total: 544 | I: 169 C:132 Total: 301 | I:0 C:0 Total:0 | Not reported | I:130 C:115 Total:245 | I: 77% C: 87% Total: 81% | |
| Leu 2005 | Intervention: Automated wireless messaging system(I) Control: Presumed Usual Care (C) | Total: 50 | I: 25 C:25 Total:50 | I:0 C:0 Total:0 | Not reported | I:21 C:21 Total:42 | I: 82% C: 82% Total:82% | |
| Lim 2011 | Intervention: U-healthcare (I) | Total: 180 | I:51 C:52 | I:0 C:0 | Not reported | I: 49 C: 48 | I: 96.1% C: 92.3% | |

| | Control: Usual Care (C) | | Total: 103 | Total:0 | | Total: 97 | Total: 94% | |
|--------------|--|--------------|--|------------------------|------------------------|---|-----------------------------------|--|
| Lo 1996 | Intervention: CAL (I) Control: Presumed Usual Care (C) | Not reported | I: 12 C: 20 Total: 32 | I:0 C:0 Total:0 | Not reported | I: 12 C: 16 Total:28 | I: 100% C: 80% Total: 88% | |
| Lorig 2010 | Intervention: IDSMP (I) Control: Usual Care (C) | Total: 1019 | I: 491 C: 270 Total: 761 | I: 0 C:0 Total:0 | I:96 C:32 Total: | I:395 C: 238 Total: 633 | I: 80% C: 88% Total: 83% | |
| Quinn 2008 | Intervention: WellDoc (I) Control: (C) | Not reported | I:15 C:15 Total:30 | I:0 C:0 Total:0 | I:0 C:0 Total:0 | I:13 C:13 Total:26 | I:87% C:87% Total:87% | |
| Quinn 2011 | Intervention: Group 2 Coach only (I) Control: Usual Care (C) | 2602 | I: 38 C: 63 Total = 101 | I:0 C:0 Total:0 | I:0 C:0 Total:0 | I: 23 C: 56 Total = 79 | I: 61% C: 90% Total: 78% | |
| Smith 2000 | Intervention: Firstclass software(I) Control: Hard copies of materials(C) | Total: 50 | I: 15 C: 15 Total: 30 | I:0 C:0 Total:0 | I:0 C:0 Total:0 | I:?15 C:?15 Total:?15 | I:?100% C:?100% Total:?100% | |
| Wise 1986 | Intervention: ICT +KAP (IV) Control: Presumed Usual Care (C) | Not reported | Not reported | Not reported | Not reported | I: 21 C:21 Total:42 | I: 21 C:21 Total:42 | only 2 people dropped out of the whole study of 174 patients |
| Yoo 2009 | Intervention: UCDC (I) Control: Usual Care (C) | Not reported | I: 62 C: 61 Total: 123 | I:0 C:0 Total:0 | I: C: Total: | I:57 C:54 Total:111 | I: 92% C: 86% Total: 90% | |
| Zhou 2003 | Intervention: Diabetes Diet Advisor V1.0(I) Control: Fixed carbohydrate content (C) | Not reported | I: 88 C:62 Total:150 | I:0 C:0 Total:0 | I:0 C:0 Total:0 | I:88 C:62 Total:150 | I:100% C:100% Total:100% | |
| <i>Total</i> | | | <i>I: 1665</i> <i>C: 1351</i> <i>Total: 3016</i> | | | <i>I: 1344</i> <i>C:1122</i> <i>Total: 2623</i> | | Requested data from Glasgow 1997, 2003 and Wise 1986 |



Topic Guide for patients Version 1.1 05/11/10

Introduction

Arrive – drink etc. 15mins

Introduce Facilitators

You have all been sent a copy of the participant information sheet but we're just going to give you a brief overview of the study.

We have been awarded a grant to develop a new digital programme to improve diabetes self-management in adults with type 2 diabetes. We'd like to have a discussion about what you would like to see in such a programme and any features you think would be useful and attractive.

