The use of email and text message prompts to engage users of a digital intervention

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Declaration

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

Thesis overview

Engagement with a digital intervention, defined in this thesis as a user's regular interaction with part or all of a programme that provides information and support (emotional, decisional and/or behavioural) for physical and/or mental health problems via a digital platform (i.e. website, computer), is considered a key ingredient in determining the impact of a digital intervention. However, low engagement with digital interventions is a major challenge in the eHealth field. Effectiveness of digital interventions is associated with how engaged users are with the intervention. This thesis explores the effectiveness and methodological challenges of developing engagement prompts delivered via emails and text messages. The thesis background, rationale and aims are provided in Chapter 1. This background chapter looks at what the literature says about eHealth specifically digital interventions, engagement and email and text message prompts. This thesis is guided by the Medical Research Council guidance for complex interventions to develop the intervention; therefore, it consists of a series of empirical studies to inform the development and testing of engagement prompts. The first study conducted was a systematic review to evaluate the technological strategies used to optimise engagement with digital interventions in order to find out what the literature recommends with regards to engagement prompts and their characteristics (Chapter 2). The second study was a mixed methods study to identify the characteristics of prompts, specifically the content and delivery mode, that have the potential to promote engagement with an online Type 2 Diabetes self-management programme, called HeLP-Diabetes (Chapter 5). The final study consisted of two pilot randomised controlled trials that tested the impact of different content and delivery modes of prompts on engagement with HeLP-Diabetes (Chapter 6). The detailed methodology of the overall thesis, challenges encountered, and context of the PhD is described in Chapter 3. Chapter 4 describes a qualitative study that was planned but not conducted due to recruitment issues, and the adapted study that was conducted instead. The final chapter (Chapter 7) contains the overall thesis discussion.

Table of Contents

Thesis overview 5

List of Tables 14

List of Figures 15

List of Abbreviations 17

Acknowledgement 18

Publications related to this thesis 19

Chapter 1 Engagement with digital interventions and the use of email and text message prompts to promote it. 20

1.1 Abstract 21

1.2 Background 22

1.2.1 eHealth 22

1.2.2 Digital interventions 23

1.2.3 Engagement with digital interventions 31

1.2.4 Engagement prompts 40

1.2.5 Types of prompts 42

1.2.6 Engagement prompts as complex interventions 44

1.3 Thesis Rationale 45

1.4 Thesis aim, context and objectives 46

1.4.1 Thesis aim 46

1.4.2 Context 46

1.4.3 Objectives 46

Chapter 2 The effectiveness of technology-based strategies to promote engagement with digital interventions: systematic review 47

2.1 Abstract 48

2.2 Background 50

2.3 Aim and objectives 52

2.4 Methods 52

2.4.1 Criteria for considering studies for review 52
2.4.2 Search strategy 56
2.4.3 Data collection and analysis 57
2.5 Results 62
2.5.1 Results of the search 62
2.5.2 Included studies and participants' description 67
2.5.3 Aim of studies 101
2.5.4 Characteristics of study participants 101
2.5.5 Digital interventions 102
2.5.6 Engagement strategies 102
2.5.7 Comparators 106
2.5.8 Outcomes 107
2.5.9 Risk of bias 109
2.5.10 Effects of engagement strategies 111
2.5.11 Engagement strategies' characteristics 114
2.5.12 Unpublished data 118
2.5.13 Changes after the original paper was published 118
2.6 Discussion 118
2.6.1 Summary of findings 119
2.6.2 Bias assessment 122
2.6.3 Overall completeness and applicability of evidence 122
2.7 Conclusion 129
Chapter 3 The methodology for developing and testing HeLP-Diabetes email and text message prompts 131
3.1 Abstract 132
3.2 Background 133
3.2.1 Importance of this chapter in relation to other chapters 133
3.3 Objectives 134
3.4 Methodology 135
3.4.1 Medical Research Council guidance 135
3.4.2 Developing a complex intervention 137

3.4.3 Describing the context as part of the development stage of the Medical Research Council guidance 146
3.4.4 Assessing feasibility and piloting methods 157
3.4.5 Evaluation 180
3.4.6 Implementation 181
3.5 Discussion 182
3.5.1 Summary of application of Medical Research Council guidance 182
3.5.2 Applicability of the Medical Research Council guidance 184
3.5.3 Final thoughts and lessons learned 184
Chapter 4 Experience with a patient-led rollout of HeLP-Diabetes and the use of engagement prompts: providers' and patients' perspectives 185
4.1 Abstract 186
4.2 Background 187
4.2.1 Qualitative research about engagement 187
4.3 Context of the qualitative study 188
4.3.1 Background information about the Diabetes Modernisation Initiative group 189
4.4 Aims and objectives 192
4.5 Methods 192
4.5.1 Design 192
4.5.2 Pilot phase 193
4.5.3 Participants 193
4.5.4 Conduct of interview/data collection for HeLP-Diabetes users 196
4.5.5 Data analysis 197
4.6 Results 199
4.6.1 Time scale of the study 200
4.7 Discussion 201
4.7.1 Recruitment 201
4.7.2 Final thoughts and lessons learned 203
Chapter 5 Promoting engagement with HeLP-Diabetes using email and text message prompts: a mixed methods study 205

5.1 Abstract 206
5.2 Background 208
5.2.1 Chapter rationale 208
5.2.2 Usability study 208
5.2.3 Usage data 209
5.2.4 Think aloud interviews 211
5.2.5 Combining usage data and think aloud interviews-a mixed methods approach 212
5.3 Aim 213
5.3.1 Objectives 213
5.4 Study 1-Quantitative component 214
5.4.1 Methods 214
5.4.2 Results 222
5.5 Study 2 Qualitative component 236
5.5.1 Methods 236
5.5.2 Results 239
5.6 Discussion 248
5.6.1 Principal findings 249
5.6.2 Research implications 251
5.6.3 Strengths and limitations of the study's methodology 252
5.6.4 Final thoughts and lessons learned 253
5.7 Conclusion 256
Chapter 6 Content and delivery modes of HeLP-Diabetes prompts: two pilot randomised controlled trials 257
6.1 Abstract 258
6.2 Introduction 260
6.2.1 Chapter rationale and link with previous chapters 260
6.2.2 Rationale for investigation of content and delivery mode of prompts 260
6.2.3 Randomised controlled trials for testing prompt characteristics within HeLP-Diabetes 262
6.3 Aim 263

6.4 Methods 264
6.4.1 Design 264
6.4.2 Setting and Participants 264
6.4.3 Recruitment 266
6.4.4 Consent 266
6.4.5 Randomisation 267
6.4.6 Intervention 267
6.4.7 Analysis 273
6.4.8 Data collection 276
6.4.9 Statistical analysis 276
6.4.10 Confidentiality and data handling 277
6.4.11 Data checks 278
6.4.12 Measures to avoid bias 278
6.4.13 Data Monitoring and Ethics Committee 279
6.5 Results 279
6.5.1 Sample Size and power calculation 279
6.5.2 Trial 1 279
6.5.3 Trial 2 282
6.6 Discussion 285
6.6.1 Principal findings 285
6.6.2 Fit with literature and previous research 286
6.6.3 The intervention 286
6.6.4 The trial 287
6.6.5 Implications for future research 288
6.6.6 Strengths and limitations of the study's methodology 289
6.6.7 Final thoughts and lessons learned 290
6.7 Conclusion 290
Chapter 7 Overall discussion of thesis 292
7.1 Abstract 293
7.2 Aim, objectives of PhD and how they were achieved 294

7.2.1 Determine the effectiveness and range of technology based engagement prompts 294

7.2.2 Identify the methodological and practical challenges of developing engagement prompts and integrating them with a digital intervention 294

7.2.3 Identify the characteristics of prompts, specifically the content and delivery mode, that have the potential to promote engagement with HeLP-Diabetes 295

7.2.4 Test the potential impact of prompts on engagement with HeLP-Diabetes 295

7.3 Summary of PhD findings 295

7.3.1 Study 1: Systematic review of technological-based strategies to promote engagement with digital interventions 295

7.3.2 Study 2: A mixed methods study of email and text message prompts used to promote engagement with HeLP-Diabetes 296

7.3.3 Study 3: Pilot randomised controlled trials testing different prompt content and delivery modes to promote engagement with HeLP-Diabetes 296

7.3.4 Summary of overall finding of this thesis, areas for further research and issues to consider 297

7.3.5 Strengths and limitations of this thesis 300

7.3.6 Ethics 301

7.3.7 Fit with other literature and implications for research 302

7.3.8 What I could have done differently? 304

7.3.9 Reflection on PhD and personal journey 304

7.4 Conclusion 305

Appendices: 306

Appendix 1: MEDLINE Search strategy 306

Appendix 2: List of ongoing studies 308

Appendix 3: Behaviour Change Techniques definitions used by study 309

Appendix 4. Analysis 1.3. Comparison engagement strategy vs.no engagement strategy, dichotomous outcomes-sensitivity analysis-removing Schneider et al. 2012 311

Appendix 5: Data and Analysis- additional data analysis figures: 312

Appendix 6: Screenshot of HeLP-Diabetes home page 316

Appendix 7: Invitation email....317
Appendix 8: Email prompt analysis steps:....319
Appendix 9: Percentage of users who opened or did not open an email prompt and visited HeLP-Diabetes up to three days after an email prompt is sent....320
Appendix 10: Text message prompt analysis steps:....321
Appendix 11: Email prompts used in think aloud interviews....322
Appendix 12: Participant information sheet and consent form....336
Appendix 13: Results of adjusted logistic regression....342
Appendix 14: Cochrane definition of sources of bias....344
Appendix 15: Published papers....345
References....368

List of Tables

Table 1: List of excluded studies *(alphabetical order by first author)* 65
Table 2: Characteristics of included studies (*alphabetical order by first author*)69
Table 3: Characteristics of study participants included in the review 100
Table 4: Main engagement outcomes and findings reported in included studies 115
Table 5: List of prompts details (delivery mode, title, date, content) 163
Table 6: List of the main technical difficulties and actions taken to solve them 177
Table 7: List of data sets used from JamoolaWatch. 216
Table 8: List of the prompts with available usage data 223
Table 9: Chi-square test results for users who opened or did not open an email prompt and visited HeLP-Diabetes up to five days after an email prompt was sent 230
Table 10: Chi-square test results for users who subscribed or unsubscribed to text message prompts and visited HeLP-Diabetes before the next prompt was sent 235
Table 11: Think aloud interviews participants' demographics 240
Table 12: Three levels of themes identified through think aloud interviews 241
Table 13: Difference in intervention textual content for Trials 1 and 2 269
Table 14: Characteristics of Trial 1 Participants 281
Table 15: Characteristics of Trial 2 participants 283
Table 16: List of results of Trial 1 and Trial 2 285

List of Figures

Figure 1: Engagement prompt logic model 42
Figure 2: Study flow diagram (PRISMA diagram) 64
Figure 3: Risk of bias summary: judgements about each risk of bias item for each included study 110
Figure 4: Risk of bias graph: judgments about each risk of bias item for each included study 111
Figure 5: Analysis 1.1: Technology-based engagement strategy compared to no strategy-dichotomous outcomes 112
Figure 6: Analysis 1.2: Technology-based engagement strategy compared to no strategy-continuous outcomes 113
Figure 7: MRC framework for complex interventions 136
Figure 8: The COM-B model 141
Figure 9: Behaviour Change Wheel 143
Figure 10: Timeline for prompts decisions 161
Figure 11: MRC Framework Application 183
Figure 12: Original recruitment process of HeLP-Diabetes users 195
Figure 13: Study steps 213
Figure 14: Percentage of users who received an email prompt and visited HeLP-Diabetes before the next one was sent (email prompt dates listed in descending chronological order – most recent emails from top) 225
Figure 15: Percentage of users who opened or did not open an email prompt and visited HeLP-Diabetes before the next one was sent 226
Figure 16: Percentage of users who opened or did not open an email prompt and visited HeLP-Diabetes up to 5 days after an email prompt is sent 228
Figure 17: Percentage of users who opened or did not open an email prompt and visited HeLP-Diabetes up to 5 days after an email prompt was sent (for email prompts with a significant association) 233

Figure 18: Percentage of users who visited HeLP-Diabetes when a text message prompt was sent for subscribers and non-subscribers and before the next prompt was sent.....234
Figure 19: CONSORT diagram for participants' flow through the study for both trials.....268
Figure 20: Screenshot of prompts used in Trial 1.....270
Figure 21: Screenshots of prompts used in Trial 2.....271
Figure 22: Study timeline.....272

List of Abbreviations

BCT Behaviour change techniques

BCW Behaviour Change Wheel

CI Confidence Interval

COM-B ('Capability', 'Opportunity', 'Motivation'– 'Behaviour')

DESMOND Diabetes Education and Self-Management for Ongoing and Diagnosed

DMI Diabetes Modernisation Initiative

GP General Practitioner

HbA1c Haemoglobin A1c

HeLP-Diabetes Healthy Living for People with Type 2 Diabetes

MRC Medical Research Council

NHS National Health Services

NICE National Institute for Health and Care Excellence

NIHR National Institute for Health Research

PPI Patient Public Involvement

RCT Randomised Controlled Trial

RR Relative Risk

PRISMA Preferred Reporting Items for Systematic Reviews and Meta-Analyses

SMD Standardised Mean Difference

UCL University College London

UK United Kingdom

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Publications related to this thesis

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Alkhaldi, G., Hamilton, F.L., Lau, R., Webster, R., Michie, S. and Murray, E., 2016. The Effectiveness of Prompts to Promote Engagement with Digital Interventions: A Systematic Review. *Journal of medical Internet research*, *18*(1), p.e6.

