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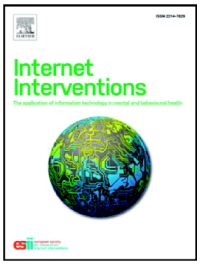

A digital self-management intervention for adults with type 2 diabetes: Combining theory, data and participatory design to develop HeLP-Diabetes

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Title: A digital self-management intervention for adults with type 2 diabetes: Combining theory, data and participatory design to develop HeLP-Diabetes

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Abbreviations*:*
T2DM = Type 2 diabetes mellitus
MRC = Medical Research Council
HeLP Diabetes = Healthy Living for People with Type 2 Diabetes
HCPs = Health Care Professionals
NPT = Normalisation Process Theory
NICE = National Institute for Health Care Excellence
CBT = Cognitive Behaviour Therapy
LLTTF = Living Life to the Full
HealthTalk Online = HTO
RNIB = Royal National Institute of Blind People

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Competing interest: EM is the managing director of a not-for-profit community interest company established to disseminate HeLP-Diabetes across the NHS.

Human Rights: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent: Informed consent was obtained from all individual participants included in the study.

Welfare of Animals: This article does not contain any studies with animals performed by any of the authors.

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Abstract

Background: Digital health interventions have potential to contribute to better health outcomes, better healthcare and lower costs. However, evidence for their effectiveness is variable. The development and content of digital health interventions are often not described in enough detail to enable others to replicate the research or improve on previous interventions. This has led to a call for transparent reporting of intervention content and development.

Purpose: To describe the development process and content of a digital self-management intervention for people with type 2 diabetes (HeLP-Diabetes) that has been found to achieve its target clinical outcome, the reduction of HbA1c, a measure of glycaemic control.

Method: We synthesised theory, data from existing research evidence and international guidelines, and new qualitative data from target users to identify the determinants of self-management and the content to be included in HeLP-Diabetes. Using an ongoing iterative participatory design approach the content of the intervention was written, produced, reviewed and changed.

Conclusion: It is possible to develop and transparently report self-management programmes for long-term conditions, which reflect current best evidence, theoretical underpinning and user involvement. We intend that reporting the development process and content will inform future digital intervention development.

Keywords: Diabetes mellitus, type 2; Self-management; Patient education as topic; Internet; Digital intervention development; Participatory design

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1. BACKGROUND

Type 2 diabetes mellitus (T2DM) is one of the commonest long-term conditions, affecting about 10% of the global population, or around 422 million people (1). People with diabetes are more likely to have or develop health complications such as cardiovascular disease and to die prematurely than people without diabetes (2). Many of these complications can be avoided if people with diabetes are supported to understand and self-manage their condition (3-6). Current international guidelines promote the provision of self-management support and diabetes education, usually through face-to-face group-based structured education sessions (7-8). However, uptake of such education is low. For example, in 2015 in the UK, less than 9% of patients reported attending a structured education session within one year of diagnosis (9), possibly because face-to-face group-based courses may not suit people who work, have caring responsibilities at home, have mobility problems, or who find group interactions difficult (10-11). Thus, there is an urgent need to find cost-effective and acceptable methods of delivering sustainable self-management education for people with T2DM.

One possibility is the use of digital health interventions (i.e. interventions delivered via digital technologies such as websites or smartphones) as an alternative or additional method of delivering self-management education. These have many potential advantages over group-based education, including convenience, accessibility and anonymity. They also have the potential to help meet healthcare's triple aim of better health outcomes, better healthcare and lower costs (12-14).

1.1 Digital health interventions for T2DM self-management

A systematic review and meta-analysis of randomised controlled trials of digital self-management interventions for people with T2DM , showed overall a small positive effect on glycaemic control (pooled effect on HbA1c = -0.21%; CI -0.37% to -0.05%; Z =

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2.63) (15). Each 1% reduction in HbA1c is associated with a risk reduction of 21% for deaths related to diabetes and a 37% risk reduction for microvascular complications (16). However, the review found no statistically significant differences between the control and intervention groups of the five studies that measured health-related quality of life. The effects of the individual interventions included were also inconsistent for secondary outcomes such as, knowledge, self-efficacy for managing diabetes, social support, health behaviours and emotional outcomes such as anxiety and depression. More recent studies that were not included in the review have shown that digital interventions developed for both people with type 1 and type 2 diabetes can be effective in reducing depressive symptoms and diabetes related distress compared to a wait list control (17) and an online psychoeducational program (18). The differences in effectiveness between these studies and those included in the review are likely to be related to differences in the content and delivery of the interventions as well as levels of user engagement. However, as these were rarely described in detail, it was not possible for the reviewers to identify factors associated with beneficial impacts (15).

This problem has been noted for health and behaviour change interventions more generally (19), making it difficult for future researchers to replicate or improve on previous research. This lack of understanding in turn impacts on our ability to generate an accumulating knowledge base around such interventions, needed both for developing more effective interventions and for informing practice and policy (20). Attempts to improve the reporting of interventions include the Medical Research Council's (MRC) guidance on developing, evaluating and implementing complex intervention (21), and the TIDieR (template for intervention description and replication) guidelines on reporting of interventions (22). The TIDieR guidelines focus on reporting the final content of interventions; however, the process of development

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can be as important as the final content. Moreover, as the development of digital health interventions for self-management is a relatively new field, it can be hard for researchers or practitioners to know how to approach the development process.

The aim of this paper is to describe the development process of a digital self-management intervention for people with T2DM (Healthy Living for People with type 2 Diabetes (HeLP-Diabetes: https://www.help-diabetes.org.uk). HeLP-Diabetes has been found to be cost-effective and effective at reducing glycated haemoglobin (Hb1Ac), but not at reducing diabetes-related distress in a randomised controlled trial (23-25). HeLP-Diabetes was intended to be used as an unguided intervention, which would support users from diagnosis through to the end of their illness journey with diabetes, unlike programmes such as DESMOND (Diabetes Education and Self Management for Ongoing and Newly Diagnosed), which are specifically aimed at newly diagnosed patients (5). It is due to be widely implemented into routine NHS care, initially through a commissioning model by individual Clinical Commissioning Groups, and more recently through a license to NHS England. The work involved in developing HeLP-Diabetes took place between March 2011 and March 2013. The randomised controlled trial ran from 2013 to 2016. We hope this will provide transparency for readers and an example for others who want to develop digital health interventions in the future.

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2. METHODS

2.1 Design.

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We used the MRC framework for development of complex interventions (21) as an overarching guide to our development process. The framework suggests: 1) identifying appropriate theory, 2) collecting primary qualitative research to identify target users' needs, and 3) identifying existing research evidence in order to determine the content to be included within HeLP-Diabetes. A participatory design (26) approach was used to synthesise these three sources by mapping, integrating and revising to co-create the final intervention.

2.2 Theoretical frameworks and models.

Based on our research group's previous experience in e-health (27-32) we identified three key areas for creating effective self-management digital interventions for long-term conditions that we wished to build on and would benefit from a strong theoretical underpinning. These were: a) understanding the overall impact of a long-term condition on a person's life and sense of self, and the importance of taking a holistic approach to the work required for self-management; b) behaviour change support (as so much of diabetes management requires changes to behaviours such as diet and physical activity; and c) the challenge of ensuring that the final intervention could be effectively implemented into routine healthcare.

2.2.1 Corbin and Strauss' Model of Living with a Long-Term Condition

A key theoretical model that describes the overall impact of a long-term condition on people's lives and sense of self is the Corbin and Strauss' (1988) model (33), which describes three areas of work required by those affected: illness work, everyday life work, and biographical work. This leads to three areas of self-management: medical management (e.g. remembering to take medications regularly, managing interactions with Health Care Professionals (HCPs), eating healthily and exercising more, and stopping or cutting down smoking and drinking alcohol);

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emotional management (e.g. managing the many cognitions and emotions such as anger, fear, anxiety, guilt, frustration, sadness, depression and denial, that are commonly experienced by people with a long-term condition); and role management (e.g. managing the biographical disruption and changes to identities and roles required by living with a long-term condition), with all three areas being equally essential.

2.2.2 Taxonomy of Behaviour Change Techniques

There are many psychological theories predicting behaviour change, several of which include overlapping concepts (34). Rather than opt for one specific theory, and because we were more interested in ***changing*** behaviour than ***predicting*** it, we adopted the Abraham and Michie taxonomy of behaviour change techniques (35) rather than a single theory. Behaviour change techniques were selected based on research evidence for the user-defined target behaviours and behaviour change techniques from the qualitative data with target users.

2.2.3 Normalisation Process Theory (NPT)

A priority was to ensure that the final intervention could be easily implemented into routine care within the British National Health System (NHS). There were two reasons for this: first, that despite the potential of digital health interventions to improve care, there are few examples of their use in routine care, limiting their impact on health; and secondly, we hypothesised that integrating the intervention into routine care would enhance uptake and use by patients. This would help address two main concerns about digital health interventions, namely the problem of low use and low adherence to such interventions (36), and the problem of the "digital divide", or the way that such interventions may widen health inequalities between those who do and do not use digital interventions (37). To maximise the likelihood of our intervention being easily incorporated into routine health care (normalised), we applied the principles of

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Normalisation Process Theory (NPT) during the development process. NPT is a sociological theory focusing on the work of implementation and integration of complex interventions into routine health care (38). It has been used extensively to understand the success or failure of implementations and more recently, to predict and plan for successful implementation (39-40). There are four main components to the theory: coherence; cognitive participation; collective action and reflexive monitoring (38). For an intervention to 'normalise' HCPs need to: understand the purpose of the intervention (coherence); be prepared to invest time and energy into it (cognitive participation); feel that it fits well with their current work (collective action); and perceive the intervention to be worthwhile (reflexive monitoring). Thus our work with HCPs focused on identifying and including features that would promote these four factors, while avoiding those that would have a negative impact on them.

2.3 Identifying user requirements.

Establishing user requirements for any proposed intervention is an essential first step (41). Our target users were people with T2DM and the HCPs caring for them. We conceptualised user requirements as "wants", which were features which would make them ***want*** to use it and "needs" which were features ***needed*** to improve health outcomes. For people with T2DM, our primary data collection method was focus groups which allowed participants to clarify their views through interactions with each other (42) and explore their underlying reasons for differing perspectives allowing for consensus building around solutions which would meet a range of user requirements.

NPT predicted that integration of the intervention into routine health care (normalisation) required including features that maximised the coherence and cognitive participation of HCPs, while minimising the work of implementation (collective action) and promoting reflexive monitoring. A combination of individual

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interviews and focus groups were used to collect data from HCPs, because of the challenges of recruiting and bringing HCPs together at a mutually convenient time and location.

2.3.1 Ethics

Ethics approval was provided by the North West London Local Research Ethics Committee on behalf of the National Research Ethics Service (reference number: 10/H0722/86).

2.3.2. People with T2DM

Four focus groups and one interview were conducted in a community centre in London with a total of 20 people with T2DM. For details of the recruitment strategies, data collection and analytical procedures please see Pal et al. (43). We advertised online and offline, aiming to recruit a maximum variety sample in terms of demographic factors (e.g. age, sex, and ethnicity) and clinical factors (e.g. duration of DM since diagnosis, current treatment). The number of participants in each focus group ranged from three to six. The majority of participants were white British (14/20) but Black, Asian and Other (Iranian) ethnicities were also represented. Just over half were male (12/20), with a mean age of 56.8 years (range 36-77 years). The time since diagnosis of diabetes ranged from three months to 36 years (see Table 1 for participant characteristics).

Insert Table 1 about here

The focus groups with people with T2DM lasted 3 hours and were led by at least two facilitators (EM, FS, CD & KP). At the start of the group, participants were asked to spend their time on individual computers using three self-management websites for T2DM that ranged in their content, tone, and complexity. Participants were given a maximum of 30 minutes to try each website to explore what they liked or disliked about

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it and how it might be useful to them. Participants then came together for a group discussion guided by one of the facilitators.

The topic guide for this discussion was semi-structured and informed by the components of NPT and Corbin and Strauss' model. Participants were asked about their overall impressions of the usefulness of the three websites, followed by specific likes and dislikes, and the reasons for these reactions. This led into a discussion of ideas for 'ideal' content on a website to aid self-management. Participants were encouraged to voice issues that were important to them, rather than respond to researcher prompts. Participants were also asked why and when they might use such a website, what would encourage them to use it, whether they would like to share health-related data with their HCPs, and whether they would like a health care professional to facilitate use, and if so, how.

2.3.3. Healthcare professionals

In parallel, four focus groups and seven individual interviews (N = 18) were conducted with a variety of HCPs (endocrinologists, general practitioners, a dietician, practice nurses, diabetes specialist nurses, a nurse consultant) recruited via advertising and snowball sampling. The number of participants recruited to take part in each focus group ranged from two to four. Over half were female (11/18), with a mean age of 49 years (range 32-64 years). Nearly all (17/18) HCPs were white British (see Table 2 for HCPs participant characteristics). For more details of the methods see Murray et al. (44).

Insert Table 2 about here

The focus groups and interviews with HCPs lasted between 30-90 minutes and were led by at least one facilitator (FS, CD, KP). The topic guide was informed by NPT, and focused on features that would distinguish our proposed intervention from

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available websites (coherence), features that would encourage (or conversely discourage) HCPs from using the intervention and recommending it to their patients (cognitive participation), features that would make it easy to use in clinical practice (collective action), and information that would promote use (reflexive action), while using open questions to enable participants to think widely around the issues of self-management and to encourage them to bring up ideas that were important to them, rather than the research team.

2.3.4.Data analysis

Data analysis was undertaken in parallel with data collection, which continued until thematic saturation had been reached, defined as no new codes or themes emerging in subsequent transcripts. All focus groups and interviews were audio taped and transcribed verbatim, with initial analyses focused on determining the content and design features of the intervention. This analysis was based on a coding framework agreed in a multidisciplinary meeting comprising of a medical sociologist, health psychologists and GPs. Transcripts were independently read by each researcher and themes were extracted. Focus groups and interviews continued until no new data emerged regarding content (e.g. data saturation). An overview of the findings is shown in Table 3.

2.3.5. Researcher's background

Being explicit about values and beliefs is an integral part of qualitative research (45-46) and our multi-disciplinary team (psychologists, sociologists, GPs) provided a range of perspectives in planning and conducting the research as well as informing analytic discussions.

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2.4 Process of synthesis

We synthesised the data using an iterative participatory design approach with 3 main steps: mapping and writing; integrating; and revising. This approach was chosen as research has shown that interventions developed using participatory design are more likely to be acceptable, are more likely to be engaging (e.g. lower attrition) and are more likely to be effective (47).

2.4.1 Mapping & writing

A core interdisciplinary writing team consisting of 2 psychologists (CD, JR), 3 general practitioners (EM, KP, EG) and 3 dieticians mapped the information to be covered on to initial intervention components (see Table 3). Components were then written by team members according to areas of expertise and experience. This content was then reviewed and agreed upon with the rest of the team. All content was evidence-based, in that it reflected current best practice (represented by the National Institute for Health and Care Excellence (NICE) clinical guidelines) (7), and current evidence on factors like maximising accessibility to people with low literacy skills or low vision.

2.4.2 Integrating

We worked with software engineers and a web designer to integrate the written content onto a website. This ensured that content was presented in a user friendly way that was easy to navigate with a professional finish. The software engineers were able to integrate the functionality of the interactive components (e.g. forum, quizzes, self-assessments, action planning, goal setting, reviewing & feedback on goals, reminders, integrating videos and previously developed digital interventions) so that the content could be tailored to individual users.