Show examples of computer programme(s) 1.5 hours

What we are going to ask you to do first is to look at three existing self-management programmes on the computer. You will each have a computer and we will come round and start you off with the first programme. After that you are free to explore the programme as you want for a maximum of half an hour. This should hopefully give you enough time to get an idea of what you like or dislike about it and form an opinion of how useful it might be to you when we come to discuss it later. Please use the note sheets provided to write down your thoughts about it as you're using it, this may help you remember them in the discussion later. After half an hour we will set you up with a second computer programme to explore, and then the third after another half hour.

You are free to take a break at any time, we will not be rushing from one to the next if you don't want to. You may not need the full 30 minutes to explore each one and it is fine to spend less time, but please try and see as much as you can to be able to give your views later.

We will give you the website addresses of all the programmes we are showing you today, so if information in any of the programmes interests you and you want to spend longer than the half hour, you will be able to see it again another time. Today, however, we are going to limit you to half an hour on each so that you can compare all three and so that we don't tire you out.

When you've had a chance to look at all three we'll sit down as a group and discuss what you thought of them. **Is everyone happy to take part in this?**

Does anyone have any questions before we start?

Break/Food – 30mins

Discussion – 1.5 hours

We've now got roughly an hour and a half to discuss the programmes you have just seen.

We'd like to record the discussion if that's okay with all of you. Anything you say here will be anonymised and won't link anything to your name. All the information will be stored securely and only researchers working on this study will have access to them. All the recordings will be destroyed at the end of the study.

Is everyone happy to take part in this?

Does anybody have any questions?

We will go round the group and everyone can introduce themselves with the name they would like to be used in the discussion.

Q1: Overall what did you think about the programmes you used here?

- How do you think they might help you to manage your diabetes?

Q2: When do you think you might use one of these?

(Probe: after the doctor had told you you had the condition, before or after a visit to the doctor, if you were trying to make a decision about treatment, if you were explaining to a friend or relative what was wrong with you, if someone you knew thought they had a similar problem, to help with frustrations and negative feelings towards the condition, other)

- How much do you think you would use something like this? Why?

- What would make you use it more or less?

Q3: Which one did you prefer and why?

Follow up with what did they like in each one? Which features of the websites do you think would be helpful in managing your diabetes?

Q4: Which one did you like least and why?

Follow up with what they didn't like in each one? What was annoying?

Q5: Is there anything about the programme (s) you would like to change? (If yes, what? Why? What would this add?)

Q6: Was there anything you looked for in the programme (s) that you couldn't find? If so what? What features would you like to see? What areas would you like more information or help with?

Q7: Would it be useful to be able to enter certain data and why?

- What type and why?

Q8: How would you like to share that data?

- Who with?

Q9: Do you think your General Practice could help you (use a programme like this)?

- If yes: WHY, HOW and WHO?
- What would be helpful? What would be annoying

Q10: Finally are there any further comments or suggestions?

Q11: Would anybody be interested in helping us develop a new computer programme to improve patient self-management of diabetes? We would show you our programme at various stages of its development to get your feedback on it, whether it is user friendly etc.

Appendix 5 Confirmation of REC approval



10 January 2011

Telephone: 020 8869 5446
Facsimile: 020 8869 5222

Dr Kingshuk Pal
Clinical Associate
Camden PCT
eHealth Unit, PCPH
Upper 3rd floor, Royal Free Hospital
Rowland Hill Street, London
NW3 2PF

REC Office
Maternity, Level 7
Northwick Park Hospital
Watford Road
Harrow
HA1 3UJ

Dear Dr Pal

Study Title: Development, evaluation and implementation of a computer-based self-management programme for people with type 2 diabetes.
REC reference number: 10/H0722/86

Thank you for Ms O'Donnell's email of 22 December 2010 and your email dated x, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