Chapter 1 Engagement with digital interventions and the use of email and text message prompts to promote it.

1.1 Abstract

In this chapter I provide the background and rationale for this thesis, beginning with the importance, necessity, advantages and disadvantages of digital interventions and how engagement is a potential key factor for improving digital intervention effectiveness. I then detail what I mean by engagement and how to promote it, possibly using email and text messages. I conclude the chapter with the rationale for this thesis and its aim and objectives.

1.2 Background

1.2.1 eHealth

The term ‘eHealth’ first came into use in 2000. It was used when technology was mentioned in association with health care; it included surgical procedures or equipment used as a medical intervention to individuals (Pagliari et al., 2005). Nowadays, however, the use of technology in health care has expanded, and eHealth encompasses any use of information and communication technology in health care. One broad definition of eHealth is:

> An emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies. In a broader sense, the term characterises not only a technical development, but also a state-of-mind, a way of thinking, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology (Eysenbach, 2001,p.2)

Importance

“Information and communication technology can be our most powerful ally for good and affordable health care. “- (European Commission, 2014)

The importance of eHealth lies in the fact that there is an increased burden on health services due to the world’s population ageing rapidly: it is estimated that 22% of the world’s population will be aged 60 years or older by 2050; this is double the proportion observed in 2000 (Dann, 2014). This older population group is the most susceptible to disease and disability, and its increasing size will lead to an increase in the prevalence of long-term health conditions, many of which result from unhealthy behaviours (Christensen et al., 2009b). A study showed that even when elderly people are healthy, they still have similar cumulative health expenditures as elderly in poor health until death (Lubitz et

al., 2003). It is therefore projected that the cost of health services for those over 60 years will increasingly account for a large proportion of health budgets in the future as their differing health needs are accommodated. Health care organisations around the world are currently planning how to cope with the consequences of an ageing population, and strategies for mitigating this impending healthcare cost crisis are top policy priorities. One such possible solution advocated by policy makers and health organisations is the development and increased use of eHealth interventions (World Health Organization, 2005, European Commission, 2012).

Categories

eHealth interventions are comprised of four broad categories (Open Clinical, 2005):

- Electronic medical records (including patient records)
- Telemedicine and tele-care services
- Decision support tools
- Digital interventions

Each category contains various applications for health information communication and services delivery. This thesis will focus on the use of engagement prompts in the last category, digital interventions.

1.2.2 Digital interventions

Definition in this thesis

Digital interventions are defined in this thesis as programmes that provide information and support (emotional, decisional and/or behavioural) for physical and/or mental health problems via a digital platform (i.e. website, computer) (Bailey et al., 2010). I chose this definition because it includes offline and online interventions and specifies the purpose of the digital intervention without limiting it by listing specific characteristics (Barak et al., 2009).

Use of digital interventions in health care

Digital interventions have been developed and used in three main health domains: chronic disease management, health promotion and mental health (Murray, 2012). The literature suggests that the evidence for the effectiveness of digital interventions' functions differ depending on both the health condition/behaviour targeted and other factors relating to the context, such as the population and characteristics of the digital intervention. However, as the context of digital intervention has previously not been clearly described, their effectiveness evidence has been summarised below according to the aforementioned three health domains. These domains, include some examples of digital interventions targeting a variety of health conditions/ behaviours:

- Chronic diseases management: There are numerous chronic diseases for which a digital intervention can facilitate patients' self-management such as diabetes, asthma and hypertension. The evidence regarding these types of intervention is complicated as they have multiple outcomes (e.g. health, cognitive, emotional), thus some studies might show improvement in some of the outcomes but not others. For example, digital interventions focusing on Type 2 diabetes self-management were evaluated in a Cochrane review published in 2013. The review explored their effectiveness. It included 16 studies, and found that digital interventions (specifically computer-based ones) had small benefit on lowering blood glucose and no benefits were found in relation to cognitive, behavioural and emotional outcomes (Pal et al., 2013b). Another example is a review of reviews of digital interventions targeting asthma management. This showed that they led to improved knowledge, medication use, and quality of life but there was no evidence in improving lung function or health service use. The review concluded that more evidence is needed to determine the applicability and overall effectiveness of such interventions (Morrison et al., 2014a). A final example would be a review of hypertension digital interventions. Four of the seven included randomised controlled trials (RCT) showed a signficant reducation in blood pressure (weighted

mean difference=-3.74 mmHg, 95% confidence interval (CI) -2.19 to -2.58) while the others showed no difference between the control and intervention group (McLean et al., 2016).

- Health promotion: Although chronic disease management includes promoting numerous health behaviours, there are digital interventions that focuses on promoting health behaviours among healthy individuals (as opposed to people living with chronic conditions). These interventions are numerous and varied. For example, smoking cessation interventions were explored in a review that included 40 RCTs. The review showed that digital interventions were better at promoting abstinence from tobacco smoking among adults compared to printed materials (Graham et al., 2016). Also a Cochrane review showed similar results (Civljak et al., 2013). Physical activity digital interventions were evaluated in a review (Foster et al., 2013), that concluded that these interventions led to significant moderate effect on improving physical activity levels (standard mean difference= 0.20; 95% CI 0.11 to 0.28). Excessive alcohol consumption' digital interventions were evaluated in one review, which reported that digital intervention may be better at supporting alcohol reduction compared to assessment only, but further research is needed (Khadjesari et al., 2011). A final example was a review of sexual health promotion, 36 RCTs were included and it was reported that digital interventions can improve knowledge, self-efficacy, sexual behaviour but more research is needed to explore whether they can improve sexual health (Wayal et al.,2014).
- Mental health: This field has been researched extensively as evidenced by the plethora of mental illness digital intervention reviews listed below. Most mental health digital interventions consist of a type of cognitive behavioural therapy. Digital cognitive behaviour therapy seems to be effective for treatment and management of common mental disorders (Andersson and Titov, 2014). For example, it resulted in improvement of psychological and physical outcomes for patients with chronic somatic

conditions (Van Beugen et al., 2014), youths suffering from depression and anxiety (Ebert et al., 2015), university students (Davies et al., 2014) and adults (Olthuis et al., 2015, Arnberg et al., 2014).

Different types of digital interventions have different functions. They can be used as symptom checkers for numerous health conditions (NHS Choices, 2015, Your.MD, 2016); provider of health information (Patient info, 2015) and a source for behaviour change support or information such as support to reduce excessive alcohol consumption (DownYour Drink, 2013); or providers for support for emotional management and role management by helping patients adapt to social life and work after diagnosis of specific health conditions such as Type 2 diabetes (Health talk, 2016); or source of peer support through the use of eforums (Diabetes UK, 2015b). They can also be used for treatment, such as those using computerised cognitive behaviour therapy for patients with anxiety or depression (Beating the Blues, 2015), as well as for facilitating access to health services, such as the use of appointment tools (Guys and st Thomas, 2015).

Digital interventions evaluation

Evaluating a digital intervention successfully needs a careful and thorough consideration and planning (Murray et al., 2016). It has to start with an exhaustive and comprehensive appraisal of the digital intervention to find out whether it is needed, whether it can acquire enough reach and uptake among the targeted population to be effective and cost-effective, whether a causal relationship between the digital intervention and desired outcome exists, what components does the digital intervention need to achieve the desired outcome, whether the digital intervention is better than existing interventions, whether the digital intervention can be flexible and tailored to participants' needs and preferences overtime and what are the costs and harms of developing and using the digital intervention(Murray et al., 2016). All those research questions during appraisal would need to be tackled using appropriate research methods

and facilitate the use of different resources (e.g. human or monetary). For example, in order to determine the need and reach of a digital intervention, patient or public representatives of the target population and health professionals will be needed to determine that and to get their perspective on how to maximise the uptake of the intervention.

Digital interventions cost-effectiveness determination

The relative costs and benefits of digital interventions determine policy makers' decisions for whether or not to recommend or commission digital interventions. Economic analysis data are needed alongside effectiveness data when presenting them to policy makers. There is an expectation that digital interventions will help meet health care's triple aim of better health, better health care and lower costs (Wachter, 2016). However, a review published in 2009 showed a paucity of economic analysis data and studies for digital interventions (Tate et al., 2009). Following this review, developers and researchers attempted to conduct economic analysis alongside their effectiveness studies showing digital intervention to be potentially cost-effective (Chen et al., 2012, Kruger et al., 2014, Murphy et al., 2016). However, reliable evidence for cost that can be generalised across large scale business models or projects is still limited (Bergmo, 2015). In order to overcome this limitation and increase the reliable and concrete evidence to assist policy makers with their decisions to use digital interventions, a recent published paper highlighted key issues in how to design and conduct economic analysis studies for digital interventions (McNamee et al., 2016). The key issues were that digital interventions are complex interventions, they are influenced by complex factors including environmental ones, which need to be considered when conducting economic analysis. This can be done by using complex (but flexible) modelling techniques, which include all interactive factors between and across the digital intervention and its intended environment (McNamee et al., 2016).

Advantages of digital interventions

There has been substantial investment in digital interventions in developed countries, and the literature suggests that they have many benefits to users, and can improve many outcomes such as knowledge (Morrison et al., 2014a), behavioural and clinical outcomes (Andersson and Titov, 2014, Arnberg et al., 2014, Civljak et al., 2013, Davies et al., 2014, Ebert et al., 2015, Foster et al., 2013, Khadjesari et al., 2011, Olthuis et al., 2015, Pal et al., 2013b, van Beugen et al., 2014). Digital interventions have been used with benefit in the following areas.

Public health: It is estimated that around 44% of the world's population use the internet, with higher estimates in Europe (79.3%) (Internet World Stats, 2015). The United Kingdom's Office for National Statistics reports that 78% of adults are internet users, with 49% of adults accessing health information online (Office for National Statistics, 2015). With such high numbers of users, digital interventions have the potential to deliver health promotion interventions that can be accessed by a large number of people at a convenient time and location. Furthermore, unlike conventional public health interventions that use media outlets such as television, digital interventions are able to provide structured, interactive and tailored interventions to targeted groups (Bennett and Glasgow, 2009, Murray et al., 2005, Schneider et al., 2012).

Health services: digital interventions provide the means to rapidly update health information and disseminate evidence to health professionals and patients. They can also provide a convenient way of accessing services that otherwise might not be accessible due to long waiting times or patients being in geographically isolated areas (Finfgeld-Connett and Madsen, 2008). Information can also be delivered in a variety of formats such as pictures, videos or text to accommodate different patient group preferences and literacy levels (Murray, 2009). Digital interventions can reduce time and work pressure on staff (Wyatt and Sullivan, 2005). It is also assumed that the cost of digital interventions is low compared with conventional face-to-face health services as costs are only

incurred during development and maintenance stages (Bennett and Glasgow, 2009, Griffiths et al., 2006). However, the evidence for reduced cost is not clear as few studies have attempted to evaluate the overall cost of developing and implementing digital interventions (Tate et al., 2009).

Individuals/patients: digital interventions are accessible for patients in a way that can help facilitate behaviour change promotion, informed decision-making, peer and emotional support by allowing patients to access a variety of information and resources multiple times at their convenience (Murray et al., 2005). Digital interventions can also provide private and anonymous services to individuals who are unlikely to seek help regarding stigmatising health problems or issues, like sexual problems (Bailey et al., 2010) or excessive alcohol consumption (Khadjesari et al., 2011).

Disadvantages of digital interventions:

There are some disadvantages to using digital interventions, including issues to do with privacy, especially for sensitive topics (e.g. sexual health), and online security. However, there are some methods used to minimise these concerns, including using Secure Sockets Layer certificates, which provide an encrypted link between the user's browser and the website's server ensuring the privacy of all transmitted data between them, as well as using anonymous login user identifications and timed logoffs from the website (Barak et al., 2009, Harris and Birnbaum, 2015). Unexpected technical problems and faults are also major concerns and challenges for digital interventions, such as losing connection (Harris and Birnbaum, 2015) (see Chapter 3, Section 3.4.4, for technical difficulties encountered in my PhD).

Not being able to establish rapport between a health professional and a client online is one non-technical issue that also causes concern with regards to digital interventions (Harris and Birnbaum, 2015). There is also the possibility of unintended harm when users do not understand or misinterpret health-related information (Harris and Birnbaum, 2015) and intended harm, such as that

caused by interventions encouraging harmful behaviours such as pro-anorexia websites (Steakley-Freeman et al., 2015) or interventions encouraging alcohol consumption (Weaver et al., 2013).

Limitations to digital interventions

Although the potential advantages of digital interventions are numerous, there are three main specific issues potentially limiting their effectiveness:

Digital divide: An important challenge of digital interventions is that developing and using them might widen the 'digital divide', which refers to the inequalities in individuals' access to computers and the internet due to social or economic reasons (Dutton et al., 2013). The digital divide may also lead to the development of other problems such as isolation; for instance, older people who cannot access digital interventions might feel isolated and uncared for if services are only delivered via the internet. A lack of interest in the internet and computer access also contributes to the digital divide and is important in the context of delivering digital interventions (Dutton et al., 2013); this lack of interest might also contribute to the other two main disadvantages listed below.