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2.4.3 Revising

Iterations of the integrated content were shown and tested by two complementary participatory design groups: one of HCPs (GPs, practice and diabetes specialist nurses) and one of people with T2DM.

The Health Care Professional (HCPs) group had four sessions where they focused on ensuring that the content was accurate, evidence-based and consistent with NICE guidelines and best clinical practice; the programme could be used in routine care; likely to be acceptable to HCPs; and whether anything was missing or could be improved.

The T2DM participatory design group was made up of a number of people with T2DM who regularly used the website at home and in sessions with the research team and were heavily involved in providing feedback on all the content created. Feedback included whether it met their needs, how it was presented, the design and name of the website and creating or suggesting new content. This on-going involvement meant that users shaped whole additional components of the website. For example, for the physical activity components of the website, users suggested that videos demonstrating how to perform a range of physical activities would be useful as there was some uncertainty about what to do. Users were also clear that it was important that the people doing the activities in these videos were real people with T2DM (rather than what one user called "lycra lovelies" with a range of abilities (Beginners & reduced mobility, Intermediate, Advanced). Based on this feedback we worked with a film director, personal trainer and three people with T2DM to make a range of physical activity videos. These were integrated within the website by our software engineers and reviewed by our users again. In this second iteration of feedback users suggested some sort of playlist function so that different physical activity videos could be viewed as a circuit. We worked with

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the software engineers to integrate these suggestions on the website. Users were asked to confirm whether the changes and integrations had been made in line with their suggestions.

Additional feedback was given on the pre-existing interventions Down Your Drink and Living Life To The Full that were incorporated into HeLP-Diabetes (see Results section) in order to tailor the existing content to people with T2DM. For example, information was added to Down Your Drink about the effects of alcohol on blood glucose levels. Diabetes-related behaviours that may cause stress (e.g. taking medicines as prescribed, eating out) were added to the Living Life to the Full audios.

The regular website users participatory design group met on eight sessions which were facilitated by CD and JR. In-between each session the core writing team met to discuss suggestions and where feasible implement them. If changes were not made the reasons for these were explained to the group at the next session (e.g. the group's suggestion to encourage website users to monitor their blood glucose levels would conflict with current evidence based recommendations from NICE (7) on blood glucose monitoring for people with T2DM). Additionally, two separate groups of people with T2DM who only occasionally used the website met less regularly (four sessions per group) in order to provide insight from a new user's point of view.

2.5 Additional feedback and usability testing

A multidisciplinary steering group (e.g. psychologists, medical sociologists, patient representatives, GPs, diabetes consultants, cardiologists, primary care specialists) also reviewed and commented on the intervention content and usability. In addition, a number of naïve users with no experience of the intervention took part in usability testing sessions where they had to carry out a series of pre-defined tasks and 'think aloud' while completing them (e.g. where would you go to find out about diabetes

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and holidays?) This allowed the web designer to optimise the navigation, look and feel of the intervention and improve the usability of the interactive features (e.g. quizzes, self-assessments, action planning, goal setting, feedback etc.). Thorough proofreading and editing were essential for credibility and maintaining users' trust in the intervention (27). A professional editor reviewed and edited all content for any errors in writing.

2.6 Facilitating Engagement

Data from our qualitative work with both users emphasised the importance of ensuring that the intervention was used in interactions with HCPs, and was perceived as an integral part of the total care package, not an optional add-on. We therefore developed a 5-10 minute registration and facilitation process where a health care professional (e.g. usually a practice or research nurse or health care assistant) registered a user, introduced users briefly to each of the sections of the intervention and went into detail around one area that the user wanted to work on (e.g. losing weight, or understanding medication). A step-by-step booklet was produced for HCPs so that they could easily navigate the intervention without prior experience. In addition a patient user activity booklet was developed with some details of where to find commonly requested information and activities to do using the interactive tools (e.g. goal setting, action planning, setting a prompt). These were developed by CD and JR and reviewed by the core team and participatory design groups.

Engagement was also encouraged through regular emails and/or texts (48) that contained links to topical content within the intervention (e.g. information around flu vaccinations in winter). The content of these was suggested by our participatory design groups and then written by the team. They were reviewed by the participatory design group for acceptability and then sent to all registered users.

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3 RESULTS

The primary qualitative data on user requirements is summarised in Tables 3 and 4. Table 4 shows how the primary qualitative data were mapped onto Corbin & Strauss' model of self-management. Using Normalisation Process Theory allowed us to identify intervention features that were needed to improve the chances of engagement and normalisation of the intervention. Integrating the results of the analyses of the qualitative data with the Corbin and Strauss model enabled us to generate an overall list of required components to be included within the intervention (See column 3 of Table 4). We then reviewed the existing research evidence in terms of empirical papers, systematic reviews and clinical guidelines to identify best practice, strategies and interventions that have been shown to be effective at targeting these components.

Tables 3 and 4 about here.

As Table 4 makes clear, the final intervention required a great deal of content. We wanted to avoid duplicating efforts already made by leading researchers in the field of digital health interventions, and therefore decided that where there were existing interventions that could be usefully and easily incorporated into our intervention, we would do so. We developed criteria to guide selection of existing interventions which were: that they were readily available to the research team (i.e. we already knew about them, or they were easily located through literature searches and we could easily negotiate permission to license their content); developed using theory and user input (as this reflected best practice); had been evaluated and had some evidence of effectiveness; and could be easily incorporated into our intervention (this included

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technical compatibility, being in English, and having a tone and approach to self-management that reflected the ethos of the main intervention). External content that was licensed in is described in the relevant sections below.

3.1 Medicine and Treatments

NICE guidelines and pathways were reviewed to provide the content for the current medications and treatments for people with T2DM (7). Patients value being given written information about the medicines they have been prescribed (49-50), and in particular the answers to the questions: What are the side effects? What does the medicine do? What lifestyle changes are involved in taking the medicines (e.g. Can I still drive? Can I drink alcohol?); and How do I take the medicine (e.g. When, how much, with food or on an empty stomach?) (51). This guided the information that needed to be written in the intervention. How medicines information was presented followed recommendations for risk communication (e.g. presenting data using absolute risk reduction and frequencies rather than percentages) (52).

3.2 Changing Behaviour

From the combined qualitative data and theory described above we identified a number of behaviours which people with T2DM may need to modify in order to successfully self-manage their condition. These included: dietary intake, weight management, levels of physical activity, alcohol consumption, smoking and taking medications. We identified three pre-existing behaviour change interventions that met our criteria for inclusion in our intervention: 1) Down Your Drink (DYD), a digital intervention that aimed to help hazardous and harmful drinkers to reduce their alcohol consumption (29-30), 2) PoWER, which targeted weight loss (53) and 3) StopAdvisor, a digital smoking cessation intervention (54).

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We were unable to identify digital behaviour change interventions, which met our criteria for eating healthily, being more physically active and taking medicines as prescribed so we designed our own. To do this, we selected appropriate behaviour change techniques using Abraham and Michie's taxonomy (35), which have been shown to be effective in previous research. Goal setting (behaviour); Action planning; Prompt review of behavioural goals; Barrier identification/Problem solving; Prompt self-monitoring of behaviour and Provide feedback on performance were chosen as this cluster of techniques have been found to be associated with positive outcomes of previous behaviour change interventions (55-56) and are consistent with Self-regulation (control) Theory (57). Prompt self-monitoring of behaviour and Provide feedback on performance were also the most commonly used techniques in digital health interventions that had an impact on glucose control (15).

3.3 Changing affect

Corbin and Strauss' (1988) model (33) suggests that managing the many strong negative emotions (e.g. anxiety depression, anger, guilt, stigma and shame) that are associated with having a long-term condition are key determinants to good self-management. This was also confirmed in the focus group data with both people with T2DM and HCPs stressing the emotional impact caused by T2DM. Research evidence has also found high levels of depression and diabetes-related distress for people with diabetes (58). We reviewed the literature and found the evidence for internet Cognitive Behaviour Therapy (CBT) for managing depression, anxiety and a range of other mental health problems was strong (59-62) and likely to be effective in helping our users to manage their emotions. Rather than develop our own content, we searched for existing digital interventions that had been shown to be effective in reducing mild to moderate anxiety and depression. Living Life to the Full (LLTTF) was chosen as it met our criteria

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of availability, evidence of effectiveness, and fitting with the overall approach of our intervention (63). It mapped onto our user requirements better than alternative digital interventions (e.g. Beating the Blues) in that it was UK centric and the approach taken is informed by CBT to give people the skills to manage low mood and stress, rather than treat clinical depression or anxiety.

3.4 Improving perceived social support

The data from our users identified that hearing or reading about other people's experiences and responses to similar challenges (e.g. the diagnosis) could be useful in managing their emotions. This view was supported by the research evidence where hearing or reading about other people's stories has the potential to improve a person's sense of social support and how they cope with some of the emotions related to illness (64-65) in addition to providing information that may impact decisions about self-management. Moreover, there is increasing evidence supporting the use of narrative as a form of communication, as it can facilitate information processing (particularly by people with low literacy, and / or low health literacy (66)) and address emotional and existential issues (67-68). Rather than create our own range of people's stories we approached the world leader in provision of such "personal stories" called HealthTalk Online (HTO) (previously DiPEX; (69)) to incorporate their module of patient experiences for T2DM. This included 40 videos and transcripts of interviews with people from range of ethnic and socio-economic backgrounds, (as it is important that viewers can identify with the narrator (70)). The interviews were carefully curated to present a balanced and comprehensive overview of patient experiences.

In addition to the HTO personal stories, we included a moderated forum, as users requested this as a means of sharing their thoughts and emotions with others. There was also evidence supporting this suggesting that forums can have impact on a person's

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sense of social support as well as providing experiential knowledge on how to cope with conditions and stressful situations (71). There is also an emerging literature of importance of identifying the various 'systems of support' that are available to individuals (72). A moderated forum provides a means of expanding users' social network. We appreciated that not all users would want to use the forum, so it was available but with no compulsion to use it. Alongside this, we wanted to provide users with tailored information about the local resources available to them in their location in terms of health care professionals, non-health care professionals and voluntary and community groups.

3.5 Changes in role and identity

Corbin and Strauss' (1988) model (33) emphasises the work of managing biographical disruption (changes to their and roles) caused by a diagnosis of T2DM. This was confirmed in our primary data with users describing this disruption as a feeling of loss (43). Users were particularly interested in content that would enable them to continue with actions that had previously been "taken for granted", such as social occasions, holidays, travel, insurance, eating in restaurants, cafes or work canteens, and variable working hours, such as with shift work. Users wanted tools to help manage changes to roles within relationships and families. We could find little evidence on the effectiveness of interventions addressing these issues, and so were mainly guided by our user data. The resulting content included acknowledgement that the diagnosis of diabetes can be life-changing, that some previously routine activities and relationships can become challenging, and providing information on how to manage them. This information ranged from practical advice about managing medication and diet when working shifts, to resources around employment law. Users identified again that hearing other people's experience about living and working with T2DM may be

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useful to realise they are not alone in experiencing these problems and to feel supported. The HTO videos described above included how other people had felt and their methods of managing these challenges (e.g. sexual problems, medication side effects). We also envisaged the forum as a place where users could exchange information about specific practical challenges (71)

3.6 Presentation of information

We took a patient centred approach to presenting information, in a positive (e.g. what I can do rather than cannot do), non-judgemental way in order to empower, motivate and increase confidence. We followed the best practice guidance from the Royal National Institute of Blind People (RNIB) to ensure the website was accessible for people with visual impairments and available checklists for the content to be included in patient information materials (73). We used a range of modes to communicate information (e.g. written, pictures, videos) in order to suit a range of user preferences.

3.7 Final Intervention

The above steps determined the components of the intervention and how this information should be presented. The final intervention was (and is) a very large website, with over 560 pages.

3.7.1 Content.

The overall content was broken down into eight sections:

1. **Understanding diabetes** (145 pages; information about the nature and causes of diabetes, and how it affects the body);
2. **Staying healthy** (107 pages; motivational material about how to maintain optimal physical and emotional health and the importance of self-management; new behaviour change modules and previously validated programmes for diet, weight

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loss, physical activity, smoking cessation, moderating alcohol intake, and taking medicines);

3. **Treating diabetes** (70 pages; information about medications used in diabetes, including information about indications, side effects and monitoring; importance of managing cardiovascular risk factors as well as glycaemic levels; importance of regular monitoring to prevent retinopathy, neuropathy and nephropathy; and types and roles of different HCPs in caring for people with diabetes);
4. **Living and working with diabetes** (87 pages; focus on managing social and work situations, such as shift work, parties, or holidays; impact on relationships, including sexual relationships; and possible impact on emotions and feelings of self-worth);
5. **Managing my feelings** (61 pages; self-assessment tools for identifying low mood; CBT modules; mindfulness-based approaches);
6. **My health record** (45 pages; opportunity to record appointments with HCPs and results of tests or self-monitoring, with opportunities for graphical displays and feedback);
7. **News and research** (16 pages; updates about diabetes treatment, in-depth articles about seminal research papers); and information for HCPs such as NICE guidelines;
8. **Forum and help** (28 pages; moderated forum; videos of personal stories about diabetes used with license from healthtalk.org; additional resources, including local resources tailored to the CCG).

Each section combined written information with videos and other graphics. There were interactive and tailored components in each section apart from news and research. Behaviour change and emotional management sections included opportunities for self-assessment, in the form of validated questionnaires with

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automated feedback which contained recommendations for action. Users could set the programme to send them automated texts or email reminders and alerts when new entries were posted in the forum. They could opt out of the regular engagement emails and newsletters described above.

More details of the website's content, with screen shots, are provided in *Appendix 1*, with a site map in *Appendix 2*. The TIDIER check list forms *Appendix 3*.

4 DISCUSSION AND IMPLICATIONS

4.1.Main findings

We have described the different sources (e.g. theory, research evidence, primary data from users, clinical guidelines) that guided the content and presentation of HeLP-Diabetes and our methods of combining them using participatory design. The intervention has been evaluated and found to improve diabetes control but not diabetes-related distress (23-24), to be highly cost-effective with users having better health outcomes and reduced health care costs (25) and implemented in general practices across the UK where it has been shown to be used by a wide demographic (40, 74). Over half our users are from Black and Minority Ethnic (BME) backgrounds, a third left school at minimum school leaving age with either no, or minimal qualifications, and a third described their computer skills as "basic". This combination of effectiveness, cost-effectiveness, use by a wide demographic, and subsequent large-scale implementation is unique amongst digital diabetes self-management programmes. We hope by describing the content and development other researchers will be able build in future research so that science is cumulative. This is particularly important in the field of digital health interventions for self-management where the development and content

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of such interventions is rarely described in detail making it difficult for other researchers and practitioners to know how to start the development process (19). We hope that by reporting the process we used this may act as an exemplar for other researchers or clinicians wanting to develop self-management interventions for other long-term conditions in the future.

4.2 Strengths & Limitations

Particular strengths of our approach to intervention development included using participatory design methods, where prospective users worked with us as partners to determine the content and design. The explicit use of theory was also essential, with the Corbin and Strauss model (33) providing an overarching guide to content, the Abraham and Michie behaviour change technique taxonomy (35) guiding specific content around behaviour change, and NPT (38) ensuring we thought about implementation at every step of the process. Having a diverse multi-disciplinary team which included health psychologists, sociologists, clinicians, information scientists, software engineers, web-designers and editors was beneficial. The use of evidence from a wide range of disciplines, such as human-computer interaction and health education as well as the more traditional biomedical literature was a strength.