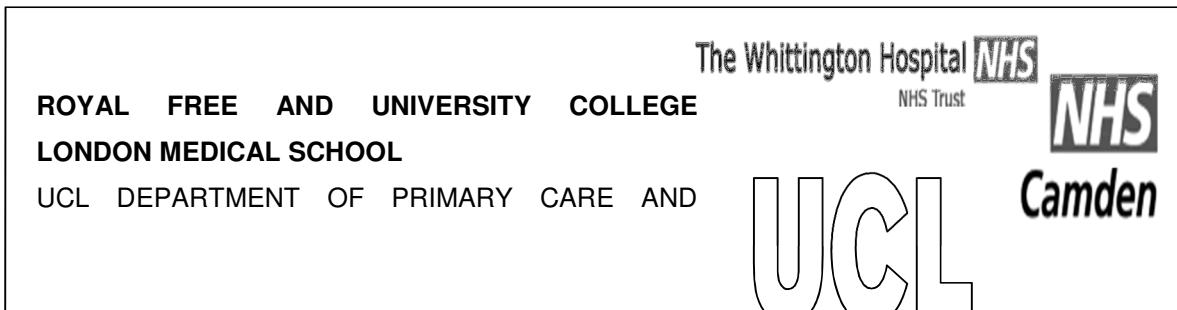
The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisation(s) involved in the study in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System (IRAS) or at <http://www.rdforum.nhs.uk>.

This Research Ethics Committee is an advisory committee to London Strategic Health Authority
The National Research Ethics Service (NRES) represents the NRES Directorate within

Appendix 6 Patient information leaflet



Study Title: A Qualitative study to determine patient preferences for internet based diabetes self-management programmes for adult patients with type 2 diabetes.

You are being invited to take part in this research study. Before you decide whether you want to participate, it is important that we explain why the research is being done and what it will involve for you. Please read the following information carefully and take time to decide whether you want to take part. If you have any questions or feel that anything has not been explained clearly please do not hesitate to contact us for more information.

Why are we doing this study?

We know that living with a chronic condition like diabetes is a lifelong commitment that can be quite challenging. People with diabetes need support, good quality information and help with the demands of managing diets, lifestyles or the different tablets and injections that might be used as treatments.

Currently not all patients are able to get the information, support and training they need to become experts at managing their diabetes.

One way of getting better support and information about diabetes is through computers connected to the internet. But one of the biggest problems with computer programmes like this is that after some time, most people stop using them. We would like to know what features someone like you might like from a computer programme to help support you with managing your diabetes and any features that would make it easier for you to continue using it.

Why have we approached you?

We are looking for people aged 18 and above who have type 2 diabetes who would be interested in taking part in a focus-group. We are looking for a broad range of views so we would like to hear from people who are controlling their diabetes through what they eat, tablets, insulin or any combination of those treatments. This is to make sure that all parts of the population are represented. The information volunteers send back to us will help us select volunteers from a range of backgrounds. Therefore we might not be able to invite everyone to take part who expresses an interest.

Do you have to take part?

Absolutely not. It is completely up to you whether or not you choose to participate in this study. You will be asked to sign a consent form to confirm you wish to take part before you start in the study, but you can withdraw at ANY time you want and you can do so without giving a reason. Declining to take part or withdrawing from the study will NOT have any effect on the care you receive from your doctor.

What will happen to you if you take part?

If you choose to take part you will be invited to attend a focus-group with between 4-7 other participants who will also be adults with type 2 diabetes. It will be a group discussion that will be led by one of the members of the research group. There will be a few topics that we would specifically like to cover and we will be asking everybody's opinion about them. The group will have plenty of time to interact and discuss any interesting ideas that come up.

The participants of the focus group will be given an opportunity to try some examples of existing computer programmes to help people with diabetes. We will see what you think about them and how you think they could be improved.

After the focus group, we hope that some participants would like to continue using these programmes from their home computers for some time. We would

then arrange another focus-group so people could discuss their experiences of using the programmes and come up with ideas about what they liked, did not like and any features that would make it more likely that they would continue using the programme. If someone was too busy and could not attend a follow-up focus group they would be offered a 1 hour interview instead where they will be asked about their experience of using the programme.

All of the focus groups or interviews will be audio-taped so we do not lose any of the valuable ideas or views that are expressed during the sessions.

The focus groups may discuss participants' experiences of diabetes and complications arising from it; some of this might be personal or sensitive information and we would expect everyone to respect the confidentiality of all participants. If at any stage there are issues you do not feel comfortable discussing please let us know and we will address this immediately.

What are the possible benefits of taking part?