Uncertainty about effectiveness: The effectiveness of digital interventions is still being investigated; some systematic reviews and meta-analyses of digital interventions have shown that digital interventions might be potentially effective in changing health outcomes and improving health behaviour, but have concluded that more research is needed (Wayal et al., 2014, Khadjesari et al., 2011, Foster et al., 2013, Civljak et al., 2013, McLean et al., 2016, Morrison et al., 2014a). This is to be expected, as digital interventions are an emerging type of intervention that needs strong evidence-based guidance to help researchers develop and evaluate them appropriately. Guidance is still being developed regarding the proper methodology to develop digital interventions, evaluate their effectiveness through the conduct of RCTs and implement them in real world settings (Bradbury et al., 2014, Eysenbach, 2011). eHealth interventions are complex, including numerous components, and their mechanism of action is not

clear (this issue is further compounded by developers not describing their interventions clearly in the published literature).

Lack of engagement: lack of engagement is a major problem encountered by the majority of digital intervention researchers regardless of the aim or target of the digital intervention. This lack of use of digital interventions will result in a reduction in, or even absence of, health benefits and positive behaviour change. This problem will be discussed below, as this thesis focuses on providing a solution for promoting engagement with digital interventions.

1.2.3 Engagement with digital interventions

Research suggests that the outcomes of a digital intervention can be mediated by users' level of engagement, with a tendency toward a dose-response relationship (Hutton et al., 2011, McClure et al., 2013, Strecher et al., 2008). For example, one study found that users of a smoking cessation digital intervention had better quit outcomes if they had a greater number of visits (OR= 1.19; 95% CI: 1.08 to1.31) (Zbikowski et al., 2011). Another study found that use of a digital intervention may have promoted vegetable and fruit intake (Couper et al., 2010), and a descriptive systematic review exploring the relationship between engagement and digital intervention outcomes found that improvement in physical health outcomes was associated with better engagement (Donkin et al., 2011). Therefore, repeated use and/or completed use of a digital intervention can be important for its effectiveness (Eysenbach, 2005, Danaher et al., 2005).

A number of studies have reported that behaviour change, in particular, will be less likely to occur when users do not complete the digital intervention programme. Antecedents of behaviours (e.g. knowledge) themselves may change but not the behaviours targeted by the digital intervention (Bennett and Glasgow, 2009, Strecher et al., 2008, Schulz et al., 2012, Morrison et al., 2014b).

Ensuring people use digital interventions for a sufficient frequency and an adequate period of time is therefore necessary and could even be called a prerequisite for digital interventions to be effective in improving health outcomes or changing behaviour (Hutton et al., 2011, McClure et al., 2013, Strecher et al., 2008, Brouwer et al., 2011).

Definition of engagement

'Engagement' has been defined in many ways. The most commonly used terminology in relation to engagement with digital interventions is 'stickiness', which is the ability of digital interventions to attract and maintain users' interest (Lin, 2007, Couper et al., 2010) . However, this definition describes engagement due to the digital intervention itself, rather than a behaviour done by the user. eHealth researchers also define engagement by how it is measured, such as by using website metrics like the number of visits, duration of time spent on digital interventions or number and type of pages viewed and visited (Strecher et al., 2008, McClure et al., 2013, Danaher et al., 2006).

Another word used to describe engagement is 'adherence', although there seems to be a distinction between these terms as adherence is the active use of the digital intervention as its developers intended or as a health professional prescribed while engagement is starting and continuing to use the digital intervention (Bennett-Levy et al., 2010).

In this thesis, the following definition of engagement was constructed based on my review of the literature and experts' opinions, while bearing in mind the aim of my PhD: "*engagement is a user's regular interaction with part or all of the digital intervention"*. This definition posits that engagement is a behaviour done by the user.

It should be noted that disengagement or low engagement is often synonymous with 'non-usage attrition', which is when users are not using, or discontinuing the use of, digital interventions. This allows for differentiation from 'dropout

attrition', which is loss to follow- up; that is, users not adhering to an online trial evaluating a digital intervention (Eysenbach, 2005). This distinction is important, as one study reported that there is a difference between engagement measured by visits to a digital intervention targeting workplace health promotion and dropout attrition measured by completing surveys (Robroek et al., 2012). Similarly, another study examined the relationship between dropout attrition and disengagement from an intervention and found that the relationship between these two is complex and that factors associated with greater adherence to a trial or better engagement to an intervention were not similar (Murray et al., 2013).

Engagement phases

Brouwer et al. (2008) reported that engagement has three phases: visiting the digital intervention for the first time; prolonging the first visit, as in not merely logging in; and revisiting the digital intervention. Despite this classification by Brouwer et al. (2008), not many studies have measured the different engagement phases, and most have merely concentrated on reporting overall engagement at the end of a RCT evaluating a digital intervention (Brouwer et al., 2008). A notable exception is a study that measured first use and sustained participation in a digital intervention targeting healthy behaviours such as increasing physical activity. This study found that the number of participants in the first two phases was low, but number of participants revisiting tended to be even lower (Schneider et al., 2012).

Understanding low engagement with digital interventions

Unlike other interventions, the nature of digital interventions facilitates the study of engagement due to the availability of logs of access and usage data, which can provide an important tool to understand the dynamics of engagement and how it can be enhanced (Wantland et al., 2004, Couper et al., 2010). Numerous studies have suggested that users' engagement with digital interventions is not as high as developers and researchers think (Schulz et al., 2012, Eysenbach, 2005, Danaher et al., 2006), and that disengagement rates increase over time,

regardless of the content or aim of the intervention (Verheijden et al., 2007, Farvolden et al., 2005, Christensen and Mackinnon, 2006, Christensen et al., 2004). One study analysed disengagement rates in three different digital interventions (diabetes self-management, smoking cessation and personal health records) and found that the majority of users disengaged early from the intervention and usage declined with time (Wangberg et al., 2008). Similarly, in a study assessing participants' engagement in a diabetes self-management program using peer support, the average number of user visits decreased from 18.7 visits in the first three months to 6.7 visits after four months (Glasgow et al., 2003). However, it is also important to note that low engagement does not necessarily mean that the users did not benefit from the digital intervention or it was not effective, as it is possible that a digital intervention used as a brief intervention, targeting excessive alcohol consumption for example, might affect behaviour change from just a single visit (Donoghue et al., 2014).

Measuring engagement

Engagement is measured in three different ways because it is a multifaceted and complex phenomenon, as explained. These approaches can be used either together or separately, depending on the aim of the researcher. The following is a list of the approaches and when is it appropriate to use them and which of them were used in this PhD.

Physiological measures: Body functions are measured through the use of physiological measures; for example, sweating might indicate nervousness and red cheeks might indicate embarrassment. The cognitive or affective state of the person can be measured to assess their engagement and captured by sensors, cameras and trackers (Lalmas et al., 2014). The main three types mostly used in this approach are outlined below. Eye tracking is one type of physiological measure used to measure affective or cognitive state. Eye tracking looks at the point of gaze, which is the motion of the eye relative to the head, measuring where exactly a person is looking. Changes in pupil dilation can also be measured (Lalmas et al., 2014). Eye tracking has been shown to be

an indicator of whether a person is immersed in a task or not; for example, one study has shown that when gazing at a web page, eye movement is very quick when the person is not highly engaged but slows down when a person is engaged as they focus on specific content or targets (Jennett et al., 2008, Lalmas et al., 2014). Mouse movement or cursor tracking is the use of a tracking program that collects user data on position of the mouse cursor, scroll movement and the number of clicks. This is mostly used in understanding search behaviour (Lalmas et al., 2014). As for engagement, it has been used to show which parts of the web page or its content the user is more interested in (Lalmas et al., 2014). Facial expression is defined as the movement, whether motions or positions, of muscles in the face (Lalmas et al., 2014). There are tools that track facial expressions while users are browsing a website and analyse in real-time emotional reactions of users such as joy, frustration and sadness. However, tracking of facial expression has not been as extensively researched in engagement as eye and mouse tracking (Lalmas et al., 2014).

Physiological measures have many advantages, as they are objective measures that do not depend on users' memory, and they provide information while the users are involved in the task. They can also add valuable information on emotional and cognitive responses that the users themselves are unaware of. However, their main disadvantages are that most of these measures need expensive and complicated tools or labs and can also be intrusive to research participants; they cannot be applied to large-scale samples; and physiological responses might be an indication of more than just one experience (e.g. red cheeks might indicate embarrassment or anger). For this reason, it has been suggested that a physiological approach should be used for more extreme emotions, such as extreme immersion while playing a computer game (Lalmas et al., 2014). Because of these disadvantages, physiological measures have not been used in this PhD.

Website analytics: Analysis of usage data or measuring engagement using website analytics or metrics is the process whereby parameters that are

constructed from digital traces left by users of digital interventions are extracted to be analysed (Lalmas et al., 2014). There are two categories of usage data or website metrics measures: intra-session measures, which assess the ability of the digital intervention to encourage users to remain as long as possible in a single session and inter-session measures, which look at long-term engagement (Lalmas et al., 2014). Usage data or website metrics measures can then be classified in three different ways. 'Popularity' metrics show how interesting a website is to users as measured by the total number of users on the website. 'Activity' explores how users use a website, such as their number of clicks and the time they spend on the website. 'Loyalty' looks at how often users return to a website. An engaging website then might have a large number of users who do lots of activities on it and who return to it often (Lehmann et al., 2012). Loyalty is the classification of website metrics used in this thesis.

Self-report measures: Self-report measures can be categorised into questionnaires and interviews. Questionnaires can be administered electronically, on paper or orally; they can ask closed questions, for which the responses are analysed quantitatively or open-ended questions, analysed qualitatively (Lalmas et al., 2014). There are different types of questionnaires designed to measure engagement with digital interventions. One example is the "eHealth Engagement Scale", which measures engagement with eHealth-related digital interventions that focus on behaviour change (Lalmas et al., 2014, Lefebvre et al., 2010).

Interviews involve asking questions and getting answers from individuals in a study by telephone, face-to-face sessions or even emails (Lalmas et al., 2014). There are three main interview types. The first type is open or unstructured interviews, where the interviewer uses open-ended questions and does not restrict the participant to a specific structured interview guide. This type of interview is used in observational or ethnographic studies. The second type is semi-structured interviews, where the interviewer has a structured interview guide and follows it, but might deviate from it when appropriate. The final type is

structured interviews, where the interview has a very structured interview guide and does not often use open-ended questions or allow for deviations from the topic guide (Lalmas et al., 2014, Ritchie J., 2014).

Engagement promotion

Engagement can be described as being multidimensional; there are many domains that can be targeted to improve engagement. In order to mitigate the problem of disengagement, it is important to obtain evidence related to user engagement and to consider the different domains that may affect engagement when developing a digital intervention. Such domains identified by digital intervention researchers and developers include user characteristics, the health condition/health behaviour addressed by the intervention, the digital intervention features, and external push factors or prompts (Murray et al., 2013). Those domains are interlinked, and an effective intervention should take all into account during development (Murray et al., 2013).

Characteristics of users

User characteristics might be context-specific, as some studies have shown, including one study that reported that users who were motivated to change their behaviour, such as quitting smoking, were more likely to engage with the digital intervention (Danaher et al., 2006). In other studies, programme-completers were more likely to be female, middle-aged, have a medium to high education and a healthy lifestyle (Brouwer et al., 2010, Schulz et al., 2012, Van 't Riet et al., 2010).

Differences in the characteristics and behaviours of participants have also been observed in the different engagement phases. Robroek et al. (2012) found that users of a digital intervention targeting worksite physical activity and nutrition were more likely to start using the programme, and sustain usage, when they were aged 30 years or older, while those with low intention to increase their physical activity levels were less likely to start using the programme.

While it is important to know about people using a digital intervention, it is also crucial to know about those not using it in order to identify potential ways of improving engagement. For example, one study found that patients less likely to engage with digital interventions were those following unhealthy lifestyles (Schulz et al., 2012), while another study found that those with unhealthy lifestyle would start using the digital intervention but not engage over time (Schneider et al., 2012). Hence, identifying characteristics of users most likely to engage and designing interventions targeting them might lead to greater health inequalities.

Characteristics of the health condition or health behaviour.

There is a paucity of evidence about the effect of health condition characteristics on engagement (Murray et al., 2013). For example, it is hypothesised that digital interventions targeting chronic disease management (e.g. diabetes) may need prolonged and intensive engagement in order to enable optimal support and resources provision, and also to allow the user to become familiar with the intervention content, involved with its components and ultimately to change their behaviour or improve their health (Danaher et al., 2006, Eysenbach, 2005, Schneider et al., 2012, Verheijden et al., 2007). However, evaluations of digital interventions targeting chronic diseases or conditions have found low engagement (Glasgow et al., 2003) or users not willing to engage except if they feel the urgent need for it (Vosbergen et al., 2013). Moreover, across the health domains themselves, there might be variance in engagement amongst the different conditions. A systematic review looking at engagement with digital interventions targeting mental disorders found that engagement rates differed between digital interventions targeting depression, anxiety, social phobia, panic disorder and post-traumatic stress disorder (Christensen et al., 2009a). This finding indicates that targeting an intervention to a specific health condition is not enough, and that other factors might be involved, including designing engagement-promoting components or features of a digital intervention.