There were also some limitations to our work. In hindsight, the research team could have included human-computer interaction (HCI) expertise, rather than relying on commercial software and web design partners. Such expertise may have helped us with our participatory design and user testing methods, and helped us communicate with our commercial partners. Our emphasis on participatory design meant that, almost by definition, our patient partners were those most interested in self-management, and hence not representative of patients for whom self-management is a lower priority. Our selection and combination of theoretical models can be criticised;

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however, we found that they were fit for purpose and were easily combined, and would recommend this combination for future similar projects. Finally, there is no doubt that the process initial development was long (two years) and expensive. This can only be justified where there is a large potential population who can benefit from the intervention, or where there is significant learning which can be applied to help future clinical and academic development. Both factors apply in this case.

4.3.Conclusion

It is possible to use participatory design principles to integrate theory and evidence to create acceptable and effective digital health interventions.

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7 REFERENCES

1. NCD Risk Factor Collaboration (NCD-RisC) (2016). Worldwide trends in diabetes since 1980: a pooled analysis of 751 population-based studies with 4·4 million participants. *Lancet* (London, England). 2016; 387(10027):1513-1530. doi:10.1016/S0140-6736(16)00618-8.
2. National Collaborating Centre for Chronic Conditions. (2008) Type 2 Diabetes: National Clinical Guideline for Management in Primary and Secondary Care (Update). Royal College of Physicians, London.
3. Davies, M. J., Heller, S., Skinner, T. C., et al (2008). Effectiveness of the diabetes education and self management for ongoing and newly diagnosed (DESMOND) programme for

ACCEPTED MANUSCRIPT

people with newly diagnosed Type 2 diabetes: cluster randomised controlled trial. *British Medical Journal* 336; 491–95

4. Deakin, T. (2011). The diabetes pandemic: is structured education the solution or an unnecessary expense? Practical *Diabetes* 28 (8); 1–14
5. Khunti, K., Gray, L. J., Skinner, T. C., et al (2012). Effectiveness of a diabetes education and self management programme (DESMOND) for people with newly diagnosed Type 2 diabetes mellitus: three year follow-up of a cluster randomised controlled trial in primary care. *British Medical Journal* 344; e2333
6. Steinsbekk, A. Rygg, L. O., Lisulo, M., et al (2012). Group based diabetes self-management education compared to routine treatment for people with Type 2 diabetes mellitus. A systematic review with meta-analysis. *BMC Health Services Research* 12; 213
7. National Institute of Health and Care Excellence (NICE) Guideline NG28. (2015). Type 2 diabetes in adults: Management https://www.nice.org.uk/guidance/ng28
8. American Diabetes Association. (2015). 4. Foundations of Care: Education, Nutrition, Physical Activity, Smoking Cessation, Psychosocial Care, and Immunization. *Diabetes Care*, 38 (Supplement 1) S20-S30; DOI: 10.2337/dc15-S007
9. National Diabetes Audit (2018). National Diabetes Audit 2016-2017: Care Processes and Treatment Targets. [Accessed on February 1st, 2019]. Available from: https://www.hqip.org.uk/wp-content/uploads/2018/03/National-Diabetes-Audit-2016-17-Report-1-Care-Processes-and-Treatment-T....pdf
10. Winkley, K., Evwierhoma, C., Amiel, S. A., Lempp, H. K., Ismail, K., & Forbes, A. (2015). Patient explanations for non-attendance at structured diabetes education sessions for newly diagnosed Type 2 diabetes: a qualitative study. *Diabetic medicine: a journal of the British Diabetic Association*. 2015;32(1):120-8.
11. Horigan, G., Davies, M., Findlay-White, F., Chaney, D., & Coates, V. (2016). Reasons why patients referred to diabetes education programmes choose not to attend: a systematic review. *Diabetic Medicine*, 2016;34:14 - 26.
12. Berwick, D.M., Nolan, T. W., & Whittingdon, J. (2008). The Triple Aim: Care, Health and Cost. *Health Affairs*, 27 (3): 759-769.
13. Wachter, R. M. (2015). Making IT Work: Harnessing the power of health information technology to improve care in England. Report of the National Advisory Group on Health Information Technology in England. 2016. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/550866/Wachter_Review_Accessible.pdf. Accessed 27 Sept 2016.
14. Craig, C., Eby, D., & Whittington, J. (2011). Care Coordination Model: Better Care at Lower Cost for People with Multiple Health and Social Needs. IHI Innovation Series white paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2011. http://www.ihi.org/resources/Pages/IHIWhitePapers/IHICareCoordinationModelWhitePaper.aspx Accessed 27 Sept 2016.
15. Pal, K., Eastwood, S.V., Michie, M., Farmer, A. J., Barnard, M. L., Peacock, R., Wood, B., Innis, J.D., & Murray, E. (2013). Computer-based diabetes self-management interventions for adults with type 2 diabetes mellitus. *Cochrane Database of Systematic Reviews*. 2013 Mar 28;(3):CD008776. doi: 10.1002/14651858.CD008776.pub2.
16. Stratton, I. M., Adler, A. I., Neil, H. A., et al. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. *British Medical Journal (Clinical research ed)*, 2000; 321(7258):405-12.

ACCEPTED MANUSCRIPT

17. van Bastelaar, K. M., Pouwer, F., Cuijpers, P., Riper, H., & Snoek, F. J. (2011). Web-based depression treatment for type 1 and type 2 diabetic patients: a randomized, controlled trial. *Diabetes care*, *34*(2), 320-5.
18. Nobis, S., Lehr, D., Ebert, D. D., Baumeister, H., Snoek, F., Riper, H., & Berking, M. (2015). Efficacy of a web-based intervention with mobile phone support in treating depressive symptoms in adults with type 1 and type 2 diabetes: a randomized controlled trial. *Diabetes Care*, 38(5):776-83. doi: 10.2337/dc14-1728.
19. Michie, S., Fixsen, D., Grimshaw, J. M., & Eccles, M. P. (2009). Specifying and reporting complex behaviour change interventions: the need for a scientific method. *Implementation Science*. 2009; 4: 40.
20. Murray, E., Hekler, E. B., Andersson, G., Collins, L. M., Doherty, A., Hollis, C., Rivera, D. E., West, R., & Wyatt, J. C. (2016). Evaluating Digital Health Interventions: Key Questions and Approaches. *American Journal of Preventative Medicine*. 2016 Nov;51(5):843-851. doi: 10.1016/j.amepre.2016.06.008.
21. Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., & Petticrew, M. (2008). Developing and evaluating complex interventions: the new Medical Research Council guidance. *British Medical Journal*, 2008; 337: a1655.
22. Hoffmann, T. C., Glasziou, P. P., Boutron, I., Milne, R., Perera, R., Moher, D. et al. (2014). Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *British Medical Journal*, 2014; 348 :g1687
23. Murray, E., Dack, C., Barnard, M., et al. HeLP-Diabetes: randomised controlled trial protocol. *BMC Health Services Research*, 2015;15:578. doi:10.1186/s12913-015-1246-9.
24. Murray, E., Sweeting, M., Dack, C., Pal, K., Modrow, K., Hudda, M., Li, J., Ross, J., Alkhaldi, G., Barnard, M., Farmer, A., Michie, S., Yardley, L., May, C., Parrott, S., Stevenson, F., Knox, M., & Patterson, D. (2017). Web-based self-management support for people with type 2 diabetes (HeLP-Diabetes): randomised controlled trial in English primary care. *British Medical Journal Open*, 2017; 7; e016009. doi: 10.1136/bmjopen-2017-016009
25. Li, J., Parrott, S., Sweeting, M., Farmer, A., Ross, J., Dack, C., Pal, K., Yardley, L., Barnard, M., Hudda, M., Alkhaldi, G., & Murray, E. (2018). Cost-Effectiveness of Facilitated Access to a Self-Management Website, Compared to Usual Care, for Patients With Type 2 Diabetes (HeLP-Diabetes): Randomized Controlled Trial. *Journal of Medical Internet Research*, 2018;20(6):e201
26. Kushniruk, A., & Nohr, C. (2016). Participatory Design, User Involvement and Health IT Evaluation. *Studies in Health Technology and Informatics*. 2016;222:139-51.
27. Kerr, C., Murray, E., Stevenson, F., Gore, C., & Nazareth, I. (2006). Internet interventions for long-term conditions: patient and caregiver quality criteria. *Journal of Medical Internet Research,* 2006;8(3):e13
28. Kerr, C., Murray, E., Noble, L., Morris, R., Bottomley, C., Stevenson, F., Patterson, D., Peacock, R., Turner, I., Jackson, K., & Nazareth, I. (2010). The potential of Web-based interventions for heart disease self-management: a mixed methods investigation. *Journal of medical Internet research*, *12*(4), e56. doi:10.2196/jmir.1438
29. Linke, S., McCambridge, J., Khadjesari, Z., Wallace, P., & Murray, E. (2008). Development of a psychologically enhanced interactive online intervention for hazardous drinking. *Alcohol and Alcoholism*, 2008;43(6):669-74.
30. Wallace, P., Murray, E., McCambridge, J., Khadjesari, Z., White, I. R., Thompson, S. G., Kalaitzaki, E., Godfrey, C. & Linke, S. (2011). On-line Randomized Controlled Trial of an

ACCEPTED MANUSCRIPT

Internet Based Psychologically Enhanced Intervention for People with Hazardous Alcohol Consumption. *PLoS ONE*, 2011; 6(3): e14740.

31. McCarthy, O., Carswell, K., Murray, E., Free, C., Stevenson, F., & Bailey, J. V. (2012). What Young People Want From a Sexual Health Website: Design and Development of Sexunzipped. *Journal of Medical Internet Research*, 14(5):e127
32. Carswell, K., McCarthy, O., Murray, E., & Bailey, J. V. (2012). Integrating Psychological Theory Into the Design of an Online Intervention for Sexual Health: The Sexunzipped Website. *JMIR Research Protocol*, 1(2):e16
33. Corbin, J. M., & Strauss, A. L. (1988). Unending Work and Care: Managing Chronic Illness at Home. San Francisco, CA: Jossey-Bass Publishers; 1988.
34. Armitage, C. & Conner, M. (2000). Social cognition models and health behaviour: A structured review. *Psychology & Health*, 15:2, 173-189
35. Abraham, C., & Michie, S. (2008). A taxonomy of behavior change techniques used in interventions. *Health Psychology*, Vol 27(3), May 2008, 379-387. http://dx.doi.org/10.1037/0278-6133.27.3.379
36. Eysenbach, G. (2005). The Law of Attrition. *Journal of Medical Internet Research*, 2005;7(1):e11. DOI: 10.2196/jmir.7.1.e11
37. Viswanath, K., & Kreuter, M. W. (2007). Health Disparities, Communication Inequalities, and e-Health: A Commentary. *American Journal of Preventive Medicine*, 2007;32(5 Suppl):S131-S133. doi:10.1016/j.amepre.2007.02.012.
38. May, C., & Finch, T. (2009). Implementation, embedding, and integration: an outline of Normalization Process Theory. *Sociology*, 2009;43(3):535-54.
39. May, C. R., Cummings, A., Girling, M., Bracher, M., Mair, F. S., May, C. M., Murray, E., Myall, M., Rapley, T., & Finch, T. (2018). Using Normalization Process Theory in feasibility studies and process evaluations of complex healthcare interventions: a systematic review. *Implementation Science* : IS, 13(1), 80. doi:10.1186/s13012-018-0758-1
40. Ross, J., Stevenson, F., Dack, C., Pal, K., May, C., Michie, S., Barnard, M., & Murray, E. (2018). Developing an implementation strategy for a digital health intervention: an example in routine healthcare. *BMC Health Services Research*, 18(1), 794. doi:10.1186/s12913-018-3615-7
41. Bartholomew, L. K., Parcel, G. S., & Kok, G. (1998). Intervention Mapping: A Process for Developing Theory and Evidence-Based Health Education Programs. *Health Education & Behavior*, 25(5), 545–563. https://doi.org/10.1177/109019819802500502
42. Kitzinger J. (1995). Qualitative Research: Introducing focus groups. *British Medical Journal,* 1995; 311 :299
43. Pal, K., Dack, C., Ross, J., Michie, S., May, C., Stevenson, F., Farmer, A., Yardley, L., Barnard, M., & Murray, E. (2018). Digital Health Interventions for Adults With Type 2 Diabetes: Qualitative Study of Patient Perspectives on Diabetes Self-Management Education and Support. *Journal of medical Internet research*, *20*(2), e40. doi:10.2196/jmir.8439
44. Murray, E., Ross, J., Pal, K., Li, J., Dack, C., Stevenson, F., Sweeting, M., Parrott, S., Barnard, M., Yardley, L., Michie, S., May, C., Patterson, D., Alkhaldi, G., Fisher, B., Farmer, A., & O'Donnell O. (2018). A web-based self-management programme for people with type 2 diabetes: the HeLP-Diabetes research programme including RCT. *NIHR Programme Grants for Applied Research*, 2018;06(05)
45. Barker, V., & Pistrang, N. (2005). Quality criteria under methodological pluralism: implications for conducting and evaluating research. *American Journal of Community Psychology*, 35 (3-4),201–212.

ACCEPTED MANUSCRIPT

46. Elliott, R., Fischer, C. T., & Rennie, D. L. (1999). Evolving guidelines for publication of qualitative research studies in psychology and related fields. *British Journal of Clinical Psychology*, 38, (3), 215–229.
47. DeSmet, A., Thompson, D., Baranowski, T., Palmeira, A., Verloigne, M., De Bourdeaudhuij, I. (2016). Is Participatory Design Associated with the Effectiveness of Serious Digital Games for Healthy Lifestyle Promotion? A Meta-Analysis. *Journal of Medical Internet Research*, 2016;18(4):e94.
48. Alkhaldi, G., Modrow, K., Hamilton, F., Pal, K., Ross, J., & Murray, E. (2017). Promoting Engagement With a Digital Health Intervention (HeLP-Diabetes) Using Email and Text Message Prompts: Mixed-Methods Study. *Interactive Journal of Med Research* 2017;6(2):e14
49. Busson, M., & Dunn, A. P. M. (1986). Patients' knowledge about prescribed medicines. *Journal of Pharmaceutics*, 1986;236674- 676
50. Weinman, J. (1990). Providing written information for patients: psychological considerations. *Journal of the Royal Society of Medicine*, 1990;83:303–305.
51. Berry, D. C., Gillie, T., & Banbury, S. (1995). What do patients want to know: An empirical approach to explanation generation and validation. *Expert Systems with Applications*, 1995; 8: 419–428.
52. Gigerenzer, G. & Edwards, A. (2003). Simple Tools For Understanding Risks: From Innumeracy To Insight. *British Medical Journal*, 327, (7417), 741-744
53. Yardley, L., Ware, L. J., Smith, E. R., Williams, S., Bradbury, K. J., Arden-Close, E.J., Mullee, M. A., Moore, M. V., Peacock, J. L. Lean, M. E., Margetts, B. M., Byrne, C. D., Hobbs, R. F., & Little, P. (2014). Randomised controlled feasibility trial of a web-based weight management intervention with nurse support for obese patients in primary care. *The International Journal of Behavioral Nutrition and Physical Activity*, 11: 67
54. Brown, J., Michie, S., Geraghty, A.W., Yardley, L., Gardner, B., Shahab, L., Stapleton, J. A., & West, R. (2014). Internet-based intervention for smoking cessation (StopAdvisor) in people with low and high socioeconomic status: a randomised controlled trial. *The Lancet Respiratory medicine*, 2014; 2(12): 997-1006.
55. Michie, S., Abraham, C., Whittington, C., McAteer, J., & Gupta, S. (2009). Effective techniques in healthy eating and physical activity interventions: A meta-regression. *Health Psychology*, 28(6), 690-701. http://dx.doi.org/10.1037/a0016136
56. Michie, S., Whittington, C., Hamoudi, Z., Zarnani, F., Tober, G. & West, R. (2012), Identification of behaviour change techniques to reduce excessive alcohol consumption. *Addiction*, 107: 1431–1440. doi:10.1111/j.1360-0443.2012.03845.x
57. Carver, C. S., & Scheier, M. E. (1982). Control theory: a useful conceptual framework for personality-social, clinical, and health psychology. *Psychological Bulletin*, 1982, 92(1):111-35.
58. Nicolucci, A., Kovacs Burns, K., Holt, R. I. G., Comaschi, M., Hermanns, N., Ishii, H., Kokoszka, A., Pouwer, F., Skovlund, S. E., Stuckey, H., Tarkun, I., Vallis, M., Wens, J., Peyrot, M., & the DAWN2 Study Group. Diabetes Attitudes, Wishes and Needs second study (DAWN2™): Cross-national benchmarking of diabetes-related psychosocial outcomes for people with diabetes. *Diabetic Medicine*, 30, 767–777 (2013). http://dx.doi.org/10.1111/dme.12245
59. Kaltenthaler, E., Brazier, J., De Nigris. E., Tumur, I., Ferriter, M., Beverley, C., Parry, G., Rooney, G., & Sutcliffe, P. (2006). Computerised cognitive behaviour therapy for

ACCEPTED MANUSCRIPT

depression and anxiety update: a systematic review and economic evaluation. *Health Technology Assessment*, 2006;10(33):iii, xi-iii,168.