Taking part in this research will not have any benefits for your health. But your opinions will inform further research in the area and hopefully help us to develop programmes that aid people with type 2 diabetes to get the help and support that they need to better manage this lifelong condition. We hope that it will help the development of a tool to reduce some of the complications that can happen if people struggle to get good control of their diabetes.

We will be able to refund travel expenses up to £10 and we will provide £25 as a token of our appreciation to any person who takes part.

What are the possible risks of taking part?

There will be no risks to your health from taking part in this study. All of the focus groups will have 2 members of the research group present to facilitate the discussions. Everybody will have a chance to express their opinions and each

participant will be expected to treat their colleagues with respect. Any participants who breach these rules will be asked to leave the study.

Will all information about you be kept confidential?

Absolutely. All the information about your participation in this study will be kept confidential and transcripts will be anonymised. Any information you give us will be handled according to the Data Protection Act 1998. Any publication of the information will be completely anonymous with no way of identifying individual participants.

What will happen to the results of this study?

We hope that the results of this study will be helpful for further research in this area and they will be submitted for publication in academic journals. We would be happy to send you a summary of the results – if you would like us to do so please fill in the 2nd page of the consent form.

Loss of Capacity

In the very unlikely and unfortunate event that someone who takes part in the study lost the ability to make informed decisions for him or herself, that person would not continue to take part in the study. Under normal circumstances, any information that we have received before such an event would be used in the study. If you feel this is not reasonable, please let us know.

Who are the research team?

The research team is made of doctors and lecturers at University College London.

The study is being run from the e-Health Unit in the Research Department of Primary

Care and Population Health at UCL. The Director of the unit is Dr Elizabeth Murray, an

academic GP who works in central London. The chief investigator is Dr Kingshuk Pal, a junior academic GP who works in Camden. The project researcher is Dr Charlotte Dack, a research associate who works at UCL. The

other members of the team include Dr Fiona Stevenson, a Senior Lecturer in Medical Sociology at UCL and Dr Maria Barnard, a Consultant Diabetologist at the Whittington Hospital. We also have someone with diabetes on the research team to make sure that patients are involved with all the stages of the research project.

Who can I contact if I have any problems?

We think it very unlikely that something could go wrong, but we need to tell you what procedures will be in place should you have any complaints. If you have a concern about any aspect of this study, you should speak with the main study researcher, Charlotte Dack (see contact details below) who will do her best to answer your questions.

If she does not answer your questions satisfactorily, you can contact Dr Elizabeth Murray who has overall responsibility for the study (see contact details below). She can also advise you on who else to contact if she is unable to answer your concerns or questions. If you remain unhappy and wish to complain formally, you can do this through the NHS complaints procedure.

Details can be obtained from:

NHS Direct: 0845 4647

The Independent Complaints Advisory Services: 020 7379 8598

Dr Elizabeth Murray – Project Leader

Dr Charlotte Dack – Project Researcher

Tel: + 44 20 7794 0500 (Ext: 36323)

Fax: +44 20 7794 1224

<http://www.ucl.ac.uk/pcph/research-groups-themes/e-health-pub/research>

email: c.dack@ucl.ac.uk

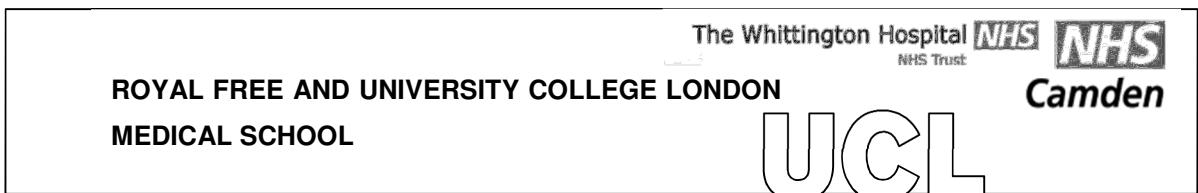
Address:

eHealth Unit, UCL Research
Department of Primary Care &
Population Health

Upper 3rd Floor, Royal Free
Hospital

Rowland Hill Street
London NW3 2PF

Appendix 7 Patient background questionnaire



Study Title: A Qualitative study to determine patient preferences from internet based diabetes self-management programmes.