Characteristics and features of digital interventions

It has been suggested that engagement with digital interventions is associated with the content, design or components of a digital intervention (McClure et al., 2013, Murray et al., 2013). Systematic reviews that have looked at digital intervention characteristics that predict adherence found that those that are regularly updated, interactive and that used peer or counsellor support had significantly better engagement than those without these characteristics (Brouwer et al., 2011, Kelders et al., 2012). Studies that have looked at providing the digital intervention modules gradually to users also found better engagement with the digital intervention than when the whole intervention was available at once (Crutzen et al., 2012, McClure et al., 2013). Features such as individual tailoring have been found to be efficacious in terms of digital interventions achieving their outcomes (Noar et al., 2009) and to have a positive effect on engagement (Couper et al., 2010, Strecher et al., 2008). However, the effect of tailoring is multifaceted, as other studies providing tailored feedback to participants about their behaviour found no difference in engagement. A study by Morrison et al. (2014b) found that self-reported engagement in a digital intervention targeting self-care of mild bowel problems was not significantly different between two self-assessment versions of the digital intervention: one with tailored feedback and one without.

In summary, and according to the Persuasive System Design Model developed by Oinas-Kukkonen and Harjumaa (2009), there are four key elements of digital intervention design that are needed to facilitate engagement. The first element is primary task support that involves principles such as tunnelling (guiding of users through the use of the intervention), reduction of complex behaviour change into steps that are simple and easy to follow and adopt, personalisation of content and services, self-monitoring of users' performance, simulation that shows users the link between using the intervention and achieving the desired behaviour or health outcome, and rehearsal of the behaviour. The second element is dialogue support, which involves offering praise and rewards, reminders and suggestions on performing the behaviour, as well as containing

content that the users like and that shares similarities with the user; for example, in terms of language. The third element is showing credibility through being a trustworthy source of information and experience; giving a positive first impression; and containing, or being referenced or verified by, an authority and well-known and respected sources. The final element is the social component: facilitating social learning and comparison of behaviours; providing opportunities for others to cooperate, compete and perform the behaviour; and also offering public recognition for achieving the targeted behaviour (Oinas-Kukkonen and Harjumaa, 2009).

However, Schneider et al. (2012) argue that even while digital intervention features can be improved to make them more engaging, using digital interventions is still a passive approach to changing behaviour or improving health, as the users need to consistently motivate themselves to use the intervention. Thus, there has to be a more proactive strategy to sustain users' regular interaction. Systematic reviews suggest that the use of technology-based prompts could promote behaviour change (Fry and Neff, 2009) and enhance engagement (Brouwer et al., 2011).

1.2.4 Engagement prompts

When engagement prompts are mentioned in the health literature, this mostly refers to adherence to medication or treatment, which is also a major challenge for health professionals (World Health Organization, 2003). A World Health Organization report showed that 30 to 50% of patients with long-term conditions do not take medication as prescribed (World Health Organization, 2003). Interventions to improve adherence to treatment are still being researched, including the use of technological prompts such as text messages (Chapman and Horne, 2013). There is some evidence that prompts, specifically text message prompts, seem to have a positive effect on health outcomes (de Jongh et al., 2012, Kauppi et al., 2014).

The study of the effects of prompts on engagement with digital interventions is an emerging field as most studies do not explore the effects of prompts separately (Brouwer et al., 2011). One study examining the effects of prompts specifically used email prompts to engage users with a digital intervention showed that although those receiving prompts visited the digital intervention more often compared with those who did not (OR: 28.92, CI 10.65–78.52; *P*< .001), the number who logged in was still low (113 logged in out of 1790 participants). The authors proposed that this might have been due to features of the prompt such its delivery mode, content or timing (Schneider et al., 2012). Other studies of the effects of prompts have suggested that prompts sent earlier in the study or those that advertise new content added to the digital intervention are more likely to positively influence user engagement (Schneider et al., 2013b, Woodall et al., 2007). In a study that sent reminders to engage health care providers with a continuing education website, intervention prompts sent during weekdays were more engaging than those sent during weekends (Houston et al., 2010a). Another study showed that the effect of prompts was short-lived, with visits decreasing with each day of follow-up (Woodall et al., 2007). Results of a systematic review showed that receiving prompts increases usage of digital interventions and leads to behaviour change; however, the authors acknowledged that much is unknown about the effective features of those most effective prompts, such as their content and frequency (Fry and Neff, 2009).

Technological prompts could be used more regularly than human contact (e.g. face-to-face sessions) in the delivery of digital interventions, not as a replacement but rather a complement, as human contact may increase the cost of delivering digital interventions and the burden on health care professionals involved in delivering the digital intervention (e.g. in term of time they spend on delivery of digital intervention). Those reasons could undermine two of the major potential benefits of digital interventions: saving time and reducing cost (Clarke et al., 2005).

The process of promoting engagement using prompts can be visualised through the logic model in Figure 1.

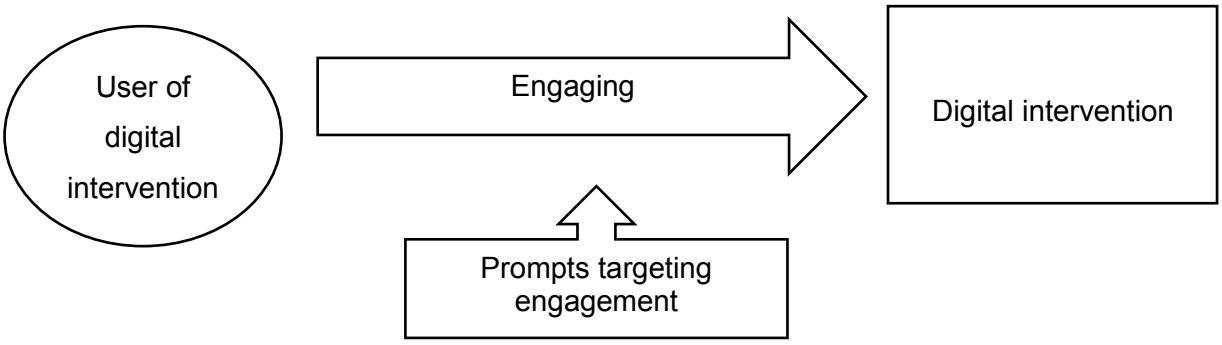


Figure 1: Engagement prompt logic model

1.2.5 Types of prompts

Delivery mode is an important characteristic of an intervention and has a big impact on behaviour (Webb et al., 2010). Engagement prompts have been frequently categorised in published literature according to their delivery modes; thus, this categorisation will be used for this thesis. The most commonly used delivery modes are the following.

Emails

Emails are letters or mails transmitted or transferred online (Bennett-Levy et al., 2010). An email can be transmitted in seconds or minutes depending on its size. The main distinctive feature of emails is that they can be sent and read at any time or anywhere as long as there is access to the internet (Frehner, 2008).

Advantages of using emails

There are many advantages to using email prompts, including email addresses being easily obtained, documents can be attached, emails are a cheap method of conveying services and information, and emails can be sent to one or more than one individual, accessed anywhere and anytime, sent via computers or smartphones. Emails facilitate equity by reaching those who cannot reach

health professionals due to geographical barriers or time, and patients feel less self-conscious about emails and can write concerns they would not be comfortable expressing face-to-face (Bennett-Levy et al., 2010).

Challenges of using emails

There are also several challenges associated with using email in eHealth. Using emails requires specialised skills and familiarity (although a minimum level of computer and reading skills) and there can be a lack of understanding or misinterpretation of the email content. There are also some concerns about confidentiality and privacy of recipients, and there can be client safety concerns, especially if emails are not read straight away and they contain life-saving information. There are also potential technical problems associated with sending emails, such as software malfunctions where emails are not sent and are kept in the outbox (Bennett-Levy et al., 2010).

The evidence for the effectiveness of emails

The most frequently used class of engagement prompts is email, and email prompts have been shown to be effective in increasing revisits to digital interventions (McClure et al., 2013, Schneider et al., 2012). For example, a study evaluating user engagement with a nutrition education website found the number of visits during days when email prompts were sent was higher than other days (OR = 3.71, 95% CI = 2.72 to 5.06) (Woodall et al., 2007). Another study showed an email reminder sent after users' initial visit to the digital intervention encouraged 56% of users to revisit (McNeill et al., 2007). A further study found that 27% who received email reminders visited the digital intervention, while only 6% of the control who did not receive email reminders visited the digital intervention; however, the difference in engagement between these groups was not statistically significant when the emails stopped (Robroek et al., 2012).The use of email prompts has been debated, as users receive many marketing emails, which might lead to users classifying prompts as spam emails and ignoring them (Murray et al., 2013, Schneider et al., 2012); hence, other methods such as text messages may be used alongside emails.

Text messages

Short message services or text messages are brief messages sent from one mobile phone to another. The distinctive feature of text messages is that they do not need an internet connection to be sent if they are not more than 160 characters (Bennett-Levy et al., 2010).

Advantages of using text messages

The main advantages of text message are that they are discrete, quick, can work even if there is no internet connection and have been used to self-monitor patients and send assessments (Bennett-Levy et al., 2010).

Challenges of using text messages

There are some challenges to using text message prompts similar to those associated with emails. These include content being misunderstood and misinterpreted, technical problems where the text messages are not sent or received in an incomprehensible format by the recipients or at the wrong time. Also, text messages are not appropriate to send lengthy content and are not applicable or appropriate to people who cannot type (if they need to respond) (Bennett-Levy et al., 2010).

The evidence for the effectiveness of text messages

Within eHealth, the field of 'm-health' or mobile health is expanding, and the use of mobile phones in interventions is increasing (Fiordelli et al., 2013). Results of a Cochrane systematic review suggest that text messages to mobile phones are effective behaviour-changing prompts (Pal et al., 2013b). Another review found that using text messages as a supplementary mode to a digital intervention has a larger effect on behaviour change than using phone calls or emails (Webb et al., 2010).

1.2.6 Engagement prompts as complex interventions

The Medical Research Council (MRC) guide for complex interventions describes complex intervention as those that contain several interacting

components (Craig et al., 2008). The degree of complexity, though, is affected by different factors such as the number and difficulty of the targeted behaviour(s), the number and variability of outcomes measured, the target population or organisation, and the difficulty of flexibility or tailoring of the intervention (Craig et al., 2008). Prompts can be considered complex interventions as they can have different components that may have different effects on engagement. They are also context-specific interventions as their components can be affected by the context within which the prompts are used. These components were explored further in the systematic review discussed in Chapter 2, and they include the duration for which prompts were used, the timing, frequency, delivery mode, content, sender, use of theory and tailoring. The MRC guidance proposes four steps to consider in developing and evaluating the effectiveness of interventions; development, feasibility and piloting, evaluation and implementation (see Chapter 3 for the application of the guide for this thesis).

1.3 Thesis Rationale

As mentioned previously, digital interventions are computer or website interventions that provide a gateway for patients to access and receive tailored, varied, private and potentially cost-effective health information and services (Bailey et al., 2010, Khadjesari et al., 2011). Digital interventions have been used successfully in many health domains including for health promotion e.g. smoking cessation (Civljak et al., 2013) and chronic disease management (Murray et al., 2005). However, benefits gained from digital interventions are known to be correlated to user engagement (Cobb et al., 2005, Couper et al., 2010, Graham et al., 2007, Hutton et al., 2011, Japuntich et al., 2006, McClure et al., 2013, Strecher et al., 2008, Zbikowski et al., 2011). Engagement can potentially be optimised through the use of context-specific prompts such as emails and text messages (Eysenbach, 2005, Murray et al., 2013, Webb et al., 2010).

1.4 Thesis aim, context and objectives

1.4.1 Thesis aim

The aim of the research discussed in this thesis is to inform, develop and test the potential of using email and text message prompts to optimise users' engagement with a digital intervention called HeLP-Diabetes (Healthy Living for People with Type 2 Diabetes).

1.4.2 Context

HeLP-Diabetes is a digital intervention targeting self-management for people living with Type 2 Diabetes. It aims to provide its users with the tools and support to improve and maintain their health and well-being.

1.4.3 Objectives

The aim of this thesis will be addressed through the following objectives and methods:

- **Inform**
  - Determine the range of technology-based engagement prompts in use and their effectiveness through a systematic review.
- **Develop**
  - Identify the methodological and practical challenges of developing engagement prompts and integrating them with a digital intervention.
- **Test**
  - Identify the characteristics of prompts, specifically the content and delivery mode, that have the potential to promote engagement with HeLP-Diabetes.
  - Test the potential impact of prompts on engagement among HeLP-Diabetes users through a pilot study.

Chapter 2 The effectiveness of technology-based strategies to promote engagement with digital interventions: systematic review

2.1 Abstract

Background: Digital interventions provide effective models for improving health outcomes, they have been used successfully for health promotion and for enabling self-management of long-term conditions. However, their effectiveness is limited by low usage rates, with non-engagement a major challenge. Hence, it is crucial to find effective strategies to increase user engagement with digital interventions. I undertook a systematic review to identify the evidence-base, especially as no systematic review of technology-based engagement strategies has been performed before, according to my knowledge.

Aim: To evaluate the effectiveness of technology-based strategies to promote engagement with digital interventions.

Method: Following the Cochrane Collaboration guidelines on systematic review methodology, I executed the search strategy across seven e-databases (including MEDLINE, EMBASE, PsycINFO and CINAHL) using the search terms 'digital intervention' and 'engagement', limited by study type (randomised controlled trial), up to 13 September 2013. I also searched the grey literature and reference lists of included studies. I screened all the titles and abstracts, then obtained and screened the full-text of potentially eligible papers. I then extracted data from eligible papers. I assessed bias using the Cochrane Bias Assessment Tool. I used narrative synthesis to report on all included studies and, where appropriate, I pooled data using meta-analysis. I reported all my findings according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis guidelines.