60. Cuijpers, P., van Straten, A., & Andersson, G. (2007). Internet-administered cognitive behavior therapy for health problems: a systematic review. Journal of Behavioral Medicine, 31(2), 169-177
61. Olthuis, J. V., Watt, M. C., Bailey, K., Hayden, J. A., & Stewart, S. H. (2015). Therapist-supported Internet cognitive behavioural therapy for anxiety disorders in adults. *The Cochrane Database of Systematic Reviews*, 2015, 5;(3):CD011565. doi: 10.1002/14651858.CD011565
62. Farrand, P., & Woodford, J. (2015). Effectiveness of Cognitive Behavioural Self-Help for the Treatment of Depression and Anxiety in People with Long-Term Physical Health Conditions: a Systematic Review and Meta-Analysis of Randomised Controlled Trials. *Annals of Behavioral Medicine*, 2015;49(4):579-93.
63. Pittaway, S., Cupitt, C., Palmer, D., Arowobusoye, N., Milne, R., Holttum, S., Pezet, R., & Patrick, H. (2009). Comparative, clinical feasibility study of three tools for delivery of cognitive behavioural therapy for mild to moderate depression and anxiety provided on a self-help basis. *Mental Health in Family Medicine*, 2009;6(3):145-54.
64. Carlick, A., & Biley, F. C. (2004). Thoughts on the therapeutic use of narrative in the promotion of coping in cancer care. *European Journal of Cancer Care*. 2004;13(4):308-17
65. Ziebland, S., & Wyke, S. (2012). Health and Illness in a Connected World: How Might Sharing Experiences on the Internet Affect People's Health? *The Milbank Quarterly*, 2012;90(2):219-49.
66. Wise, M., Han, J. Y., Shaw, B., McTavish, F., & Gustafson, D. H. (2008). Effects of using online narrative and didactic information on healthcare participation for breast cancer patients. *Patient Education and Counselling*, 2008;70(3):348-56.
67. Kreuter, M. W., Green, M. C., Cappella, J. N., Slater, M. D., Wise, M. E., Storey, D., Clark, E. M., O'Keefe, D. J., Erwin, D. O., Holmes, K., Hinyard, L. J., Houston, T., & Woolley, S. (2007). Narrative communication in cancer prevention and control: a framework to guide research and application. *Annals of Behavioral Medicine*, 2007;33(3):221-35.
68. Hinyard, L. J., & Kreuter, M. W. (2007). Using narrative communication as a tool for health behavior change: a conceptual, theoretical, and empirical overview. *Health Education & Behaviour*, 2007;34(5):777-92.
69. Herxheimer, A., McPherson, A., Miller, R., Shepperd, S., Yaphe, J., & Ziebland, S. (2000). Database of patients' experiences (DIPEx): a multi-media approach to sharing experiences and information. *Lancet*, 2000;355(9214):1540-3.
70. Slater, M. D., Buller, D. B., Waters, E., Archibeque, M., LeBlanc, M. (2003). A test of conversational and testimonial messages versus didactic presentations of nutrition information. *Journal of Nutrition Education and Behavior*. 2003;35(5):255-9.
71. Kummervold, P. E., Gammon, D., Bergvik, S., Johnsen, J. A., Hasvold, T., & Rosenvinge, J. H. (2002). Social support in a wired world: use of online mental health forums in Norway. *Nordic Journal of Psychiatry*. 2002;56(1):59-65.
72. Rogers, A., Vassilev, I., Sanders, C., Kirk, S., Chew-Graham, C., Kennedy, A., Protheroe, J., Bower, P., Blickem, C., Reeves, D., Kapadia, D., Brooks, H., Fullwood, C. & Richardson, G. (2011). Social networks, work and network-based resources for the management of long-term conditions: a framework and study protocol for developing self-care support. *Implementation Science*, 6:56. DOI: 10.1186/1748-5908-6-56

ACCEPTED MANUSCRIPT

73. Coulter, A., Entwistle, V., & Gilbert, D. (1999). Sharing decisions with patients: is the information good enough? *British Medical Journal*, 318(7179), 318–322.
74. Poduval, S., Ahmed, S., Marston, L., Hamilton, F., & Murray, E. (2018). Crossing the Digital Divide in Online Self-Management Support: Analysis of Usage Data From HeLP-Diabetes. *Journal of Medical Internet Research Diabetes* 2018;3(4):e10925

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Table 1: Participant characteristics for people with T2DM (N = 20)

Characteristic		Number of participants	%
Gender			
	Male	12	60
	Female	8	40
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 (African, Caribbean and Other)	4	20
	Asian (Indian)	1	5
	Other (Iranian)	1	5
Duration of diabetes			
	<1 year	2	10
	1-5 years	7	35

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	6-10 years	5	25
	>10 years	6	30
Diabetes management			
	Diet only	3	15
	Diet + tablets	10	50
	Diet + tablets + liraglutide injection	1	5
	On insulin	6	30
Home internet access			
	Yes	19	95
	No	1	5
Attended diabetes education			
	Yes	12	60
	No	8	40
Used the internet to look up diabetes related information			
	Yes	17	85
	No	3	15

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Table 2: Participant characteristics for Health Care Professionals (N = 18)

Characteristic		Number of participants	%
Gender			
	Male	7	39
	Female	11	61
Profession			
	GP Partner	3	17
	Salaried GP	5	28
	Practice nurse	2	11
	GP trainee	1	5
	Diabetes specialist nurse	3	17
	Dietitian	1	5
	Endocrinologist	2	11
	Diabetes nurse consultant	1	5
Ethnicity			
	White British	17	94
	Asian (Indian)	1	6

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Table 3: Users requirements from a digital self-management intervention to facilitate use and to improve health outcomes

	People with T2DM (N = 20)	Health Care Professionals (N = 18)
Likes/Features to include	- Lots of information provision (e.g. medical, dietary, physical activity, alternative medicine, pregnancy, health services, practical advice about day to day living with diabetes including dealing with emotions) - Tools to track self-monitoring data - Links to other useful websites - Ask the Expert function - Frequently Asked Questions - Personal stories - Quizzes to test knowledge and provide feedback	- Tailored Information and advice - Patient stories - Help with emotional management - Summary data for each user
Dislikes/Barriers to use	- Messy/Lots of writing - Non-British - Complicated/medical language - Broken links - Difficult to navigate - Advertisements	- Increase workload - Negative impact on HP-Pt relationship - Limited reach/increasing the digital divide
Presentation	- Consistent format - Easy to navigate - Minimise scrolling - Pages can be printed - Up to date - Colourful - Clear, concise, accessible language - Interactive and visual (e.g. quizzes, videos, images)	- Simple - Interactive and Visual (e.g. graphics and videos)
Tone	- Positive (e.g. what I can do rather than cannot do) - Encouraging and Supportive - Fun - Humorous - Professional	- Positive - Motivating
Engagement	- Easy to use - Trust content (e.g. recommended by HP or recognised body - Tailored to them - Features to enable sharing with others (e.g. forum) - Features to improve communication with HPs (summary printouts of health information in one place) - Email/Text prompts (e.g. content updates, encouragement, appointments, prescriptions)	- Time saving - Patient led - Effective (e.g. positive outcome data such as improved glucose control, blood pressure etc.) - Incentives (e.g. fits with the Quality and Outcomes Framework) - Fits in with current practice (e.g. care planning framework).

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Table 4: How theory, qualitative data from target users, and evidence-based techniques or strategies were mapped on to HeLP-Diabetes overall components.

Key Tasks to self-management identified by Corbin & Strauss (1988)	Initial User Requirements from qualitative data	Mapped Intervention Components	Behaviour Change Techniques and digital health interventions identified by the literature = RED Behaviour Change Techniques identified by users = BLUE Behaviour Change Techniques identified by both = GREEN
1. Medical Management Example tasks that were targeted • Increasing knowledge • Changing cognitions: - Beliefs about capabilities • Changing Behaviours: - Taking medications - Increasing physical activity - Smoking cessation	• What foods to eat/avoid • Weight loss • Physical activity • Pregnancy • Tools to monitor calories, activity levels, blood glucose levels (e.g. self-monitoring) • Care Planning Tools (e.g. goal setting and action planning) • Email prompts/reminders for encouragement	**Understanding diabetes** • What is diabetes • How my body can be affected **Staying healthy** • Why is lifestyle important? • Looking after yourself	• Information provision *Each component (physical activity, taking medicines and eating & drinking) had the following content*

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- Drinking in moderation - Eating healthily - Checking feet and eyes - Self-monitoring blood glucose levels • Managing interactions with health professionals		• Physical activity • Taking Medicines • Eating & Drinking	Understand - Information provision (on consequences of behaviour in general and to the individual; on when and where to perform the behaviour) - Instructions on how to perform behaviours Decide - Self-assessment - Provide feedback on current behaviour (15; 56-57) Plan - Action Planning (56-57) - Goal Setting (behaviour) (56-57) - Problem Solving/Barrier (56-57) identification Staying Motivated - Prompt Self-monitoring (behaviours) (15; 56-57) - Prompt review of behavioural goals (56-57) - Provide feedback (15; 56-57) - Prompt self-rewards - Teach to use prompts

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	• Medicines (what they do; how to take them; potential side effects) • Expected tests & checks & what the results mean • Complementary medicines • Health services available	• Losing weight • Alcohol • Smoking • Working with my diabetes team	• PoWER (53) • Down Your Drink (29-30) • StopAdvisor (54) • Information provision
	• Summary of health data • Email/text reminders about appointments	**Treating diabetes** • How is type 2 diabetes treated? • Tests to monitor diabetes • Medicines • Surgery • Complementary medicines • Vaccinations and immunisations • How the NHS can help	• Information provision following the latest NICE pathways and guidelines (7) • Information on where and when to take medicine; side effects of medicines; any changes to lifestyle; and what the medicine does (44) • Provide instruction on how to perform the behaviour (e.g. inject insulin)

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		My Health Record • My diabetes care plan • My appointments • My health tracker • My test results • My medicines • My reminders	• Action Planning (56-57) • Goal Setting (behaviour) (56-57) • Problem Solving/Barriers identification (56-57) • Prompt Self-monitoring of behaviour (15; 56-57) • Teach to use prompts
2. Emotional Management Learning to manage the many emotions that are commonly experienced by someone with a long term condition. For example: • Emotions & Cognitions - Anger - Fear and Anxiety - Frustration - Sadness and Depression - Denial - Self-efficacy - Intentions	• Information about how diabetes and feelings are related • Information on how to manage difficult feelings • Focusing on the positive (what can I do rather to improve my condition rather than what can't I do) • Information about other people's experiences of diabetes & mood (e.g. people's stories) • Ability to communicate with other people with diabetes as well as health professionals (e.g. Forum and Ask the Expert)	**Managing my feelings** • Understanding my moods • My mood tools **Forum & help** • Forum • Useful resources • People's stories • FAQs	• Information provision • Self-assessment • Computerised Cognitive Behavioural Therapy (Living Life to the Full) (59-63) • Social support (64-65) • Provide normative information about others • HealthTalk Online (69) • Information Provision
3. Role Management Maintaining, changing, and creating new	• Diabetes & shift work • Eating out and at special occasions • Information for friends and	**Living and Working with diabetes** • Food	• Information Provision

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behaviours or life roles. For example: • Environment - Changing work patterns, travel arrangements, day to day activities • Cognitions - Adopting a new identity or role.	families • Practical information about travel and health insurance and driving regulations • Ability to communicate with other people with diabetes as well as health professionals (e.g. Forum) • Signpost/links to useful organisations • Information about other people's experiences of diabetes & day to day living (e.g. people's stories) • FAQs list	• Relationships • Work • Social life • Travel • Driving • Financial support **Forum & help** • Forum • Useful resources • People's stories • FAQs	• Social support (64-65) • Provide normative information about others • Information Provision • HealthTalk Online (69)

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Annex 1: description of the intervention.[1]

Content

The overall content was broken down into 8 sections developed to improve medical, emotional and role management. The key features in each section are described and shown below.

1. ***Understanding diabetes***
   This section focused on improving people's medical management by increasing their knowledge about diabetes, targeting beliefs about diabetes and encouraging behaviour change. Information was provided to answer a number of common questions about diabetes (e.g. the nature and causes of diabetes, see Figure 1).

Figure 1: Understanding diabetes - An example of the information provided on what causes type 2 diabetes

Information was provided on how diabetes affects the body including: emotional problems; eyes; feet; heart and blood vessels; hyperglycaemia; hypoglycaemia; infections; kidneys, nervous system; and sexual problems. For each area this included an overview, advice on actions that could be taken to prevent complications occurring, checks and tests to expect, associated complications and treatments, and links to

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external organisations (e.g. Society of Chiropodists and Podiatrists; NHS SmokeFree). An example for eyes is show in Figure 2 below.

Figure 2: Understanding diabetes - An example of the information provided on how diabetes can affect the eyes including an overview, prevention, checks and tests, complications, treatment and links.

There were also a number of structured quick guides that were developed to summarise the most important content across the sections in the intervention on a number of topics. These included: About type 2 diabetes; Understanding medicines; Eating with type 2 diabetes; African and Caribbean diets; Quitting smoking; and Alcohol. Each quick guide included the same quiz at the beginning and end to assess any changes in people's

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knowledge and to provide feedback. In-between, individuals worked through a number of steps that presented them with written information about the topic and strategies to make behavioural changes (e.g. making plans, setting goals) as well as information in video format. Each guide was designed to take approximately 15 minutes to complete. An example for About type 2 diabetes is shown in Figure 3.