Thank you very much for expressing an interest in participating in our study. In order to get a wide range of opinions about this topic and try and make sense of the results we need to know a little bit about your background and experience. These results will be used anonymously in the final study. If you are happy to take part in our study please make sure you return this questionnaire with the consent form. We will contact you within 2 weeks of receiving the forms to arrange a convenient time for the focus group.

| | | | |
|--|----|----|-----------|
| Participant name | | ID | WPA - 057 |
| How/Where did you find out about the study? | | | |
| General availability | | | |
| Monday | am | | |
| | pm | | |
| Tuesday | am | | |
| | pm | | |
| Wednesday | am | | |
| | pm | | |
| Thursday | am | | |
| | pm | | |
| Friday | am | | |
| | pm | | |
| Weekend | | | |
| Specific availability | | | |
| <p>Address: _____ Telephone: _____</p> <p>Email: _____</p> | | | |
| <p>Guidance on preferences: how and when to contact</p> | | | |

What is your date of birth?

| | | |
|--|---|--------|
| Are you male or female? Please tick relevant box: | Male | Female |
| Are you currently working? Please tick the box that best describes your employment status | | |
| Employed (part or full-time) | Self-employed | |
| Full-time carer | Retired | |
| Not working but looking for work | Not working and not looking for work | |
| | School leaver | |
| What is the highest level of educational qualification that you have completed? Please tick 1 box | 'A' levels or vocational equivalent Degree, HND or similar | |

| | | | |
|---|--|--|---|
| What is your ethnic background? | | | |
| Please tick 1 box or complete 1 section which best describes your ethnic background | | | |
| White | British Irish | <input type="checkbox"/> <input type="checkbox"/> | Black or Black British Caribbean African |
| Other white background (please write in) | | Other Black background (please write in) | |
| Asian or Asian British | Indian Pakistani Bangladeshi | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | White and Black Caribbean White and Black African White and Asian |
| Other Asian background (please write in) | | Other Mixed race background (please write in) | |
| Other ethnic background | Chinese | <input type="checkbox"/> | Other ethnic background (please write in) |

What sort of diabetes do you have?

Type 1

Type 2

Don't know

How long have you had diabetes? (in years)

How is your diabetes managed? (tick as many boxes as apply)

Diet

Tablets

Insulin

Has your diabetes caused any of the following problems? (tick as many boxes as apply)

Numbness or pain in your hands or feet

Kidney problems

Problems with eyesight

Heart disease

Stroke or mini-stroke

Leg ulcers

Anxiety

Depression

How much experience do you have of using the Internet?

Please tick 1 box which best describes your level of experience.

Novice (e.g. never used the Internet before)

Basic (e.g. used the Internet a few times but not often)

Experienced (e.g. used or currently use the Internet regularly)

Expert (e.g. work is to do with the Internet)

Is there a computer linked to the Internet that you can use in your home? Please tick relevant box:

Yes

No

Have you ever attended a diabetes education programme?

Yes

No

Have you ever used the internet to look up information about your diabetes?

Yes

No

Have you ever used a computer programme to help manage your diabetes?

Yes

No

Introduction Version 1.0 05/11/10

Introduce Facilitators – Involvement in the project

You have all been sent a copy of the participant information sheet but we're just going to give you a brief overview of the study.

We have been awarded a grant to develop a new computer-based intervention to improve diabetes self-management in adults with type 2. We'd like to have a discussion about what you would like to see in such an intervention and any features you think would increase or hinder its use in practice.

We'd like to record the discussion if that's okay with all of you. Anything you say here will be anonymised and won't link anything to your name. All the information will be stored securely and only researchers working on this study will have access to them. All the recordings will be destroyed at the end of the study.

Does anybody have any questions?

Get everyone to fill in Consent forms

We will go round the group and everyone can introduce themselves with the name they would like to be used in the discussion. It would also be useful if you could say a little bit about what you do and your role in type 2 diabetes care.

A bit about how today is going to run – Timing, who will be asking the questions etc.

Q1: What are the most important issues in managing your adult patients with type 2 diabetes?