Results: I included 16 studies in the review, which included 9,049 participants. Out of the 16 studies, ten were included in the meta-analyses. My meta-analyses suggests that technology-based strategies can potentially enhance engagement when compared with using no strategy, but due to the heterogeneity of the studies included and the small sample sizes in most

studies, this result is not robust and should be treated with caution (for dichotomous outcomes: Relative Risk = 1.34; 95% CI: 1.07 to 1.67, and for continuous outcomes: standard mean difference = 0.19; 95% CI: -0.11 to 0.48). Only one study with a small sample size compared different characteristics (i.e. delivery mode and content). No studies reported adverse or economic outcomes.

Conclusion: In general, studies report a borderline positive effect of technology-based strategies on engagement compared to no strategy. However, the results have to be interpreted with caution, and more research is needed to understand what characteristics of engagement strategies are effective and the cost-effectiveness of these engagement strategies.

2.2 Background

Chapter 1 introduced the potential of technology-based prompts to engage users of digital interventions; however, there is an evidence gap when it comes to prompts' effectiveness and how this relates to different prompt characteristics. According to the Medical Research Council (MRC) guidance for complex interventions, the first step in developing any complex intervention is to identify the evidence base by carrying out a systematic review. In particular, a systematic review of randomised controlled trials (RCTs) evaluating the effect of an engagement prompt would provide the highest level of evidence (Harbour and Miller, 2001, Guyatt et al., 1995) and guide future research by illuminating the gaps in the literature.

The results of this systematic review were used to develop prompts to promote engagement of users of HeLP-Diabetes, as described in detail in Chapter 3. They also assisted me in deciding the content of the prompts I should choose to test in my randomised pilot study detailed in Chapter 6.

Previous systematic reviews published on technology-based prompts looked at how prompts affect health behaviour in the short-term, what characteristics of the prompt were more effective in promoting behaviour change (Fry and Neff, 2009) or how the additional effect of technology-based prompts enhance the effectiveness of digital interventions for behaviour change (Webb et al., 2010). The results from these reviews were duplicated in a relatively recent systematic review that found technology-based periodic prompts for behaviour change had a positive effect on health behaviour (De Leon et al., 2014). Other reviews looked at engagement's association with digital interventions' health outcomes (Donkin et al., 2011) or predicators of engagement (Christensen et al., 2009a). Other systematic reviews looked at all the digital intervention design features that influence engagement (Schubart et al., 2011), including technology-based reminders (Kelders et al., 2012, Lehto and Oinas-Kukkonen, 2011), and email and phone contact with users (Brouwer et al., 2011).

These reviews did not focus on whether prompts can promote engagement and whether the different characteristics of prompts influence engagement differently. Prompt characteristics include timing of the prompt (i.e. whether it was used early when a user registers to a digital intervention or later) (Schneider et al., 2013b), duration (i.e. for how long was the prompt used) (Brouwer et al., 2011, Eysenbach, 2005, Glasgow et al., 2003, Wangberg et al., 2008), frequency (e.g. used once or multiple times) (Fry and Neff, 2009), mode of delivery (e.g. text messages or emails) (Webb et al., 2010), sender (Johnston et al., 2011, Robinson et al., 2010), content (Michie, 2008), and theoretical underpinning (Webb et al., 2010). It has been shown that an intervention based on theory is more effective than one that is not (Noar, 2008, Webb et al., 2010).

With regards to content and theoretical underpinning, I coded the contents of the prompts using the Behaviour Change Techniques (BCTs) taxonomy (Michie et al., 2013). The BCTs are defined as "observable, replicable, and irreducible components of an intervention designed to alter or redirect causal processes that regulate behaviour" (Michie et al., 2013, p.82). By coding the BCTs, it allows for an understanding of how the prompt works and what active ingredients made it work; the more BCTs are used, the more likely the intervention would be effective (Webb et al., 2010).

The main issue with using the BCT taxonomy in this systematic review was the existence of a BCT labelled as prompt/cue , that led me to use the term 'strategy' in this review, as it is more comprehensive and adaptable, and a strategy's content can include the BCT prompt/cue or more components.

2.3 Aim and objectives

The overall aim of this study was to evaluate the effectiveness of technology-based strategies to promote engagement with digital interventions. The specific objectives were:

- To describe technology-based strategies to promote engagement with digital interventions.
- To assess the effectiveness of technology-based strategies in promoting engagement with digital interventions.
- To explore whether different characteristics such as timing, frequency, duration, content, sender, delivery mode or use of theory were associated with differential effectiveness.
- To describe the cost of technology-based strategies to promote engagement with digital interventions.

2.4 Methods

2.4.1 Criteria for considering studies for review

I used a structured approach to build the eligibility criteria, which depended on the acronym PICOS (participants, interventions, comparisons, outcome measures and study designs) (Liberati et al., 2009).

Definitions

In order to make the systematic review inclusive and comprehensive; I used the following definitions for digital interventions and constructed the definitions for strategies and engagement:

- 'Digital interventions' are programmes that provide information and support (emotional, decisional and/or behavioural) for physical and/or mental health problems via a digital platform, specifically a website or a computer (Bailey et al., 2010). I used this definition because it included

offline and online interventions and specified the purpose of the digital intervention without limiting it by listing specific characteristics, as done previously (Barak et al., 2009).

- I defined 'engagement' as user's regular interaction with part or all of the digital intervention, because engagement has been categorised into three phases: visiting the digital intervention for the first time, prolonging the first visit, and revisiting the digital intervention (Brouwer et al., 2008), the definition of engagement depends to some extent on the goal of the digital intervention and whether it has to be used once or repeatedly. In my thesis and in this review, the third phase of engagement was targeted (see Chapter 1, Section 1.2.3, for more details).
- Based on the definition of engagement above, I defined 'technology-based engagement- promoting' strategies as digital and analogue technology methods used to promote the user's regular interaction with all or part of the digital intervention, including but not limited to land line phone calls, mobile phone calls, text messages, multimedia messages, emails, automated voice calls or faxes. Examples of interventions that could be included were a computerised treatment programme with mobile phone text messages that remind the user to visit the programme or a blood pressure self-monitoring website that sends email prompts to users to enter their pressure readings on the website.

Types of participants

Studies where participants were 18 years old and older irrespective of gender, socioeconomic status, ethnicity, morbidities and health status were included in the review. I included all settings and excluded studies targeting health professionals.

Types of Interventions:

Technology-based strategies that promote engagement with digital interventions were targeted in this review. They had to meet the definitions of

digital intervention and technology-based engagement promoting strategies mentioned above to be included.

Type of comparisons

Three groups of comparisons were included:

- Technology-based engagement strategies compared to no strategy
- Technology-based engagement strategy compared to non-technological strategies; for example, emails compared to post-mail
- Technology-based engagement strategy compared to another technology based engagement strategy.

Some studies tested the cumulative effect of multiple strategies; for example, a two-arm RCT, with one arm receiving an email prompt and the other arm receiving an email and a phone call prompt.

Types of outcomes

Primary outcomes

There is no agreed upon specific measure for determining engagement with digital intervention. It can be measured by website metrics, including but not limited to the number of visits/logins, number of pages visited, number of sessions completed, time spent on the intervention website and number of digital intervention components/features used. I categorised outcomes into dichotomous and continuous engagement outcomes when analysed, in order to simplify interpretation of outcome measures:

Dichotomous engagement outcomes: any dichotomous measure of how participants engaged with the digital intervention, such as proportion of participants who visited the digital intervention.

Continuous engagement outcomes: any continuous measure of how

participants engaged with the digital intervention, such as number of digital intervention visits.

Secondary outcomes

Adverse outcomes: if any, such as users feeling frustrated and bothered by engagement prompts, users experiencing a loss of self-esteem for not being able to engage with the digital intervention, users receiving prompts with wrong information or links to the digital intervention, and exclusion for users who are not able to receive the engagement prompt.

Economic outcomes: costs associated with strategies promoting engagement to inform future cost-effectiveness analysis.

All outcomes measured in the studies that meet the inclusion criteria were intended to be included whether they were objective or self-reported.

Types of study designs

RCTs were the only type of study design to be included, as these provide the best quality evidence regarding effectiveness. Trials could either be trials evaluating strategies specifically or they could be trials of digital interventions that used strategies promoting engagement, as long as the effect of prompts on engagement could be determined. Economic evaluation would have been included if they were done alongside the main trial.

Exclusion

As for the exclusion criteria, the following were excluded:

- Trials where the Intervention was targeting health professionals only. For example, web-based decision aids to assist health professionals in making decisions with regards to treatments
- Trials where attrition from the trial and from the intervention were non-distinguishable

- Trials where the effect of the digital intervention components cannot be separated from the effect of the engagement-promoting strategy. This included when trials where the digital intervention is not compared to another digital intervention; for example, a website to lose weight with text message prompts compared with dietician face-to-face sessions with text messages from the dietician. Also, when a digital intervention with an engagement strategy is compared to a different digital intervention without an engagement strategy; for example, a basic version of the digital intervention with no email prompts compared with an enhanced version with email prompts.

2.4.2 Search strategy

In order to ensure I comprehensively covered the important disciplines that might be related to my research (i.e. medicine, psychology, social science, nursing and education), I searched seven databases from inception to 13 September 2013 with no language restrictions:

- The Cochrane Central Register of Controlled Trials (CENTRAL)
- General international health care electronic bibliographic databases: MEDLINE (Ovid platform) and EMBASE (Ovid platform)
- Social science, education, psychology and nursing electronic bibliographic databases: Web of Science, Education Resources Information Center (ERIC), PsycINFO (including studies and dissertation abstracts) and Cumulative Index to Nursing and Allied Health (CINAHL)
- I refined Medline thesaurus Medical Subject Headings (MESH) terms for each database and I sought unpublished data in the form of conference proceedings (Conference Proceedings Citation Index, formerly ISI Proceedings). I hand-searched references of the included studies and issues of key journals such as Journal of Medical Internet Research, and using Google Scholar I screened any papers citing included or key papers (Eysenbach, 2005, Fry and Neff, 2009, Murray et al., 2013, Webb et al., 2010).

I used three overlapping concepts to construct the search strategy:

1. Digital intervention

AND

2. Engagement

AND

3. RCT

I developed the search strategy and it was reviewed by the team before I undertook the main search. Initially, I selected the search terms with reference to the inclusion criteria, other related published studies, previous systematic reviews and MESH terms, and based on discussion with the research team and an information specialist. I did hand-searching to pilot the electronic database search strategy. I searched the issues of the Journal of Medical Internet Research from two years (2012-2013) before conducting the search to find related articles and to test whether the articles were identified. I then adjusted the search strategy accordingly. I assessed the validity of the search strategy by taking seven known RCTs of engagement promoting strategies and checking to see if the search strategy was able to identify them in MEDLINE database.

I deliberately decided to make the search strategy sensitive in order to identify all the relevant literature on engagement prompts (see Appendix 1: MEDLINE search strategy). I then divided the searched literature into three categories for my thesis, as done in another systematic review (Bailey et al., 2010):

- Studies included in the systematic review
- Studies used for the literature review in Chapter 1
- Studies excluded from the systematic review

2.4.3 Data collection and analysis

Selection of studies:

I downloaded all citations identified by the search strategy to the reference manager EndNote X5 and de-duplicated them. I screened all abstracts and

titles identified by the search strategy for studies meeting the inclusion criteria, then they were double-screened by three reviewers, who each screened an equal number of records (33%) to ensure none were missed. I then met with each reviewer to compare results. I then obtained full-text manuscripts for these potentially eligible articles and contacted authors directly for articles that were not retrievable through library sources. One reviewer and I then assessed the full-text articles for eligibility. Any disagreement about included or excluded studies was resolved by discussion with reference to the inclusion and exclusion criteria or if necessary with input from a third reviewer. I recorded my justification for exclusion and constructed a Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (Liberati et al., 2009) flowchart to show search, screening and selection results. All my co-authors and I were not blinded to journal or author names and had received training on systematic review methodology or were experienced systematic review researchers.

Inter-rater agreement or Kappa statics are not recommended as a standard in Cochrane reviews because they might not convey real impact of disagreement (Higgins and Green, 2011). Thus, I did not calculate them and instead, as mentioned above, the databases search results were double- screened.

Data Extraction and Management

I extracted the data using an adapted version of the Cochrane Consumers and Communication Review Group data extraction template (Higgins and Green, 2011). Data extracted included study references, aim, funders, setting, population details, study design, targeted health condition or health behaviour, participants' exclusion and inclusion criteria, digital intervention description, statistical analysis methods, follow-up duration and rates, results and risk of bias. In addition, I extracted full details of the engagement strategy, including timing, duration, frequency, mode of delivery (e.g. email, text message), content, sender and use of theory. I piloted the data extraction form and documented the changes. I extracted the data from the included studies to a

Microsoft Excel spread sheet, and a second reviewer checked the extracted data accuracy. Disagreements about the extracted data were resolved by discussion between that reviewer and me; if no agreement was reached, it was planned that a third reviewer would decide on the issues we were conflicted about. If any information was missing or needed to be clarified, I contacted the authors of the paper.

Using the behaviour change techniques taxonomy

I used the BCT taxonomy published by Michie et al. (2013) to code the content of the engagement strategies. I coded while extracting the data, then another reviewer, who has experience coding BCTs, checked the quality and accuracy of the coding. Decisions were then compared, and coding was refined by consulting a BCT-coding expert about the decisions made.