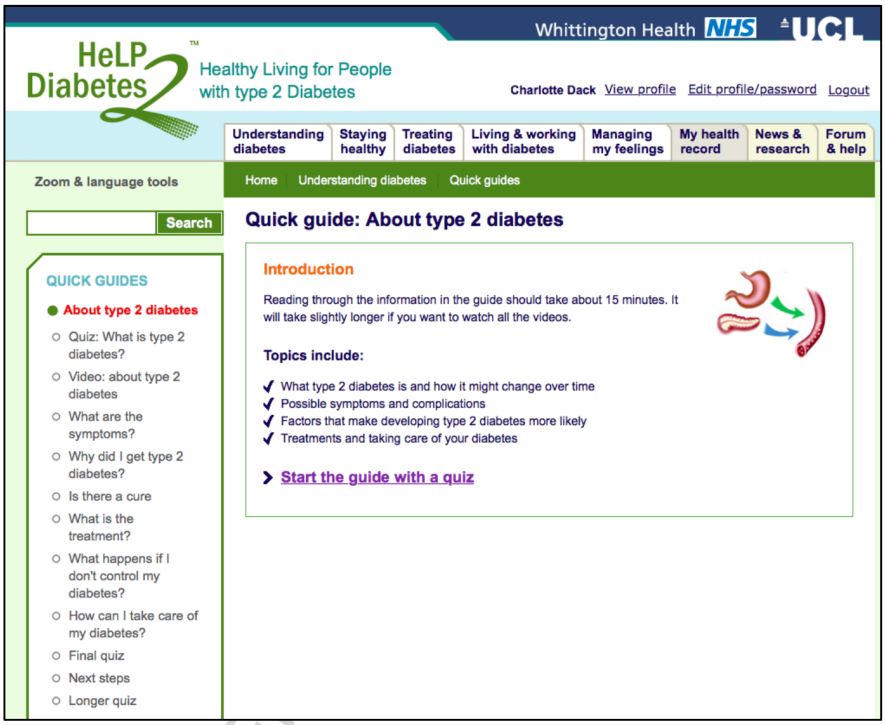

Figure 3: Understanding diabetes - An example of a quick guide for people to learn 'About type 2 diabetes'. The steps to work through include a quiz to assess knowledge and to give feedback, information about diabetes in written and video format including changes people could make to take care of their diabetes.

2. ***Staying healthy***

This section contained motivational information about how to maintain optimal physical and emotional health and the importance of lifestyle factors and self-management (see Figures 4 & 5). The main focus was on helping people improve their medical management by providing them with behaviour change techniques or previously validated behaviour change interventions that had been shown to be effective. The behaviours targeted were eating and drinking, levels of physical activity, alcohol consumption, smoking and taking medicines as well as weight management. Each behaviour change module consisted of the following headings: Understand; Decide; Plan; Staying Motivated. The section titled "Understand" provided people with information on the physical and emotional benefits of changing behaviour and ideas on

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how a change might be made (see Figure 6). Written instructions of how to perform each behaviour or videos showing people performing the behaviour were also provided (see Figure 7). In the "Decide" section people could complete self-assessment quizzes (see Figure 8) and receive feedback on whether their current behaviour could be improved in any way. The feedback directed users via links to relevant information in the intervention (see Figure 9).

Figure 4: Staying healthy – An example of information provided on why lifestyle factors are important to self-management

The "Plan" section encouraged users to commit to set a behavioural goal if the feedback from the self-assessment quiz suggested a change might be beneficial in managing their diabetes. They could either choose from a list of popular goals or add their own. To keep users motivated to change they were asked to think about their reasons for changing and to reflect on whether the goal was really important to them (see Figure 10). After choosing a goal users were asked to make an action plan on how they were going to

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achieve the goal. Users could choose prepopulated plans or they were given information on how to create their own. They were asked to commit to a date to start the plan (see Figure 11). Finally users were asked to review their goal and plan and to think about possible barriers to achieving them and potential solutions to these barriers (see Figure 12).

Figure 5: Staying healthy - An example of information provided on ideas of changes that could improve users diabetes control.

In the "Staying Motivated" section to help people keep to the goals and plans that had been set users were encouraged to reward themselves when successful, to remember the reasons they decided to make a change in the first place, to tell someone about their goal in order to receive support, to monitor their progress using the health tracker feature of the intervention and to aim to make one change at a time (Figure 13 below). Users were also encouraged to review their goals and plans rating how successful they were at achieving them (Figure 14). The intervention provided motivating messages based on the rating chosen (see Figure 15).

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Figure 6: Staying healthy: Understanding behaviour - An example of the information provided about the physical and emotional benefits of performing a behaviour (e.g. taking medicines).

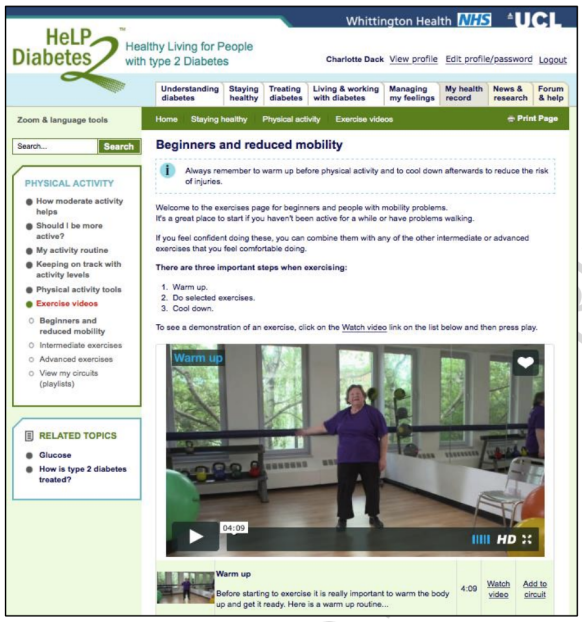

Figure 7: Staying healthy: Understanding behaviour - An example of the videos providing instructions and demonstrations of how to perform a behaviour (e.g. physical activity exercises for beginners)

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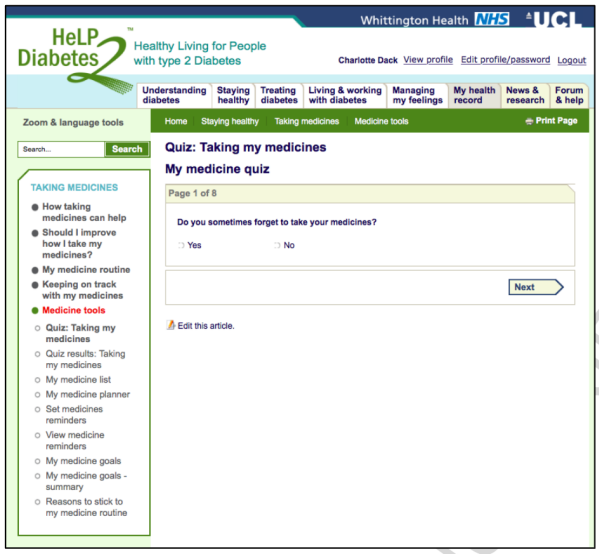

Figure 8: Staying healthy: Making a decision – An example of a self-assessment quiz for taking medicines.

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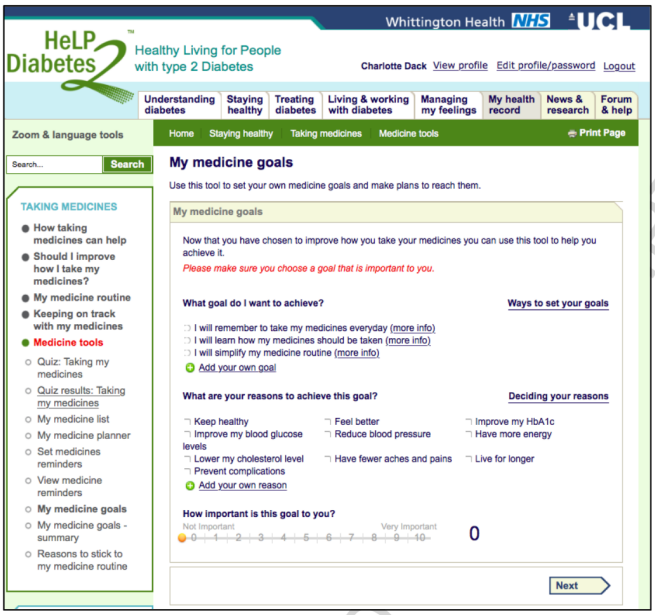
Figure 9: Staying healthy: Making a decision – An example of feedback for a user who is finding it difficult to take their medicines (at the top) and for someone who is on the whole



taking them as prescribed (bottom).

Figure 10: Staying healthy: Plan a change – An example of setting a behavioural goal and reasons for change for taking medicines.

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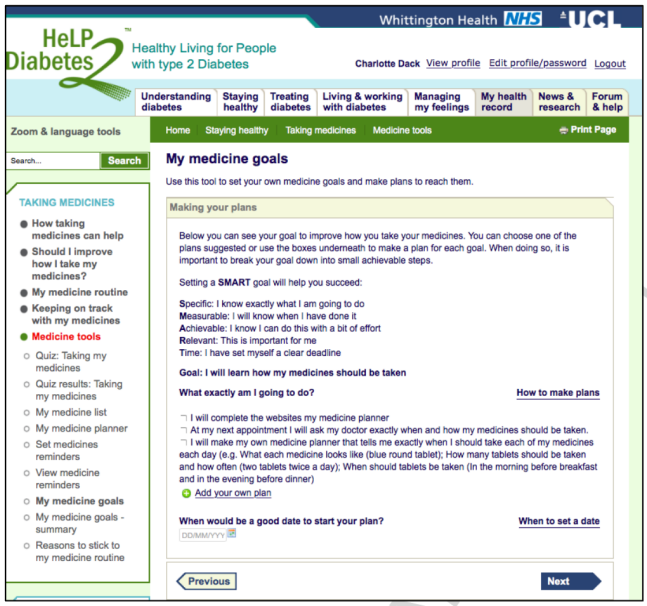

Figure 11: Staying healthy: Plan a change – An example of making an action plan and start date for taking medicines.

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Figure 12: Staying healthy: Plan a change – An example of reviewing goals and plans and problem solving for taking medicines.

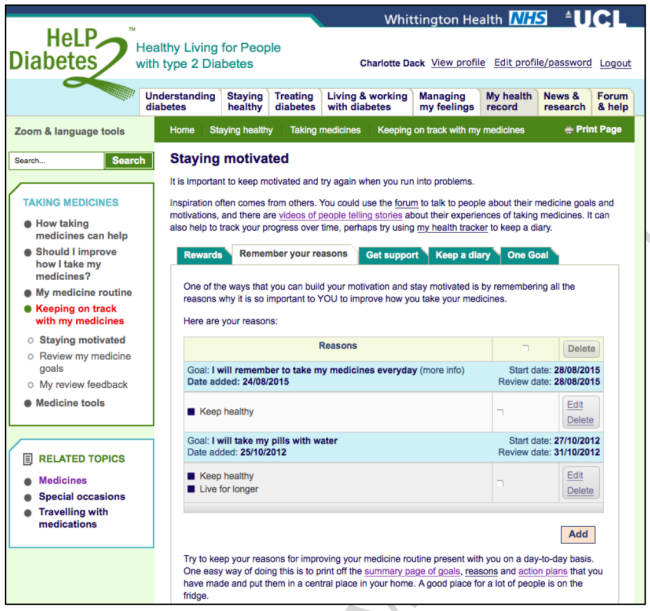

Figure 13: Staying healthy: Keeping on track – An example of the techniques provided to keep motivated with the goals and plans set for taking medicines.

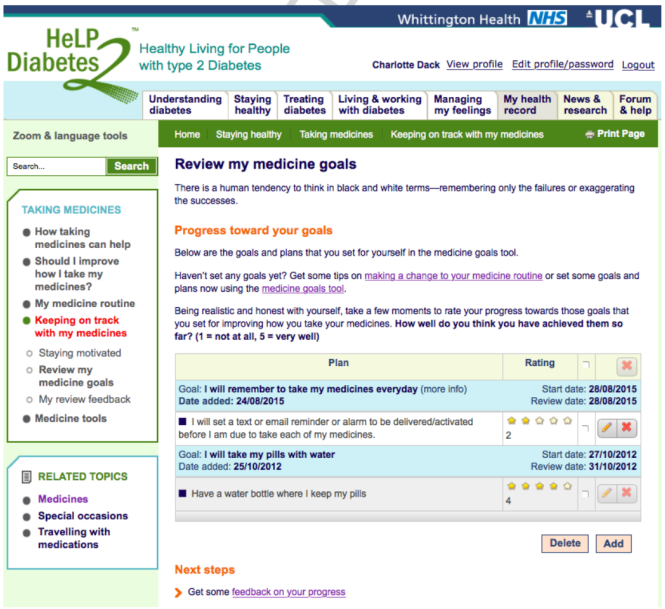

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Figure 14: Staying healthy: Keeping on track – An example of the tool provided for users to review their process with the goals and plans set.

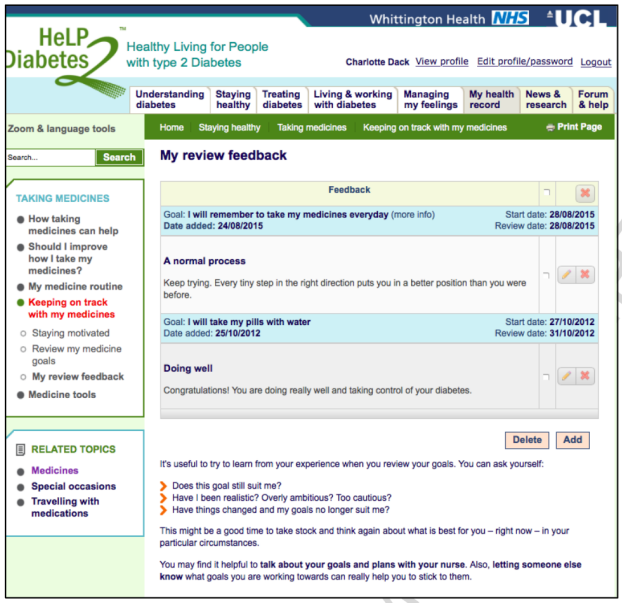

Figure 15: Staying healthy: Keeping on track – An example of the motivational feedback given to users based on their progress ratings for their goals and plans.

This section also provided users with information about how to work with their diabetes team (see Figure 16).

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Figure 16: Staying healthy – Information on how to interact with people involved in diabetes care.

3. ***Treating diabetes***

This section provided users with information about how diabetes and its related complications are treated. This included detailed information about a wide range of medicines (including why and how to take it, possible side effects and iteractions with alcohol and information about indications) for blood pressure, cholestetol, glucose control, neuropathy, sexual problems and weight loss. An example for Metformin is shown in Figure 17.

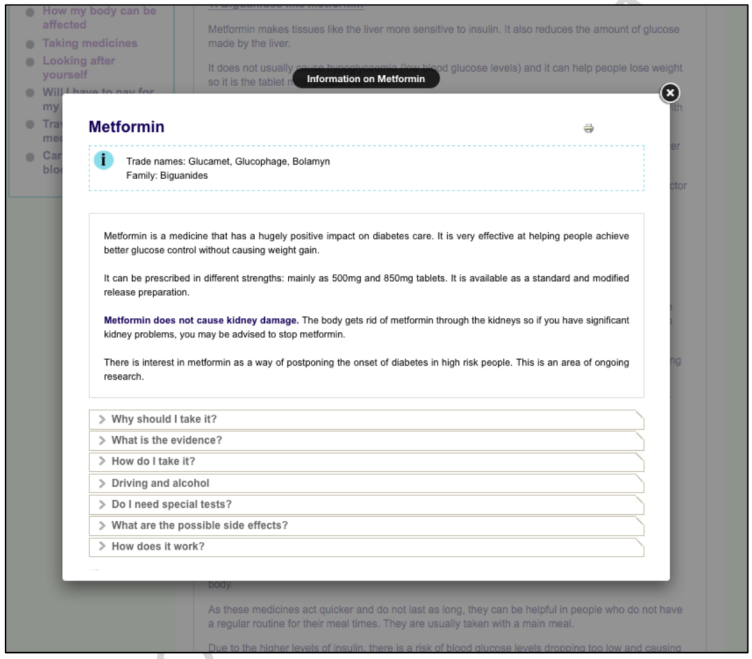

Figure 17: Treating diabetes – An example of the information provided for diabetes related medines using the example of Metformin.