Q2: Are there any features in an internet program that might help with those issues?

Patient entered data?
What type of data would be helpful?
In what quantities?
How might this data be best presented?

Q3. Give context – i.e. paers involvement with EMIS/pt records etc.

How would you feel about patients adding on data/having access to their own electronic patient record?

Q4: Do you think an internet program would impact on your workload in any way?

Positively (save time etc.)
Negatively (make you do things you don't normally do)

Q5: Can you foresee any problems that might come from using an internet program to manage diabetes?

Q6: At any point could you envisage using this programme in your consultations with your patients?

If yes – why?

Q7: Patients using this intervention might have access to a lot more information about diabetes. How do you think this might affect your interactions with patients?

Q8: What might make you recommend the programme to patients?

To your colleagues?

Q9: Why would you use a programme like this?

What would you like to see in it?

What would have to be in it to incorporate it into practice?

Q10: What evidence would convince you such an intervention was worthwhile?

Q11. Once developed, how might we integrate the intervention into routine NHS service?

Potential Barriers?

Potential Facilitators?

Q12: One of the problems we have with internet interventions is that they tend to have a higher attrition rate. So one of the things we're thinking about is having someone contact patients at regular intervals to see how they're getting on with it.

Can you envisage

- this working in the context of day to day general practice?
- do you think there would be someone at the practice who could take this on?
- how would that work?

Q13: Finally are there any other comments or suggestions?

Appendix 9 Health professional background questionnaire

ROYAL FREE AND UNIVERSITY COLLEGE LONDON
MEDICAL SCHOOL



Health Professional's questionnaire

Study Title: A Qualitative study to determine Health Professional preferences from internet based diabetes self-management programmes.

Thank you very much for expressing an interest in participating in our study. In order to get a wide range of opinions about this topic and try and make sense of the results we need to know a little bit about your background and experience. These results will be used anonymously in the final study. If you are happy to take part in our study please make sure you return this questionnaire with the consent form.

| | | |
|--|---|---------------------------------|
| What is your date of birth? | <input type="text"/> | |
| Are you male or female? Please tick relevant box: | Male <input type="checkbox"/> | Female <input type="checkbox"/> |
| What is your role in looking after patients with type 2 diabetes? Please tick the box that best describes your role | | |
| GP Partner <input type="checkbox"/> | Salaried GP <input type="checkbox"/> | <input type="checkbox"/> |
| Diabetes Specialist Nurse <input type="checkbox"/> | Practice Nurse <input type="checkbox"/> | <input type="checkbox"/> |
| Hospital Doctor <input type="checkbox"/> | Management <input type="checkbox"/> | <input type="checkbox"/> |

| | | |
|---|--------------------------------------|---|
| What is your ethnic background? | | |
| Please tick 1 box or complete 1 section which best describes your ethnic background | | |
| White | British <input type="checkbox"/> | Black or Caribbean <input type="checkbox"/> |
| | Irish <input type="checkbox"/> | Black British <input type="checkbox"/> |
| | | African <input type="checkbox"/> |
| Other white background (please write in) | | Other Black background (please write in) |
| <input type="text"/> | | <input type="text"/> |
| Asian or Asian British | Indian <input type="checkbox"/> | White and Black <input type="checkbox"/> |
| | Pakistani <input type="checkbox"/> | Caribbean <input type="checkbox"/> |
| | | White and Black <input type="checkbox"/> |
| | Bangladeshi <input type="checkbox"/> | African <input type="checkbox"/> |
| | | White and Asian <input type="checkbox"/> |
| Other Asian background (please write in) | | Other Mixed race background (please write in) |
| <input type="text"/> | | <input type="text"/> |
| Other ethnic background | Chinese <input type="checkbox"/> | Other ethnic background (please write in) |
| | | <input type="text"/> |

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Is there a computer linked to the Internet that you can use when you see patients?

Yes

No

Have you ever attended a diabetes education programme?

Yes

No

Have you ever used the internet to look up information about patients with type 2 diabetes?

Yes

No

Have you ever used a computer programme to help manage patients with type 2 diabetes?

Yes

No