Assessment of risk of bias in included studies

I did an assessment of risk of bias based on the Cochrane Risk of Bias Assessment Tool (Higgins and Green, 2011), using the following criteria:

- Was the allocation sequence adequately generated?
- Was allocation adequately concealed?
- Was knowledge of the allocated interventions adequately prevented during the study (blinding)?
- Were incomplete outcome data adequately addressed?
- Are reports of the study free of suggestion of selective outcome reporting?
- Was the study free of other problems that could put it at a risk of bias, including but not limited to, baseline characteristics differences between groups, validity and reliability of outcome measures, sample size and power.

Based on this assessment, I categorised each study as being at low risk of bias (LOW), high risk of bias (HIGH), or at unclear risk of bias (UNCLEAR) when the study did not provide enough information to judge the different aspects of trial

quality. I generated a risk of bias graph and summary table. One reviewer then checked my bias assessment, and another one resolved any discrepancies.

Unit of analysis issues

The unit of analysis was the individual as studies would have randomised digital intervention users to either intervention or control groups.

Dealing with missing data

As primary outcomes measures (i.e. website metrics/usage data) are automatically generated while a digital intervention is being used, I anticipated that missing data were most likely in secondary outcomes. Where missing data presented a clear bias to the study outcomes I noted and discussed it with the study team and contacted the authors directly for any needed clarification. Where the risk of bias could not be mitigated, I included the studies in the narrative part of the systematic review, but not in the meta-analysis.

Selection of outcomes

As mentioned above, I categorised outcome measures as dichotomous or continuous, but even within the categories of dichotomous and continuous outcomes, authors often reported more than one outcome. For example, they would report the number of sessions completed and time spent on the website. For the purpose of analysis, and after discussion with co-authors, I selected one outcome based on the following pre-specified criteria:

- The number of participants who visited the digital intervention or the number of visits was selected, as visits are the most appropriate indicators for engagement strategies (Brouwer et al., 2011, Tullis T., 2008)
- The primary outcome as defined or stated by the included study's author
- An outcome reported separately for the control and intervention group, rather than a joint one

- The highest standard (or level) for engagement (e.g. the authors report the number of participants who completed all the sessions rather than the number of participants who completed no sessions or a specific number of sessions)
- As it is important to demonstrate sustained change (Higgins and Green, 2011), data from the longest measured follow-up period were chosen.

Data analysis

I reported the results according to the PRISMA guidelines (Liberati et al., 2009) and analysed them according to Cochrane guidelines (Higgins and Green, 2011). I tabulated data from included studies to allow for narrative description of the results. This also allowed for an understanding of contributions to heterogeneity in terms of participants, digital intervention and strategy, outcomes, comparator, study design and quality of studies (risk of bias).

I tabulated data on characteristics of engagement strategies, and all authors of included studies were contacted for clarification about their strategies, although only four authors replied (Clarke et al., 2005, Farrer et al., 2011, McClure et al., 2013, Simon et al., 2011).

I intended to narratively describe data on adverse and economic outcomes and summarise statistically data on adverse outcomes depending on the type of the outcome, but no adverse or economic data were identified.

I summarised statistically data according to Cochrane systematic review methodology (Higgins and Green, 2011), and performed meta-analysis. I pooled continuous and dichotomous data from RCTs separately using a random effects model because this model assumes that the intervention effect for the individual studies vary around some overall average treatment effect, while the fixed effect model assumes that the true effect of the intervention is the same value in all studies and that any difference between study results is due only to chance

(Higgins and Green, 2011). With prompts, the chance there is heterogeneity in effect sizes is high, thus a random effect model was chosen (Brouwer et al., 2011, Donkin et al., 2011).

I determined the appropriate effect measures depending on the type of data. Website metrics (usage data) in this review were either continuous or dichotomous. For dichotomous outcomes I used Relative Risk (RR) and their 95% confidence intervals (CI), and for continuous outcomes, standardised mean difference (SMD) with 95% confidence intervals. Due to the variable nature of the interventions, I expected heterogeneity and assessed this using the I^2 statistics because it quantifies the amount of variation in results across studies beyond that expected from chance (Liberati et al., 2009). The I^2 statistic is not influenced by the number of studies or sample size as is the Q statistic, which has less power if the number of studies or samples sizes in the meta-analysis are small. A small sample size was expected for this systematic review, thus the I^2 statistic was the preferable option (Higgins and Green, 2011).

I intended to perform sensitivity analysis according to the Cochrane handbook recommendation by excluding trials with poor quality to determine their effects on the study results (Higgins and Green, 2011). I also intended to conduct a subgroup analysis of delivery mode, because delivery mode has been shown to have an effect on behaviour (Webb et al., 2010), and to construct a funnel to plot to assess reporting bias. However, there were insufficient studies to allow for a meaningful assessment, thus I was not able to do any of these three analyses.

2.5 Results

2.5.1 Results of the search

A total of 10,133 citations were screened after removing all duplicates using Endnote de-duplication function and visually scanning for duplicates in the 18,881 records generated by the database search. Of the remaining records,

10,040 were excluded after title and abstract screening, leaving 93. Three studies found by reference tracking were added, leaving 96 citations for full-text screening, of these, 77 full-text articles were excluded for various reasons, the most common being that the engagement strategy or digital intervention did not meet the definition for this review or that engagement was not measured in the study (see Table 1: List of excluded studies). Two studies were included after publishing the systemic review. Thus, 16 studies were therefore included in the review (see Table 2: Characteristics of included studies). There were four ongoing studies with only protocols available, and one study was a conference abstract (see Appendix 2: list of ongoing studies), they were not included in the narrative synthesis or meta-analysis (see Figure 2 for the PRISMA diagram showing the flow of exclusion and inclusion of identified studies).

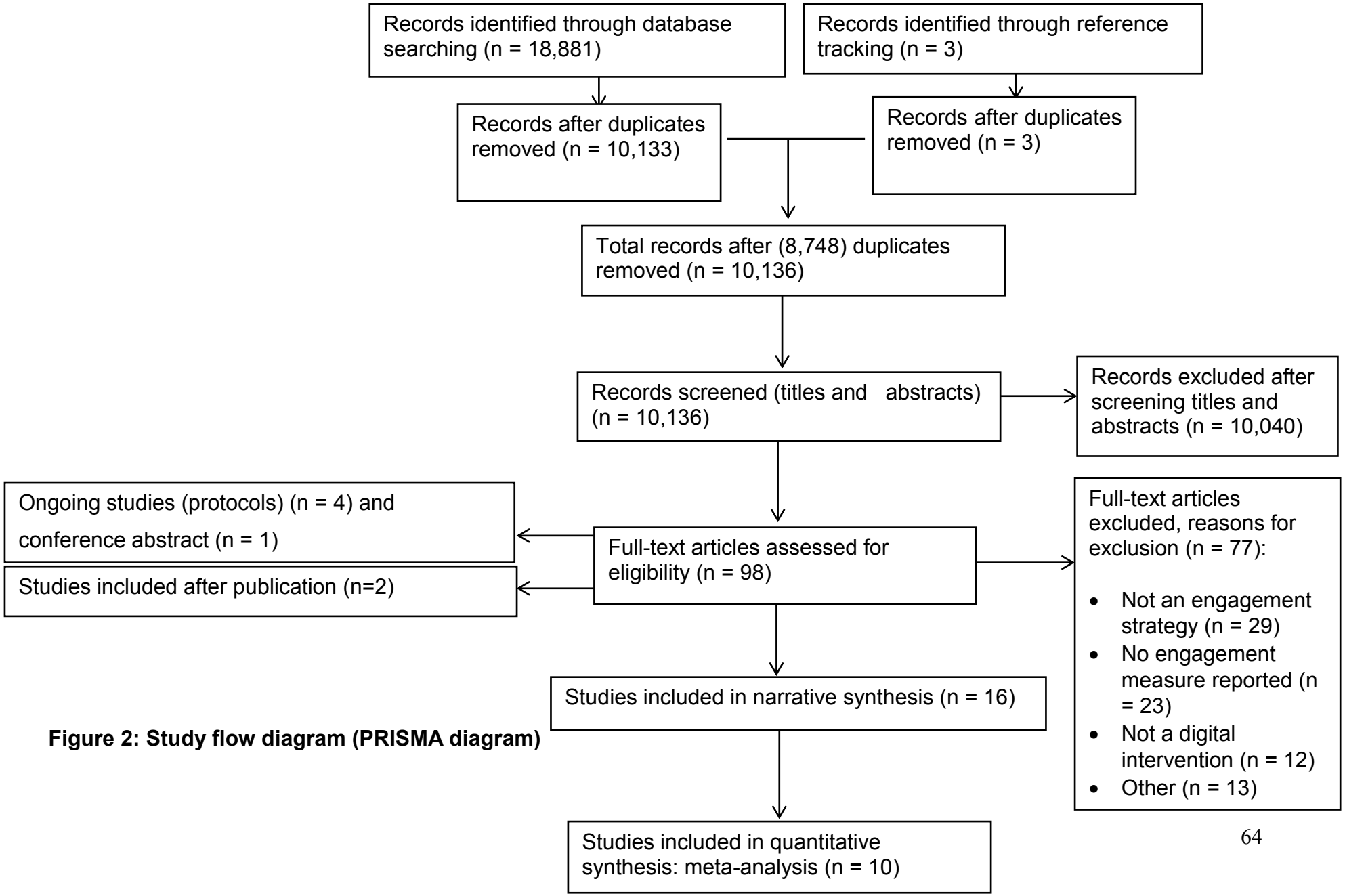


Figure 2: Study flow diagram (PRISMA diagram)

Table 1: List of excluded studies *(alphabetical order by first author)*

Study	Reason for exclusion
1. Andersson et al., 2003	No engagement outcome
2. Bickmore et al., 2010	Not digital intervention
3. Brindal et al., 2012	No engagement strategy
4. Bull et al., 2008	No engagement outcome
5. Burke et al., 2009	Not external engagement strategy
6. Burnett et al., 1992	No technology-based engagement strategy
7. Carlbring et al., 2007	digital intervention compared to a waitlist-not comparable
8. Camerini and Schulz, 2012	No engagement strategy
9. Celio et al., 2002	No comparator group using a digital intervention
10. Chiauzzi et al., 2013	No engagement strategy
11. Christensen et al., 2006	No engagement strategy
12. Collins et al., 2011	No separate outcome measure
13. Collins et al., 2012	No engagement outcome
14. Conroy et al., 2011	Not a digital intervention
15. Crutzen et al., 2011	Not engagement strategy
16. Danaher et al., 2006	No separate outcome measure
17. Danaher et al., 2008	No engagement strategy
18. Danaher et al., 2013	No separate outcome measure
19. Ei, 2007	Dropout attrition was measured not engagement
20. Freeman et al., 2008	No engagement outcome
21. Funk et al., 2011	Not randomised but single arm
22. Funk et al., 2010	Targets health professionals
23. Gabriele, 2009	Not digital intervention
24. Gabriele et al., 2011	Not digital intervention
25. Geraghty et al., 2010	Dropout attrition was measured not engagement
26. Glasgow et al., 2003	No separate outcome measure
27. Glasgow et al., 2011	No separate outcome measure
28. Graham et al., 2013	No engagement strategy
29. Green et al., 2009	No engagement strategy
30. Hasson et al., 2010	No engagement outcome
31. Hilvert-Bruce et al., 2012	No separate outcome measure
32. Hunt, 2005	No engagement strategy
33. Hurling et al., 2006	No engagement outcome
34. Hwang et al., 2013	No separate outcome measure
35. Jacobs et al., 2009	No engagement outcome
36. Jovicic et al., 2009	No engagement outcome
37. Johnston et al., 2011	No separate outcome measure
38. Kenwright et al., 2005	Not digital intervention
39. Kirwan et al., 2012	Not engagement strategy

40. Kramer et al., 2009	No engagement strategy
41. Laan et al., 2012	Not external engagement strategy
42. Lieberman, 2006	No engagement strategy
43. Martin et al., 2010	Not digital intervention
44. Micco et al., 2007	No technology-based engagement strategy
45. Mohr et al., 2010	No separate outcome
46. Muñoz et al., 2006	No separate outcome
47. Nguyen et al., 2009	Not digital intervention
48. Nijland et al., 2011	Not RCT
49. Ondersma et al., 2012	No engagement strategy
50. Owen, 2004	No engagement strategy
51. Pacaud et al., 2012	Not comparable
52. Pike et al., 2007	No separate outcome measure
53. Poirier and Cobb, 2012	Not RCT
54. Prochaska et al., 2001	Not digital intervention
55. Quinn et al., 2011	No engagement outcome
56. Quintiliani et al., 2010	Not engagement strategy
57. Rabius et al., 2008	No engagement strategy
58. Reid et al., 2011	Not engagement strategy
59. Richardson et al., 2010	No external engagement strategy
60. Robinson et al., 2011	Not digital intervention
61. Robroek et al., 2012	No separate outcome measure
62. Schneider et al., 2013a	Not engagement strategy (recruitment)
63. Schulz et al., 2012	Not external engagement strategy
64. Sevick et al., 2008	Not digital intervention
65. Shiffman et al., 2000	Not digital intervention
66. Stevens et al., 2008	No comparator group using a digital intervention
67. Stoddard et al., 2008	No separate outcomes to measure
68. Strecher et al., 2008	No engagement strategy
69. Svensson et al., 2012	Dropout attrition (i.e. reminders to complete questionnaires)
70. Tate et al., 2001	Not comparable
71. Titov et al., 2010	Not a technology-based strategy
72. Wang, 2011	Not digital intervention
73. Wangberg et al., 2008	No separate outcome measure
74. Watson et al., 2012	No engagement strategy
75. Wolf et al., 2011	No engagement strategy
76. Woodall et al., 2007	No comparator group using a digital intervention
77. Zbikowski et al., 2011	Not an engagement strategy

2.5.2 Included studies and participants' description

Sixteen studies with a total of 9,049 participants were included. The sample sizes (excluding RCT arms not meeting eligibility criteria) ranged between 43 and 3448 participants. Most of the studies were RCTs of digital interventions that had arms comparing engagement strategies with controls or other engagement strategies. The studies were published between 2005 and 2013, with only one study published in 2005 (Clarke et al., 2005), two published in 2009 (Muñoz et al., 2009, Titov et al., 2009),one published in 2010 (Couper et al., 2010), four in 2011 (Berger et al., 2011a, Berger et al., 2011b, Farrer et al., 2011, Simon et al., 2011), three published in 2012 (Greaney et al., 2012, Proudfoot et al., 2012, Schneider et al., 2012) and five were available in 2013 (McClure et al., 2013, Santucci et al., 2014, Schneider et al., 2013b, Mohr et al., 2013, Titov et al., 2013). All the studies were published in English.