Information was provided about the importance of managing cardiovascular risk factors as well as glycaemic levels and the types of monitoring and tests to expect (blood glucose, HbA1c, blood pressure, cholesterol, kidney fuction, weight) and what the results mean (see Figure 18). Information was also provided on potential surgical procedures (e.g. bariatric & vascular), complementary medicine and vaccinations and immunisations. In addition information about the types and roles of different health care professionals involved in caring for people with diabetes and what to expect from the yearly check was provided (see Figure 19).

4. ***Living and working with diabetes***

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The aim of this section was to focus on helping people with their role management including: managing social situations such eating in special circumstances (see Figure 20), travelling and holidays and driving; managaing work situations, such as shift work (see Figure 21); and managing relationships, including sexual relationships (see Figure 22) and and the possible impact on emotions and feelings of self-worth.

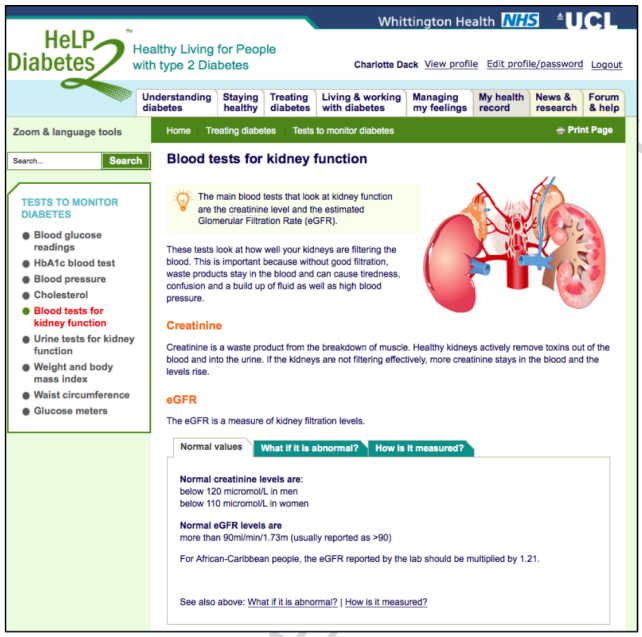

Figure 18: Treating diabetes – An example of the information provided on the type of test to expect and what the values of the results mean

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Figure 19: Treating diabetes – An example of the information provided on health care professionals and what to expect from the early checkup

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Figure 20: Living and working with diabetes – Information provision on how to manage eating at celebrations

Figure 21: Living and working with diabetes – Information provision on how to manage changes at work.

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Figure 22: Living and working with diabetes – Information provision on how to manage changes in sexual relationships

5. ***Managing my feelings***

The aim of this section was to support people to manage the emotions associated with having diabetes. Information was provided on how to cope with sadness and depression, fear and anxiety, anger and resentment, denial and guilt. There was also information on actions to take to increase feelings of confidence and happiness. In addition there were mood tools that included self-assessment quizzes for identifying low mood (see Figure 23), 8 cognitive behavioural therapy audio modules with e-books, worksheets, and planner and review sheets (see Figure 24) and mindfulness-based approaches.

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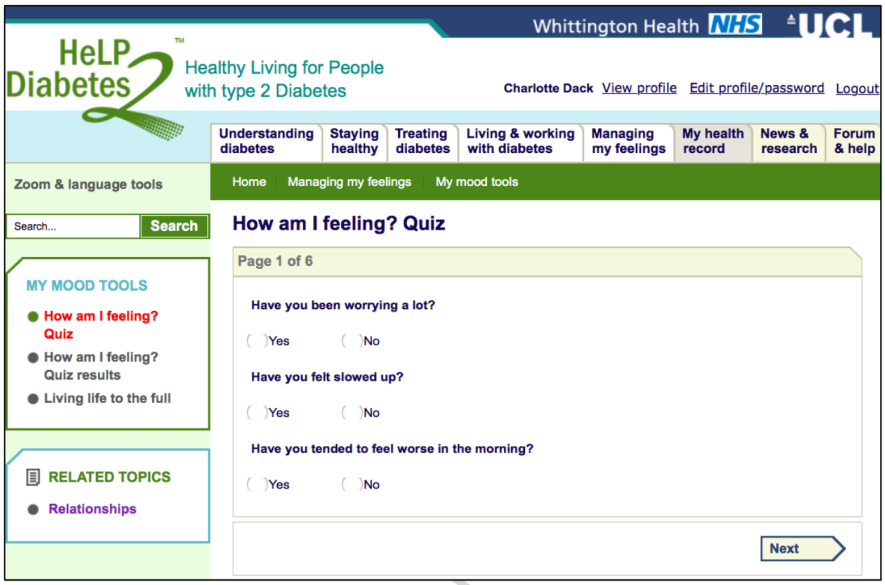

Figure 23: Managing my feelings – a self-assessment quiz to provide feedback about a users current mood.

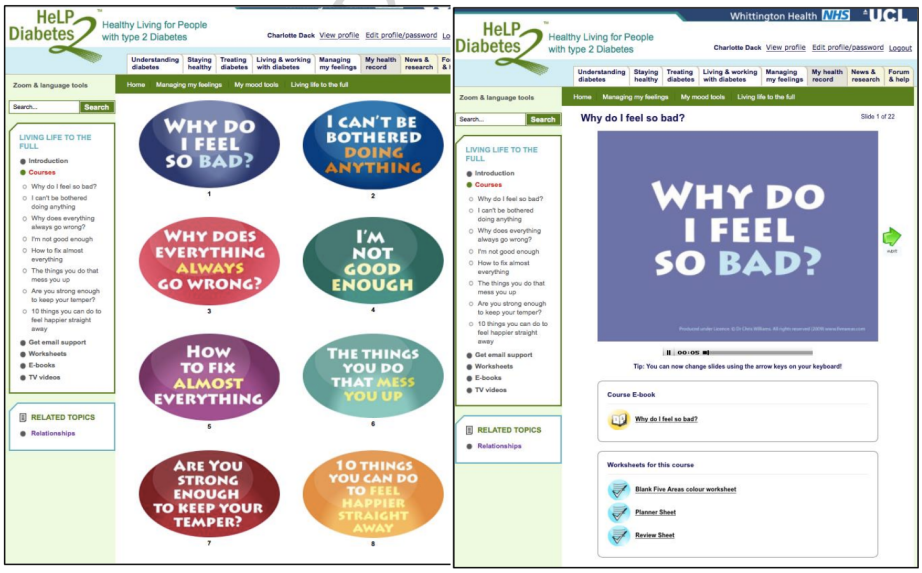

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Figure 24: Managing my feelings – examples of the cognitive behavioural therapy audio courses and associated materials

6. My health record

In this section users had the opportunity to record and keep track of important appointments with health care professionals (see Figure 25) and the results of tests used to monitor diabetes (e.g. HbA1c, blood pressure, cholesterol, kidney and liver function) with opportunity for graphical displays and feedback (see Figure 26).

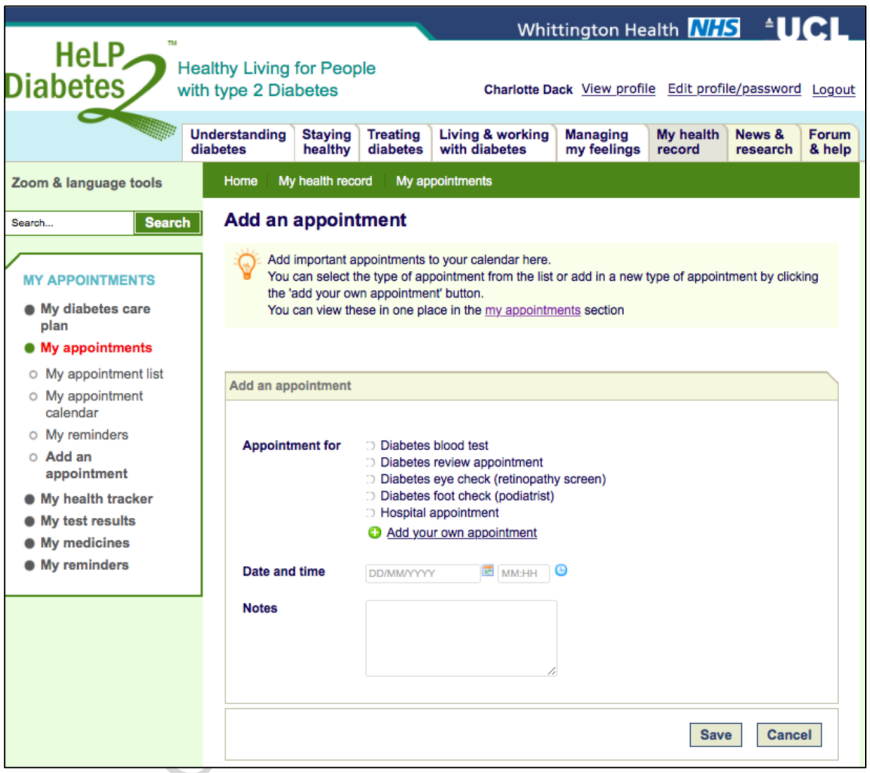

Figure 25: My health record – An example of the tools available to record appointments with health care professionals.

Users could track the results of their own self-monitoring for weight, waist circumference, calorie intake, alcohol consumption and physical activity and blood glucose levels (see Figure 27) and keep a list of all their current medicines (see Figure 28). Text or email reminders could be added to prompt people about their appointments, to take their medicines or to remind them about any goals or plans set in the Staying healthy section (see Figure 29). All of this information could also be found or added in one place called my diabetes care plan (see Figure 30).

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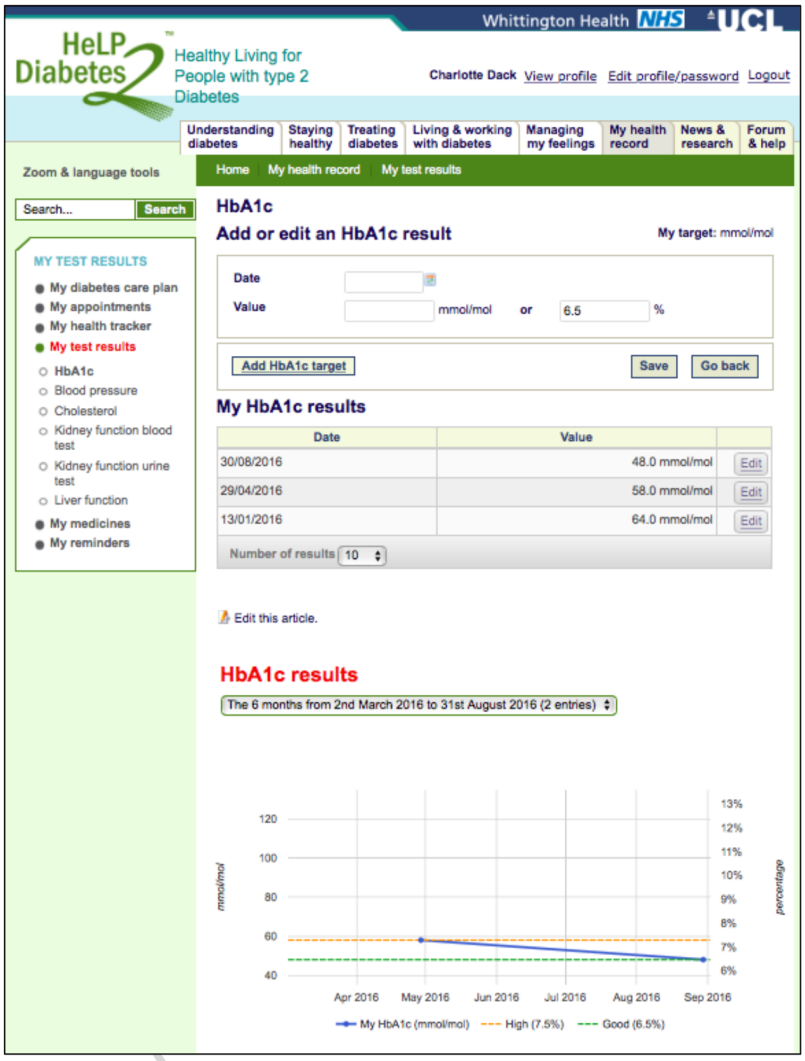

Figure 26: My health record – An example of how users could add their diabetes test results. These could be displayed graphically with feedback about what the tests meant.

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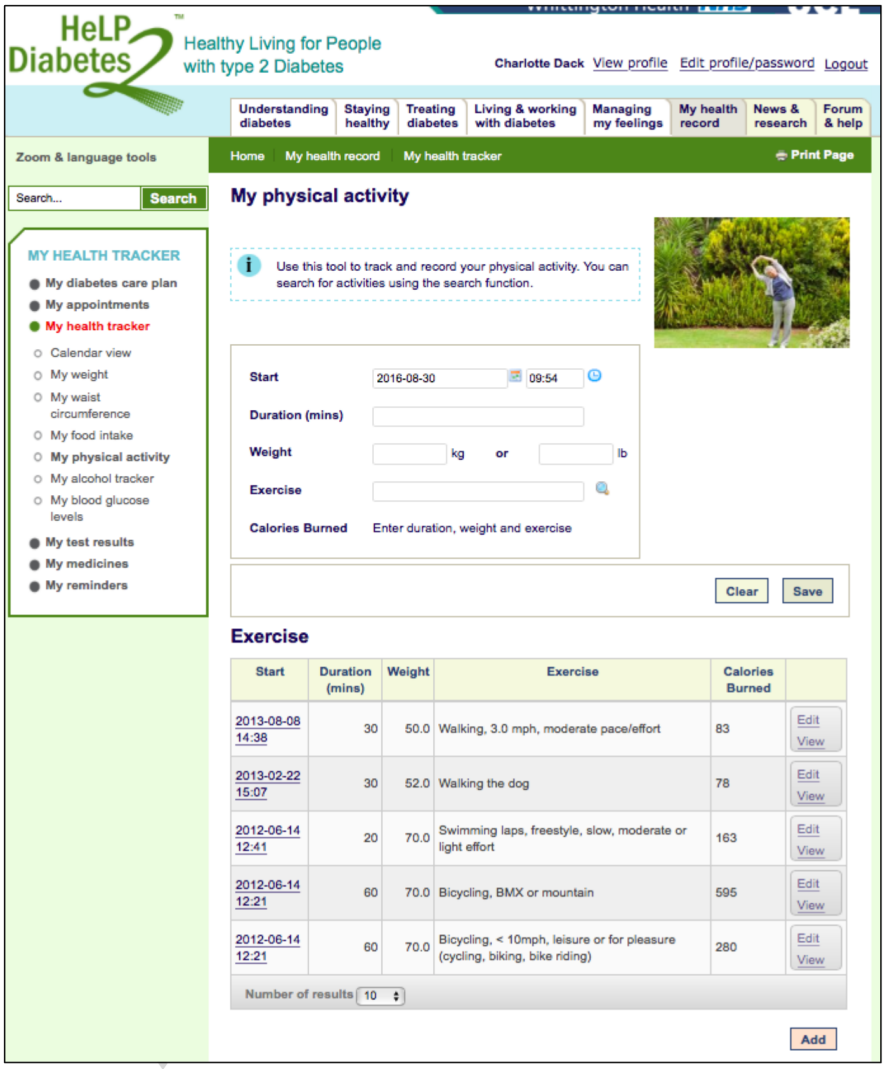

Figure 27: My health record – User could add data that might be monitored at home for example levels of physical activity

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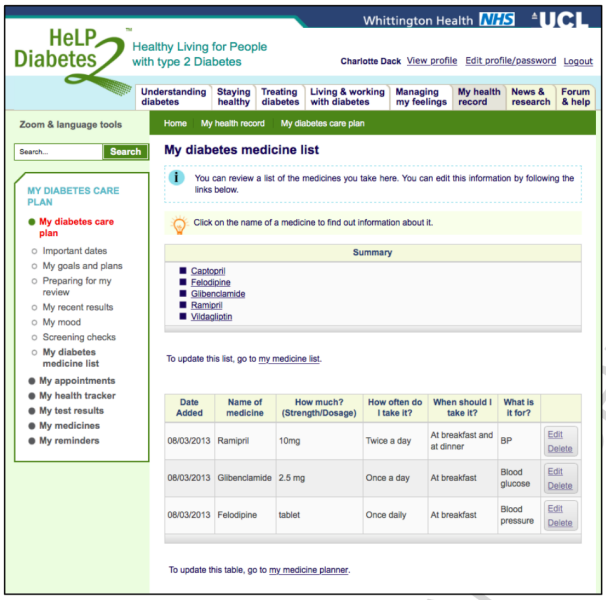

Figure 28: My health record – Users could record their current medicine list with an action plan of how to take each one.

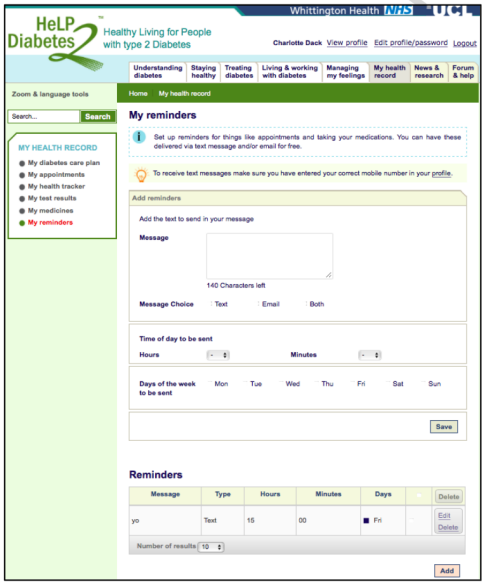

Figure 29: My health record – Email or text reminders could be set to prompt users about appointments or to take their medicines etc.

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Figure 30: My health record – Any information about appointments, test results, medicines and goals and plans set were recorded in a diabetes care plan.

7. *News and Research*

In this section there was information about diabetes related news articles that had appeared in the media (Figure 31), updates about the latest diabetes research (see

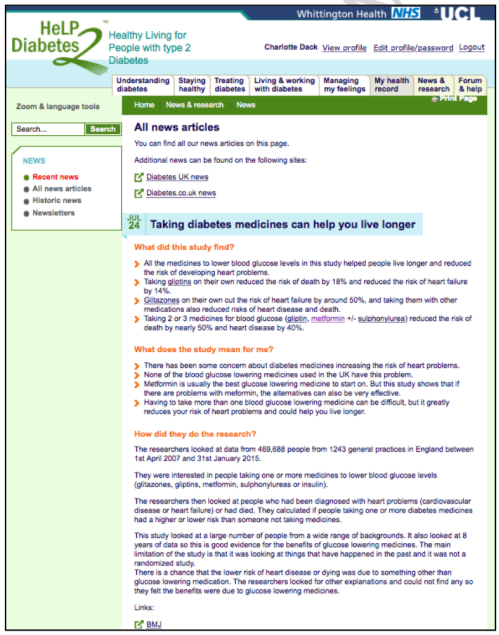

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Figure 31: News and Research – An example of the information provided about diabetes related news articles

Figure 32) and information about concerns with specific medicines (Figure 33). In depth information was also provides on articles about seminal research papers.

Figure 32: News and Research – Information provided about diabetes related research.

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Figure 33: News and Research – Information provided about concerns with diabetes related medicines.

8. ***Forum and Help***

The content in this section aimed at improving people's emotional and role management. There was a moderated forum which included an 'ask the expert' section (see Figure 34), videos of personal stories about diabetes (used with license from health talk online – see Figure 35), useful resources, with local resources tailored according to CCG (Figure 36), and a list of frequently asked questions (Figure 37).

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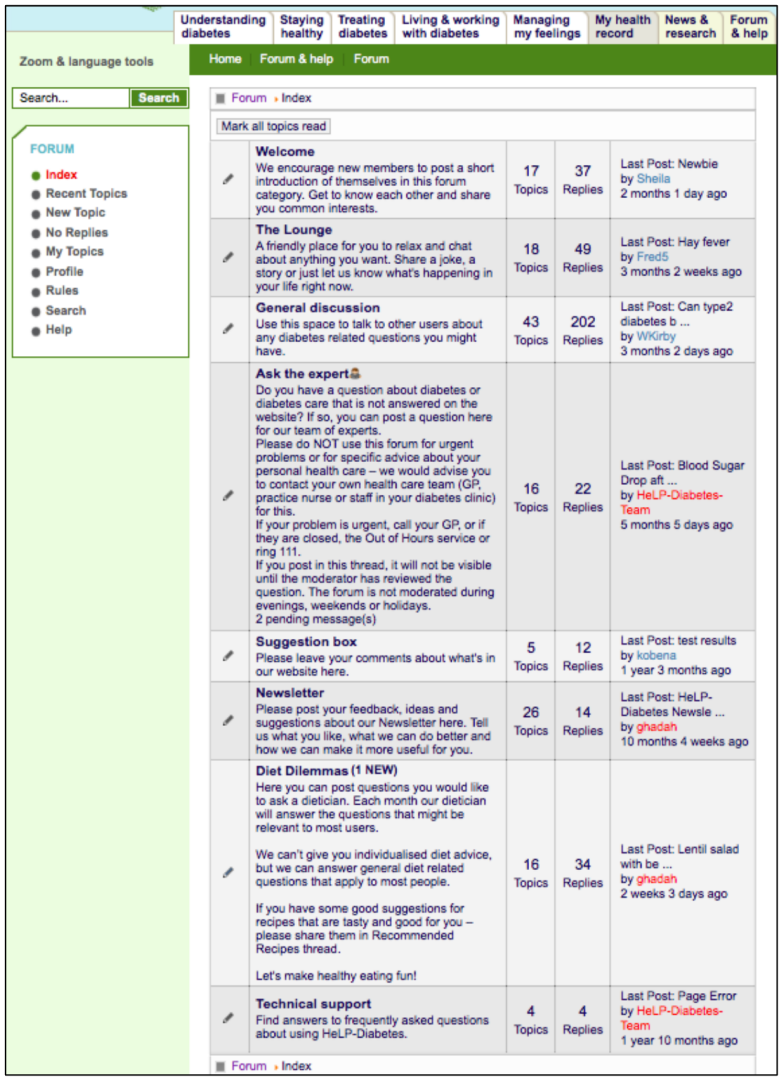

Figure 34: Forum & help – Users could interact with other users and ask health professionals question through a moderated forum.

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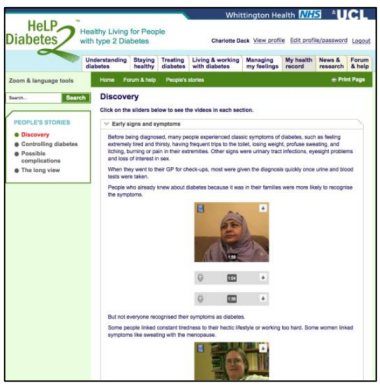

Figure 35: Forum & help – Videos, audios and transcripts of people with type 2 diabetes discussing their experiences on a range of topics including the discovery of the diagnosis, controlling diabetes, possible complications and living and working with diabetes.

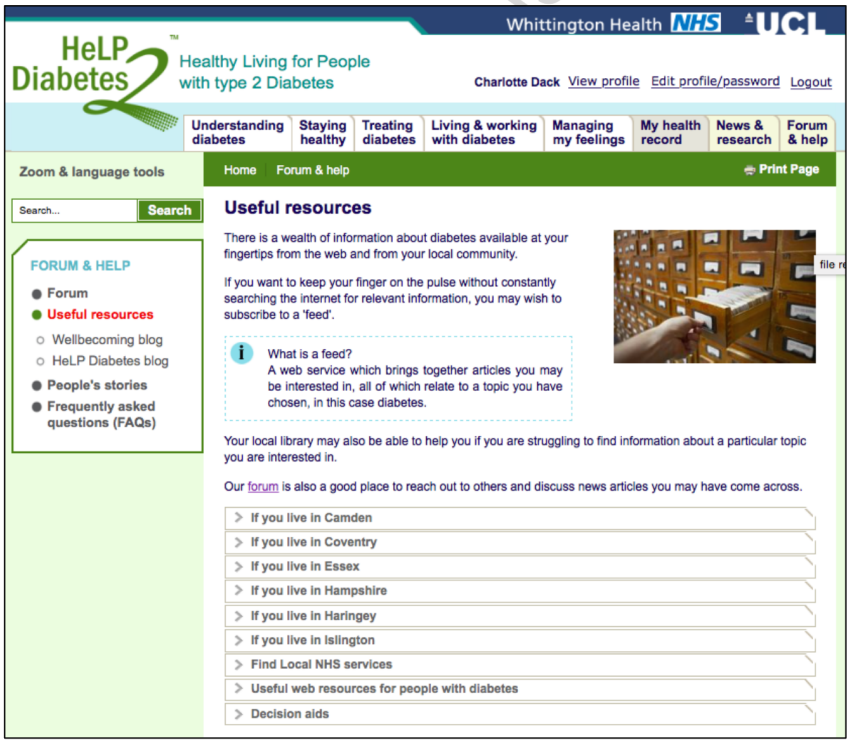

Figure 36: Forum & help – Useful resources (e.g. local groups and facilities such as free internet access) available in each CCG.

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Figure 37: Forum & help – Users were given the answers to some frequently asked questions about diabetes and using the intervention.

Appendix 2: Sitemap of HeLP-Diabetes

1 Main Menu

- Understanding||diabetes
  - Common diabetes questions
    - What is type 2 diabetes?
      - Overview
      - Diagnosis
      - Glucose
      - What happens inside the body?
      - The pancreas
      - Insulin
    - What causes type 2 diabetes?
    - What happens if I don't control my diabetes?
    - How can I take care of myself?
    - What is self-management?
      - What skills do I need?
      - How can I share decisions?
      - What is an expert patient?
    - Are there other types of diabetes?
    - Why learn more about diabetes?
    - Who gets type 2 diabetes?

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- Is there a cure?
- What is pre-diabetes?

- How my body can be affected
  - Emotional problems
    - Overview
    - Prevention
    - Checks & tests
    - Complications
    - Treatment
    - Support
  - Eyes
    - Overview
    - Prevention
    - Checks & tests
    - Complications
    - Treatment
    - Links
  - Feet
    - Overview
    - Prevention
    - Checks & tests
    - Complications
    - Treatment
    - Links
  - Heart and blood vessels
    - Overview
    - Prevention
    - Checks & tests
    - Complications
    - Treatment
    - Links
  - Hyperglycaemia
    - Overview
    - Prevention
    - Checks & tests
    - Complications
    - Treatment
  - Hypoglycaemia (hypos)
    - Overview
    - Prevention
    - Checks & tests
    - Complications
    - Treatment
  - Infections
    - Overview
    - Prevention
    - Checks & tests
    - Complications

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        - Treatment
        - Links
    - Kidneys
        - Overview
        - Prevention
        - Checks & tests
        - Complications
        - Treatment
        - Links
    - Nervous system
        - Complications
        - Treatment
        - Links
        - Overview
        - Prevention
        - Checks & tests
    - Sexual problems
        - Overview
        - Prevention
        - Checks & tests
        - Complications
        - Treatment
        - Links
- Quick guides
    - About type 2 diabetes
        - Quiz: What is type 2 diabetes?
        - Video: about type 2 diabetes
        - What are the symptoms?
        - Why did I get type 2 diabetes?
        - Is there a cure
        - What is the treatment?
        - What happens if I don't control my diabetes?
        - How can I take care of my diabetes?
        - Final quiz
        - Next steps
        - Longer quiz
    - Understanding medicines
        - Quiz: Understanding medicines
        - Understanding medicines
        - Why take medication?
        - Reasons for taking medicines
        - Common medicines
        - Insulin
        - Special situations
        - Tips for taking medicines
        - Final quiz
        - Next steps
    - Eating with type 2 diabetes

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        - Enjoying a healthy balanced diet
        - Eight steps to healthy eating
        - Step 1: eat three meals a day
        - Step 2: eat five portions of fruit and vegetables a day
        - Step 3: cut down on sugar
        - Step 4: cut down on fat
        - Step 5: eat oily fish
        - Step 6: reduce your alcohol intake
        - Step 7: eat less salt
        - Step 8: avoid diabetic products
        - Next steps
    - African and Caribbean diets
        - Food in Black African-Caribbean communities
        - Enjoying a healthy balanced diet
        - Eight steps to healthy eating
        - Step 1: eat three meals a day
        - Step 2: eat five portions of vegetables and fruit a day
        - Step 3: cut down on starch and sugar
        - Examples of healthier meals
        - Try this quiz
        - Step 4: cut down on fat
        - Step 5: eat oily fish
        - Step 6: reduce your alcohol intake
        - Step 7: eat less salt
        - Step 8: avoid special diabetic foods
        - Next steps
    - Quitting smoking
        - Quitting smoking
        - Reasons to quit:1
        - Reasons to quit: 2
        - Your smoking habits
        - Smoking routines
        - Make a plan
        - Difficult situations
        - Trying again
        - Next steps
    - Alcohol
        - Alcohol & diabetes
        - Cutting down
        - Health risks: blood glucose
        - Other health risks
        - Setting goals
        - Practical strategies
        - Slipping up
        - Next steps
- Staying||healthy
    - Why is lifestyle important?
    - Looking after yourself

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- Physical activity
  - How moderate activity helps
  - Should I be more active?
    - Advice about increasing physical activity
  - My activity routine
  - Keeping on track with activity levels
    - Staying motivated on fitness
    - Review my fitness goals
    - My review feedback
  - Physical activity tools
    - Quiz: How active are you?
    - Quiz Results: How active are you?
    - My activity goals
    - My activity goals - summary
    - Set activity reminders
    - View activity reminders
    - My physical activity tracker
  - Exercise videos
    - Beginners and reduced mobility
    - Intermediate exercises
    - Advanced exercises
    - View my circuits (playlists)
- Taking medicines
  - How taking medicines can help
  - Should I improve how I take my medicines?
  - My medicine routine
    - Forgetting your medicines
    - Suffering from side effects
    - Goal setting & making plans
  - Keeping on track with my medicines
    - Staying motivated
    - Review my medicine goals
    - My review feedback
  - Medicine tools
    - Quiz: Taking my medicines
    - Quiz results: Taking my medicines
    - My medicine list
    - My medicine planner
    - Set medicines reminders
    - View medicine reminders
    - My medicine goals
    - My medicine goals - summary
    - Reasons to stick to my medicine routine
- Eating & drinking
  - How food choices can help
    - Practical diet advice
    - Seeing a dietitian
  - Should I lose weight?