Seven studies were three-arm RCTs with two arms eligible to be included in each study (Berger et al., 2011b, Clarke et al., 2005, Couper et al., 2010, Greaney et al., 2012, Mohr et al., 2013, Proudfoot et al., 2012, Titov et al., 2013); two studies were four-arm RCTs, but only two arms in each study were included in this review (Farrer et al., 2011, Muñoz et al., 2009); four studies were two-arm RCTs (Santucci et al., 2014, Schneider et al., 2012, Simon et al., 2011, Titov et al., 2009); one study was a factorial RCT where half of the participants received the engagement strategy and half did not (McClure et al., 2013); and one study was a three-arm RCT with two arms receiving different engagement strategies and one arm acting as the control (Berger et al., 2011a). One study was a RCT with seven arms looking at the effects of different prompt content and frequencies (Schneider et al., 2013b).

All of the studies were conducted online. Two studies were done in the Netherlands (Schneider et al., 2012, Schneider et al., 2013b), four in Australia (Farrer et al., 2011, Proudfoot et al., 2012, Titov et al., 2009, Titov et al., 2013), five in United States of America (Clarke et al., 2005, Couper et al., 2010, Greaney et al., 2012, McClure et al., 2013, Simon et al., 2011), and one in

Switzerland and Germany (Berger et al., 2011b). For the rest of the studies, the location was not specified clearly, but the funding bodies for one study was in United States of America (Santucci et al., 2014) and the other in Switzerland (Berger et al., 2011a).

Table 2: Characteristics of included studies (*alphabetical order by first author*)

Berger et al., 2011a – Journal article	
Participants	81 were randomised, 6 dropped out, 75 were included in the review.
Study designs and arms	RCT (3 arms). **Included arms:** pure self-help (n = 26), guided self-help (n = 24) and step-up of support on demand (n = 25).
Digital Intervention	**Name:** not mentioned **Target health behaviour/ health condition:** social phobia • Internet-based self-help guide. Comprised five largely text-based lessons, several exercises and diaries and the option to participate in an online discussion forum. • Participants had to work through the programme in a sequential order but all lessons could be completed at once.
Engagement strategy (1)	**Arm 1: guided self-help** **Mode of delivery**: email **Content**: the therapists introduced themselves through email and informed participants that they could contact them whenever they wanted to. Therapists also sent an email with feedback to the participants on their behaviour and progress in the self-help guide. In case there was no activity by a participant during the week, therapists offered their help and assistance and asked if he or she was facing any problem with the programme or with the tasks. **Frequency, duration and timing:** weekly contact for the duration of the digital intervention (10 weeks). **Sender:** psychological therapist

Engagement strategy (2)	**Arm 2: step-up of support on demand** **Mode of delivery**: email + phone **Content:** at the end of each session of the digital intervention, participants were automatically asked if they would like to receive additional support from a therapist. In a first step, and simply by clicking on a button, participants could ask for contact with a therapist via email. In a second step, and after the email contact had been established, participants were asked at the end of each session if they would like to have additional weekly telephone calls with their therapist. In addition, automated standardised emails were sent to participants in case they did not use the program for more than seven days. These emails informed recipients about the possibility of an additional contact with a therapist via email (in a first step) or via telephone (in a second step). Participants were able to click on a link in the email if they wanted this additional contact. **Frequency, duration and timing:** weekly contact (by choice) for the duration of the digital intervention (10 weeks). **Sender:** psychological therapist
Comparator	**Comparator arm: pure self-help:** this group did not receive any engagement strategy.

Risk of Bias

Item	**Author's judgement**	**Description**
Adequate sequence generation?	LOW	'Participants were randomized into one of the three conditions using a computerized random number generator (www.random. Org)'
Allocation concealment?	LOW	'The allocation schedule was generated by an independent researcher and was unknown to the investigators'

Blinding?	HIGH	No report of blinding except for 'interviewers who could not be kept blind at the end regarding group assignment because some participants disclosed aspects of the group assignment during the interview'. However, blinding of participants could not have been possible due to the design of the study.
Incomplete outcome data addressed?	UNCLEAR	Six enrolee (one from self-help, three from guided self-help and two from step-up of support on demand) dropped out before post treatment assessment and engagement outcomes were not reported for them
Free of selective reporting?	UNCLEAR	• Engagement outcome measures were not pre-specified • Protocol was mentioned in the article but not reported fully (could not find link)
Other source of bias	LOW	No source of bias was identified
Berger et al., 2011b – Journal article		
Participants	76 were randomised, 50 were included in review.	
Study designs and arms	RCT (3 arms). **Included arms:** unguided self- help (n = 25), guided self-help (n = 25). **Excluded arm:** wait-list control (n = 26).	
Digital Intervention	**Name:** Deprexis **Target health behaviour/health condition:** depression Internet-based self-help programme. Consisted of 10 content modules and a summary module covering a variety of therapeutic content. Participants were encouraged to work through the programme in a sequential order. Modules were not made available sequentially, thus participants could complete the whole programme at once.	
Engagement strategy	**Engagement strategy arm: guided self-help** **Mode of delivery**: email	

Content: the therapists introduce themselves and informed participants that they could contact them whenever they wanted to.

Once a week, therapists wrote a short e-mail with feedback based on participants' programme usage over the previous week. The feedback did not refer to specific text passages or responses participants had selected. It was relatively generic in nature and did not discuss specific therapeutic strategies in detail. In case there was no activity by a participant, therapists offered their help and assistance and asked if the participant was facing any problem with the programme or with the tasks.

Frequency, duration and timing: weekly contact for the duration of the digital intervention (10 weeks).

Sender: psychological therapist

Comparator

Comparator arm: unguided self-help

This group did not receive any engagement strategy.

Risk of Bias

Item	Author's judgement	Description
Adequate sequence generation?	LOW	'Participants were randomized into one of the three conditions using a computerized random number generator (www.random. Org)'
Allocation concealment?	LOW	'The allocation schedule was generated by an independent researcher.'
Blinding?	UNCLEAR	Insufficient information to decide and the design of the study might make it not possible to blind participants or researchers.
Incomplete outcome data addressed?	LOW	No source of bias was identified
Free of selective reporting?	LOW	• Analysis of engagement outcome measures was mentioned • Protocol was mentioned in the article but not reported fully (could not find link)

Other source of bias	LOW	• 'First, and most importantly, the study was underpowered to detect small differences between the guided and unguided condition' • No source of bias was identified.
Clarke et al.,2005– Journal article		
Participants	255 were randomised, 155 were included in the review.	
Study designs and arms	RCT (3 arms). **Included arms:** mail reminders (n = 75), telephone reminders (n = 80). **Excluded arm:** treatment as usual (n = 100).	
Digital Intervention	**Name:** Overcoming Depression on the Internet (ODIN) **Target health behaviour/health condition:** depression A pure self-help programme offering training in cognitive restructuring. The intervention was organized in seven "chapters," each presenting a new technique via interactive examples and practise opportunities.	
Engagement strategy	**Engagement strategy arm: telephone reminders** **Mode of delivery**: telephone **Content:** brief (< 5 minutes) telephone reminders from non-clinician study staff where they first identified themselves and the study, then reminded participants of the ODIN website address and gave instructions for looking up forgotten passwords. They read a brief description of a feature of the website designed to entice the participant to make a return visit then concluded the call. **Frequency, duration and timing:** staff called at two, eight, and 13 weeks after enrolment. **Sender:** the reminder staff had no mental health background, and they were prohibited from engaging in any therapy-like activity. Staff were capable of, and limited to, answering questions only about basic website troubleshooting (e.g. difficulty logging on).	

Comparator	**Comparator arm: mail postcard reminders** **Delivery mode:** mail postcards **Content:** the content was scripted to convey information identical to that included in the telephone reminder calls. **Frequency, duration and timing:** mail was sent at two, eight, and 13 weeks after enrolment. **Sender:** reminder staff who had no mental health background.	
Risk of Bias		
Item	**Author's judgement**	**Description**
Adequate sequence generation?	LOW	'participants were automatically randomized by the website (using random sequence software) to one of the three groups'
Allocation concealment?	LOW	Randomisation was done by a website/software
Blinding?	HIGH	'Participants were not blind to their study condition'
Incomplete outcome data addressed?	LOW	No source of bias was identified
Free of selective reporting?	UNCLEAR	• Engagement outcome measures were not pre-specified • No protocol reported
Other source of bias	LOW	No source of bias was identified

Couper et al., 2010– Journal article	
Participants	2513 were randomised, 1677 were included in the review.
Study designs and arms	RCT (3 arms). **Included arms:** tailored digital intervention (n = 839), tailored digital intervention + human online behavioural intervention (HOBI) (n = 838). **Excluded arm:** untailored digital intervention (n = 836).

Digital Intervention	**Name:** Making effective nutritional choices for cancer prevention (MENU) **Target health behaviour/health condition:** health promotion (intake of fruits and vegetables). The digital intervention offered four core tailored education sessions phased over a four-month period.
Engagement strategy	**Engagement strategy arm: tailored digital intervention + HOBI** **Mode of delivery:** email **Content:** email counselling support sessions. Each counselling session was initiated by a study counsellor within a week after each web session was first visited. Counsellors provided additional support for dietary change and responded to any request for strategies or for nutrition information with a referral to the MENU website. **Frequency, duration and timing:** the counsellor initiated a maximum of four unique email discussions corresponding to each of the four web sessions when the sessions were accessed. Each email discussion was limited to four "back and forth" exchanges, and the duration of these emails was based on the web sessions, which was a four-month period. **Sender:** Counsellors
Comparator	**Comparator arm: tailored digital intervention** This group did not receive any engagement strategy.

Risk of Bias

Item	Author's judgement	Description
Adequate sequence generation?	UNCLEAR	'Randomization was assigned by study site, gender, and stage of change with eating fruit and vegetables' Insufficient information to decide
Allocation concealment?	UNCLEAR	Insufficient information to decide

Blinding?	UNCLEAR	Insufficient information to decide, and the design of the study might make it not possible to blind participants or researchers
Incomplete outcome data addressed?	LOW	No source of bias was identified
Free of selective reporting?	UNCLEAR	• Not all engagement outcomes for the RCT arms were reported(i.e. number of sessions) as data were combined • Engagement outcomes were pre-specified • Protocol was mentioned in the article but not reported fully (could not find link)
Other source of bias	LOW	No source of bias was identified
Farrer et al., 2011 – Journal article		
Participants	155 were randomised, 83 were included in the review.	
Study designs and arms	RCT (4 arms). **Included arms:** web only (n = 38), web with phone tracking (n = 45) **Excluded arms:** phone tracking only (n = 37), control (n = 35).	
Digital Intervention	**Name:** BluePages and MoodGYM **Target health behaviour/health condition:** depression The web-only intervention delivered online psychoeducation on the first week, provided by BluePages (bluepages.anu.edu.au) combined with cognitive behavioural therapy on the second to sixth weeks, provided by MoodGYM (moodgym.anu.edu.au.) BluePages is a freely accessible, psychoeducational website that contains information and resources related to depression. The MoodGYM programme is a free to end-user, online programme for depression. The programme is divided into five modules designed to be completed sequentially.	

Engagement strategy	**Engagement strategy arm: web with phone tracking** **Mode of Delivery:** telephone call **Content:** telephone call addressing any issues associated with the participants' use of the online programmes. **Frequency, duration and timing:** weekly 10 minutes calls for six weeks. **Sender:** telephone counsellor
Comparator	**Comparator arm: web only** This group did not receive any engagement strategy.