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        - Getting started ✓
    - Changing what I eat ✓
        - Consider your diet goals ✓
    - Keeping on track with my food ✓
        - Staying motivated with my diet goals ✓
        - What if I break my diet? ✓
        - Review my diet goals ✓
        - My review feedback ✓
    - 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 ✓
- Alcohol ✓
    - How alcohol can affect your health ✓
        - Drinking & type 2 diabetes ✓
        - Common problems with alcohol ✓
    - Should I cut down on alcohol? ✓
        - Safe drinking guidelines ✓
        - How much do other people drink? ✓
        - Benefits & costs of my drinking ✓
        - Binge drinking ✓
    - Cutting down ✓
        - Goal setting and making plans ✓
        - What are my drinking patterns? ✓
        - What's the best change to make? ✓
        - Reasons to cut down on alcohol ✓
        - Alcohol withdrawal ✓
        - Refusing drinks ✓
        - Assertiveness ✓
        - Dealing with cravings ✓
        - Alcohol and relationships ✓
        - Handling risky situations ✓
    - Keeping on track with my alcohol plan ✓
        - Staying motivated ✓
        - Lapses ✓
        - Sometimes I want to give up ✓
        - Review my drinking goals ✓
        - My review feedback ✓
    - Tools for cutting down on alcohol ✓
        - Quiz: Am I drinking too much? ✓
        - Quiz results: Am I drinking too much? ✓
        - My alcohol tracker ✓
        - My alcohol risk ✓

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        - My goals to cut down on alcohol
        - My goals to cut down on alcohol - summary
        - Reasons for cutting down my drinking
        - Set alcohol reminders
        - View alcohol reminders
    - Smoking
        - StopAdvisor
    - Working with my diabetes team
- Treating||diabetes
    - How is type 2 diabetes treated?
        - Lifestyle changes
        - Reducing blood glucose levels
        - Treating related problems
    - Tests to monitor diabetes
        - Blood glucose readings
        - HbA1c blood test
        - Blood pressure
        - Cholesterol
        - Blood tests for kidney function
        - Urine tests for kidney function
        - Weight and body mass index
        - Waist circumference
        - Glucose meters
    - Medicines
        - Why take medicines?
            - Feel better
            - Improve blood glucose levels
            - Protect your organs
        - Concerns about taking medicines
        - Blood pressure tablets
        - Cholesterol tablets
        - Glucose control
            - Tablets to lower blood glucose
            - Injectable medicines
        - Insulin: the basics
            - Introduction
            - Common concerns
            - Types of insulin
            - Injection regimes
            - History
        - Starting on Insulin
            - What does it involve?
            - Insulin pens
            - Injecting insulin
            - Self-monitoring on insulin
        - Managing nerve pain
        - Tablets for problems with sex
        - Tablets to thin the blood

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        - Using medicines in special situations
            - When I'm sick
            - When fasting
            - When exercising
            - Before surgery
            - Before scans
        - Weight loss
    - Surgery
        - Bariatric surgery
        - Vascular surgery
    - Complementary medicine
        - Benefits of complementary therapies
        - Problems with complementary therapies
        - Omega 3 fatty acids
        - Zinc
        - Traditional Chinese medicine
        - Ayurveda
        - Breathing exercises
    - Vaccinations and immunisations
        - Flu vaccine
        - Pneumococcal vaccine
    - How the NHS can help
        - What can I expect at my yearly check?
        - Which basic services should I receive?
        - Can I go on any courses?
        - Will I have to pay for my medicines?
        - What if I'm not getting the expected level of care?
        - What happens when I find out I have diabetes?
        - Where will my diabetes be managed?
        - What will happen at appointments?
- Living & working||with diabetes
    - Food
        - Understanding food
            - Nutrients
            - How the body uses food
            - How food is used in type 2 diabetes
            - Food groups
            - Fruit & vegetable portions
            - Bread, rice, potatoes, pasta & other starchy foods
            - Meat, fish, eggs, beans & other proteins
            - Milk & dairy products
            - Foods & drinks high in fat or sugar
            - Calories
            - Artificial sweeteners
            - Diabetic food products
            - Snacks and desserts
            - Alcohol & diabetes
                - 'Units' of alcohol

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        - Risks ✓
        - Responsible drinking ✓
    - Food labels ✓
        - Ingredients ✓
        - Nutritional information ✓
        - Nutritional claims ✓
        - Traffic light system ✓
        - GDAs ✓
    - Popular diets for weight loss ✓
    - Evidence for different diets ✓
- How food affects your body ✓
    - Food & blood pressure ✓
    - Cholesterol levels ✓
    - Carbohydrate & blood glucose ✓
        - Carbohydrate in foods ✓
        - Glycaemic index ✓
        - Glycaemic load ✓
        - GI & GL food tables ✓
    - Food & hyperglycaemia ✓
    - Food & hypos ✓
    - How eating affects your mood ✓
- Eating in special circumstances ✓
    - Special diets ✓
    - Eating at celebrations ✓
    - Eating out ✓
    - Eating at festivals ✓
    - Eating a healthy lunch at work ✓
    - Eating and shift work ✓
    - Eating on sick days ✓
    - Medications and food ✓
    - Explaining to others about your diet ✓
- Shopping for food ✓

- Relationships ✓
    - The emotional impact of diabetes ✓
    - Sex & intimacy ✓
    - Pregnancy ✓
    - Resources for family, relatives and friends ✓
- Work ✓
    - Managing diabetes at work ✓
    - When to tell employers and recruiters ✓
    - Employment law ✓
    - Shift work ✓
- Social life ✓
    - Alcohol and recreational drugs ✓
    - Special occasions ✓
    - Physical activity ✓
    - Eating socially ✓
- Travel ✓

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        - Travelling with medications
        - Maintaining healthy diet & lifestyle abroad
        - What to do if ill abroad
        - Immunisations for travel
        - Travelling internationally
        - Insurance
    - Driving
        - Do I need to inform the DVLA about my diabetes?
        - What will happen if I inform the DVLA?
        - My motor insurance
        - Hypo awareness when driving
        - Organisations that provide driving advice
    - Financial support
        - Benefits
        - Personal Independence Payment
        - Disability Living Allowance
        - Free prescriptions
    - Ramadan
        - Fasting in Ramadan
        - Looking after yourself in Ramadan
        - Diabetes tablets in Ramadan
        - Diabetes injections in Ramadan
        - Links to other websites
- Managing||my feelings
    - Understanding my moods
        - Sadness & depression
            - Sadness
            - What is depression?
        - Depression & diabetes
        - Coping with sadness & depression
        - Fear & anxiety
            - Feeling scared
            - Anxiety
        - Anger & resentment
        - Denial
            - Denial and diabetes
            - Am I struggling with denial?
            - How to tackle denial
        - Guilt
        - Confidence
        - Happiness & well-being
    - My mood tools
        - How am I feeling? Quiz
        - How am I feeling? Quiz results
        - Living life to the full
            - Introduction
            - Courses
                - Why do I feel so bad?

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        - 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
    - Worksheets
    - E-books
        - 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?
        - I feel so bad I can't go on
        - Fix your drinking problem in 2 days
        - Reclaim your life
        - Live longer: Have a heart attack
        - Stop smoking in 5 minutes
        - In case of panic, read this
        - The Worry Box - Book 1 - The Worry Box
        - The Worry Box - Book 2 - Face It
        - The Worry Box - Book 3 - Fix It
        - The Worry Box - Book 4 - Forget It
    - TV videos
        - Sleeping better
        - Healthy living
        - Assertiveness
        - Introduction
        - Problem Solving
        - Building Confidence
        - Balanced Thinking
        - Dealing with unhelpful behaviour

- My health||record
    - My diabetes care plan
        - Important dates
        - My goals and plans
        - Preparing for my review
        - My recent results
            - Diabetes control
            - Blood pressure
            - Cholesterol
            - Weight
            - Smoking
        - My mood

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        - Screening checks
            - Kidney urine test
            - Kidney blood test
            - Eye check
            - Foot check
        - My diabetes medicine list
    - My appointments
        - My appointment list
        - My appointment calendar
        - My reminders
        - Add an appointment
    - My health tracker
        - Calendar view
        - My weight
        - My waist circumference
        - My food intake
        - My physical activity
        - My alcohol tracker
        - My blood glucose levels
    - My test results
        - HbA1c
        - Blood pressure
        - Cholesterol
        - Kidney function blood test
        - Kidney function urine test
        - Liver function
    - My medicines
        - My medicine list
        - My medicine planner
    - My reminders
- News &||research
    - News
        - Recent news
        - All news articles
        - Historic news
        - Newsletters
    - Research
        - Why bother with evidence?
        - What have important trials taught us about diabetes?
    - Concerns about specific medicines
        - Does the 'glitazone' family increase the risk of heart problems?
        - Does pioglitazone increase the risk of bladder cancer?
        - Does metformin cause lactic acidosis?
    - Advanced information
        - Useful resources
        - Important papers
        - Guidelines
- Forum||& help

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- Forum
  - Index
  - Recent Topics
  - New Topic
  - No Replies
  - My Topics
  - Profile
  - Rules
  - Search
  - Help
- Useful resources
  - Wellbecoming blog
  - HeLP Diabetes blog
- People's stories
  - Discovery
  - Controlling diabetes
  - Possible complications
  - The long view
- Frequently asked questions (FAQs)
  - FAQs: Using HeLP-Diabetes
  - FAQs: Understanding diabetes
  - FAQs: Diabetes and my body
  - FAQs: Food and drink
  - FAQs: Physical activity
  - FAQs: Treating diabetes
  - FAQs: Life and work
  - FAQs: Other resources

Appendix 3: TiDIER CHECKLIST

Item	
Provide the name or a phrase that describes the intervention	Lines 78-80 "… a digital self-management intervention for people with T2DM (Healthy Living for People with type 2 Diabetes (HeLP-Diabetes: https://www.help-diabetes.org.uk"
Describe any rationale, theory or goal of the elements essential to the intervention	Section 2.2 Theoretical frameworks and models Lines 102 - 151
Materials: describe any physical or informational materials used in the intervention, including those provided to	See Appendix 1: Description of the Intervention

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participants or used in intervention delivery or in training of the intervention providers	Section 2.6 Facilitating Engagement "… a 5-10 minute registration and facilitation process where a health care professional (e.g. usually a practice or research nurse or health care assistant) registered a user, introduced users briefly to each of the sections of the intervention and went into detail around one area that the user wanted to work on (e.g. losing weight, or understanding medication). A step-by-step booklet was produced for HCPs so that they could easily navigate the intervention without prior experience. In addition a patient user activity booklet was developed with some details of where to find commonly requested information and activities to do using the interactive tools (e.g. goal setting, action planning, setting a prompt)." Section 3.7.1. Content The overall content was broken down into eight sections: 9. **Understanding diabetes** (145 pages; information about the nature and causes of diabetes, and how it affects the body); 10. **Staying healthy** (107 pages; motivational material about how to maintain optimal physical and emotional health and the

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	importance of self-management; new behaviour change modules and previously validated programmes for diet, weight loss, physical activity, smoking cessation, moderating alcohol intake, and taking medicines); 11. **Treating diabetes** (70 pages; information about medications used in diabetes, including information about indications, side effects and monitoring; importance of managing cardiovascular risk factors as well as glycaemic levels; importance of regular monitoring to prevent retinopathy, neuropathy and nephropathy; and types and roles of different HCPs in caring for people with diabetes); 12. **Living and working with diabetes** (87 pages; focus on managing social and work situations, such as shift work, parties, or holidays; impact on

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	relationships, including sexual relationships; and possible impact on emotions and feelings of self-worth); 13. **Managing my feelings** (61 pages; self-assessment tools for identifying low mood; CBT modules; mindfulness-based approaches); 14. **My health record** (45 pages; opportunity to record appointments with HCPs and results of tests or self-monitoring, with opportunities for graphical displays and feedback); 15. **News and research** (16 pages; updates about diabetes treatment, in-depth articles about seminal research papers); and information for HCPs such as NICE guidelines; 16. **Forum and help** (28 pages; moderated forum; videos of personal stories about diabetes used with license from

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	healthtalk.org; additional resources, including local resources tailored to the CCG).
Procedures: Describe each of the procedures, activities and /or processes used in the intervention, including any enabling or support activities	HeLP-Diabetes was designed to be used as part of an overall package of care for people with diabetes. Low usage, or non-adherence to internet interventions is well-recognised problem, and our preparatory work with patients and health care professionals indicated that integrating the intervention into routine care was likely to improve uptake and adherence. Hence we made the programme available to registered users only, and encouraged health care professionals to register patients. Once registered, patients could use the programme as much (or as little) as they wanted. There was no prescribed level of use, as our proposed users included patients at all stages of their illness journey, from those newly diagnosed to those who had lived with diabetes for many years. As such, we anticipated that each user would have different needs and priorities, and the programme was designed to allow users to pick and choose sections that were most relevant and beneficial for them personally. There was a limited amount of tailoring. Additional resources and sources of help were tailored by the patient's CCG, but otherwise tailoring was limited to the behaviour change and health record sections where users entered their own goals or data.
For each category of intervention provider, describe their expertise, background, and any specific training given.	Practice Nurse; Research Nurse; Healthcare Assistant. Training was given to all HCPs who planned to register patients to use the intervention. This involved being shown HeLP-Diabetes by a member of the team and taken through the step-by-step booklet. This was produced for HCPs so that they could

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	easily navigate the intervention without prior experience.
Describe the modes of delivery (such as face-to-face or by some other mechanism, such as internet or telephone) of the intervention, and whether it was provided individually or in a group	HeLP-Diabetes is a digital self-management intervention delivered through the internet to individual users. Engagement is facilitated by HCPs (see above).
Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features	Registration was undertaken in the patient's general practice. All subsequent use of the intervention was at any location convenient for the patient with internet access. For most people, we expected this to be at home, or at the home of a relative. However, all users were given information about local services (usually libraries) offering free access to an internet-connected computer.
Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule and their duration, intensity or dose.	Once registered, patients could use the programme as much (or as little) as they wanted. There was no prescribed level of use, as our proposed users included patients at all stages of their illness journey, from those newly diagnosed to those who had lived with diabetes for many years.
If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when and how.	We anticipated that each user would have different needs and priorities, and the programme was designed to allow users to pick and choose sections that were most relevant and beneficial for them personally. There was a limited amount of tailoring. Additional resources and sources of help were tailored by the patient's CCG, but otherwise tailoring was limited to the behaviour change and health record sections where users entered their own goals or data.
If the intervention was modified during the course of the study, describe the changes (what, why, when and how)	One of the key functions of the programme was to provide up-to-date, evidence-based information. Hence the site was regularly reviewed to ensure all content was up-to-date, evidence-base, and congruent with current NICE

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	guidelines. In practice, this meant small updates each month, with a complete review when the NICE guidelines on management of diabetes were updated.
Planned: if intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	Intervention use was assessed through bespoke software which recorded the date, time and pages viewed for each log in by each user. Practice nurses were trained in registration and facilitation procedures, but we were unable to monitor how well they adhered to them.
Actual: if intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	Intervention use was assessed through bespoke software which recorded the date, time and pages viewed for each log in by each user. Practice nurses were trained in registration and facilitation procedures, but we were unable to monitor how well they adhered to them.

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Highlights

- Given the low uptake of group based self-management education by people with type 2 diabetes, digital health interventions may provide an additional mode of delivery.
- A participatory design approach provides a method of synthesising theory and different sources of data to develop a self-management intervention that addresses the medical, emotional and role management of living with a long-term condition.
- It is important that the content and development process of interventions are described for other researchers to build on, so that science is cumulative.

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