Risk of Bias

Item	Author's judgement	Description
Adequate sequence generation?	UNCLEAR	'A block randomisation procedure with stratification based on sex, site of recruitment and severity of psychological distress at screening was used'. Insufficient information to decide
Allocation concealment?	LOW	'Allocation of participants to trial conditions was conducted independently by a research assistant not otherwise involved with the trial'
Blinding?	UNCLEAR	Insufficient information to decide and the design of the study might make it not possible to blind participants or researchers
Incomplete outcome data addressed?	LOW	No source of bias was identified
Free of selective reporting?	UNCLEAR	• Engagement was defined (programme adherence was measured by number of visits to the BluePages psychoeducation site and by the number of MoodGYM

		programme modules completed, ranging from 0 to 5). However, time spent on programme and number of participants were also reported. • Protocol was reported and states that internet programme usefulness/usage will be measured by a questionnaire with 14 items at post-six months and -12 months, but when author was contacted to clarify whether measurement was done using questionnaires.
Other source of bias	LOW	• Power calculations were done but the authors could not meet the target sample size • There was no significant difference in baseline variables across the trial arms • No source of bias was identified
Greaney et al., 2012– Journal article		
Participants	86 were randomised and included in the review.	
Study designs and arms	RCT (2 arms and 1 non- randomised arm). **Included arms:** automated assistance (AA) (n = 36), automated assistance + calls (AAC) (n = 50). **Excluded arm:** observation only (OO) n = 14.	
Digital Intervention	**Name:** Healthy Directions 2 **Target health behaviour/health condition:** targets self-monitoring of the following health behaviours: (1) promote physical activity, (2) reduce red meat intake, (3) increase fruit and vegetable consumption, (4) promote daily multivitamin use, and (5) promote smoking cessation. The website included a user-friendly section where patients could self-monitor all targeted behaviours at once. The website allowed participants to enter data for the day they logged into the website and for the 2 days prior. After entering data, participants received immediate feedback in the form of graphs and descriptive text. Participants could also view their data over time, to assess overall progress.	

Engagement strategy	**Engagement strategy arm: AAC** **Mode of delivery:** emails + telephone calls **Content:** participants received emails that encouraged them to track their behaviours via the study website. Email messages changed daily and included a brief message about the benefits of self-monitoring and a hyperlink to the study website. Participants also received two tailored self-monitoring reports that provided feedback to the individual about his or her frequency of tracking for each of the behaviours during the previous week. Reports were viewed as part of the prompting intervention. If participants did not self-monitor, their reports reiterated the information on the benefits of self-monitoring that was included on the daily emails and encouraged self-monitoring via the study website. Participants also received two technical assistance calls. The calls were designed to be brief (< 5 minutes) and focused on troubleshooting technical questions (e.g. trouble logging in or how to self-monitor on the website). **Frequency, duration and timing:** participants received two weeks of daily emails during the prompting period (weeks two and three) and two tailored self- monitoring reports: the first at the end of week two and the second at the end of week three The phone calls; the first call was made at the end of the first week of prompting (week two) and the second call took place at the end of the second week of prompting (week three). **Sender**: calls were made by a trained health coach
Comparator	**Comparator arm: AA** **Mode of delivery:** emails **Content:** emails were similar to those received by participants in the AAC condition. **Frequency, duration and timing:** participants received two weeks of daily emails during the prompting period (weeks two and three) and two tailored self-monitoring reports: the first at the end of week two and the second at the end of week three

Risk of Bias

Item	Author's judgement	Description
Adequate sequence generation?	UNCLEAR	Randomisation was based on the method used in the parent study where they mentioned it was done by a biostatistician only "Participants who did not meet the self-monitoring threshold during week 1 were randomly assigned, based on primary care physician, following the randomization scheme of the parent study to receive one of 2 prompting interventions" Insufficient information to decide
Allocation concealment?	UNCLEAR	Insufficient information to decide
Blinding?	HIGH	The participants were notified at recruitment that they might receive the engagement strategy
Incomplete outcome data addressed?	LOW	No source of bias was identified
Free of selective reporting?	LOW	• Engagement measures were pre-specified but measures were reported on a graph with no numbers provided • No protocol reported
Other source of bias	LOW	No source of bias was identified
McClure et al., 2013 – Journal article		
Participants	1865 were randomised and included in the review	
Study designs and arms	Randomised Factorial Trial assessing 4 design intervention features (including use of email reminders).**Included arms:** proactive email reminders (n=933), no proactive email reminders (n=932).	

Digital Intervention	**Name:** Q2 **Target health behaviour/ health condition:** smoking cessation The intervention was tailored to users' needs and delivered via the Internet. The intervention included a combination of core intervention content and additional special feature content. The core content was accessible from the main page and organized in three main drop-down headers or content areas, each targeting smokers at different stages of readiness to quit smoking.
Engagement strategy	**Engagement strategy arm: proactive email reminders** **Mode of delivery:** emails **Content:** email messages were standardised across all individuals and encouraged participants to return to the Q2 website to view the optional special feature content. **Frequency, duration and timing:** weekly (for two months)
Comparator	**Comparator arm: no proactive email reminders** This group did not receive any engagement strategy

Risk of Bias

Item	Author's judgement	Description
Adequate sequence generation?	LOW	'randomized to an intervention arm using an automated algorithm'
Allocation concealment?	LOW	'but they were not told any specifics about the treatment arm before or after accessing the intervention'
Blinding?	UNCLEAR	'Participants were blinded to their group assignment.' It was not clear whether study personnel were blinded as well.

Incomplete outcome data addressed?	LOW	No source of bias was identified
Free of selective reporting?	UNCLEAR	• Engagement outcome measures were combined • Engagement measures were pre-specified • Protocol was reported but there were differences in the way engagement strategy was used. However, results reported were preliminary, as one-year follow-up results are not available, so changes done to the engagement strategy might be clarified when the one-year follow-up results are reported. After contacting the authors for clarification, they provided the protocol and a study published in 2014 but this did not contain the engagement measures for 12 months.
Other source of bias	LOW	• The study randomised participants to four factors and they took into account how to balance this. 'Randomization to each factor was balanced across the trial arms to control for their effects on each factor of interest and stratified by baseline readiness to quit smoking' • No source of bias was identified.
Mohr et al., 2013– Journal article		
Participants	102 were randomised, 69 were included in the review	
Study designs and arms	RCT (3 arms). **Included arms**: self-directed (n = 35), coach assisted (n = 34). **Excluded arm:** waitlist (n = 33).	
Digital Intervention	**Name**: moodManager Target health behaviour/health condition: depression The digital intervention provided access to an expanded version of a web-based cognitive behavioural therapy program	

Engagement strategy	**Engagement strategy arm: coach assisted** **Mode of delivery**: phone calls **Content:** teleCoaching focused on enhancing adherence to moodManager by establishing a supportive relationship, setting and reviewing login goals, positively reinforcing login and site use, encouraging use of moodManager when login goals were not met, and answering any questions regarding the functionality of the site. Discussions related specifically the CBT content of moodManager were not permitted. When participants raised questions about life difficulties, the coach could suggest areas of the website to explore, but did not engage in a discussion of the life problem with the patient and did not assist the patient in the therapeutic use of the site. **Frequency, duration and timing:** weekly 5–10 minute calls for 12 weeks. Coaches spoke weekly by telephone with participants and were available by email. Participants received an initial "engagement session," lasting 30–45 minutes, to establish a bond, convey benevolence and expertise, and discuss treatment expectations. Subsequent conversations with the coach were intended to be 5–10 minutes in length. Participants were also permitted to email their coaches with questions during the week. **Sender:** two masters level social workers and two Ph.D. level psychologists
Comparator	**Comparator arm: self-directed** This group did not receive any engagement strategy.

Risk of Bias

Item	**Author's judgement**	
Adequate sequence generation?	LOW	'Participants were randomly assigned by a statistician. Computer generated randomization was conducted on a 1:1:1 ratio in blocks of 6, stratified by pharmacotherapy status."

Allocation concealment?	LOW	"The statistician was blinded to baseline assessment to prevent allocation bias."
Blinding?	UNCLEAR	Insufficient information to decide and the design of the study might make it not possible to blind participants but the statistician was blinded.
Incomplete outcome data addressed?	LOW	No source of bias was identified
Free of selective reporting?	LOW	• Engagement outcome measure was pre-specified • Protocol was reported
Other source of bias	LOW	• Power calculations were done • There was no significant difference in baseline variables across the trial arms • To minimize loss-to-follow-up, participants were paid up to $100 for completion of assessments. Participants were clearly informed that payment was not for use of the website, to ensure that payments did not influence treatment adherence • No source of bias was identified
Munoz et al., 2009 – Journal article		
Participants	1000 were randomised, 498 were included in the review.	
Study designs and arms	Parallel-groups RCT (4 arms). **Included arms:** Guía (n = 247), Guía + Individually Timed Educational Messages (ITEMs) (n = 251) **Excluded arms:** Guía + ITEMs + mood management course (n = 251) and Guía + ITEMs + mood management course + virtual group (n = 251).	

Digital Intervention	**Name:** Guía para Dejar de Fumar (Guide to Stop Smoking, "Guía") **Target health behaviour/health condition:** smoking cessation Web-based intervention "Guía", a National Cancer Institute evidence-based intervention initially developed for Spanish-speaking smokers. It contained an online static "Guía," a cigarette counter, and an online journal to record experiences while quitting.
Engagement strategy	**Engagement strategy arm: Guía + ITEMs** **Mode of delivery:** emails **Content:** automated emails with links to the Guía keyed to quit date. **Frequency, duration and timing:** timed to quit date for approximately eight weeks. **Sender:** automated
Comparator	**Comparator arm: Guía** This group did not receive any engagement strategy.

Risk of Bias

Item	Author's judgement	Description
Adequate sequence generation?	LOW	'Stratified randomization using gender and history of MDEs was implemented using an automated algorithm programmed into the Web site'
Allocation concealment?	LOW	Randomisation was done by software
Blinding?	HIGH	It is unclear whether users were blinded; however, the authors did mention one group that was blinded: 'Research assistants were blind to assigned condition, requested participants not to disclose their condition assignment, and limited their interaction to obtaining data'

Incomplete outcome data addressed?	LOW	No source of bias was identified
Free of selective reporting?	UNCLEAR	• The engagement outcome was mentioned in the methods, however not full data for each arm was given 'The cigarette counter and the journal were available to all participants and served as a proxy for site utilization.' • No protocol reported
Other source of bias	LOW	• Power calculations were done and the target sample size was met • No source of bias was identified
Proudfoot et al., 2012 – Journal article		
Participants	419 were randomised, 273 were included in review.	
Study designs and arms	RCT (3 arms). **Included arms:** Bipolar Education Program (BEP) (n = 139), BEP + Informed Supporters (IS) (n = 134). **Excluded arm:** control (n = 134).	
Digital Intervention	**Name:** BEP **Target health behaviour/ health condition:** bipolar disorder The online psychoeducation programme was an eight-session audio–visual programme. The programme topics were standard for all users and presented in a sequential, non-interactive manner. Behavioural tasks for completion between online sessions were added in this study to facilitate application and practice of the content. One module per week was sent to participants over eight weeks.	

Engagement strategy	**Engagement strategy arm: BEP + IS** **Mode of delivery:** emails **Content:** email coaching by people with bipolar disorder. Emails were designed to answer any questions participants may have had and to provide examples of how to apply the education material in the website to their everyday lives. Emails focused on effective self-management across three domains: medical management, emotional management and role management. Emails were linked to the content of the online psycho- education program. **Frequency, duration and timing:** emails to a participant from an Informed Supporter were restricted to two 300-word communications per week for eight weeks. **Sender:** Informed Supporters, people with bipolar disorder who had been effectively managing their condition for at least two years.
Comparator	**Comparator arm: BEP** This group did not receive any engagement strategy.

Risk of Bias

Item	Author's judgement	Description
Adequate sequence generation?	LOW	'Randomisation was conducted using electronically generated random numbers, created in blocks of 100.'
Allocation concealment?	LOW	'A researcher independent of the project conducted the random allocation procedure.'
Blinding?	LOW	Both participants and researchers were not aware of the allocation 'The researchers were not aware of, nor had any influence over, the next allocation. Participants were not aware as to whether they had been allocated to the intervention or control conditions.'

Incomplete outcome data addressed?	LOW	No source of bias was identified
Free of selective reporting?	LOW	• Engagement outcome measure was pre-specified. 'Participant adherence was defined as completion and return of four or more of the eight module workbooks', and this was reported for all arms. • No protocol reported
Other source of bias	LOW	• Power calculations were done and target sample size were met • No source of bias was identified

Santucci et al., 2014 [first available online 2013] – Journal article	
Participants	44 were randomised, 43 were included in the review.
Study designs and arms	Pilot RCT (2 arms). **Included arms:** no reminder (n = 22) and reminder (n = 21).
Digital Intervention	**Name:** Beating the Blues (BtB) **Target health behaviour/health condition:** anxiety and depression An entirely automated and tailored web-based cognitive-behavioural intervention that consisted of eight sequential weekly sessions. The programme is designed for sessions to build on one another, often providing individualisation to the patient's unique needs.
Engagement strategy	**Engagement strategy arm: reminder** **Mode of delivery:** emails **Content:** emails were sent to remind users to complete their BtB session for the week. **Frequency, duration and timing:** weekly for eight weeks. **Sender:** study staff

Comparator	**Comparator arm: no reminder** This group did not receive any engagement strategy.	
Risk of Bias		
Item	**Author's judgement**	**Description**
Adequate sequence generation?	UNCLEAR	Insufficient information to decide
Allocation concealment?	UNCLEAR	Insufficient information to decide
Blinding?	UNCLEAR	Insufficient information to decide and the design of the study might make it not possible to blind participants or researchers
Incomplete outcome data addressed?	LOW	The number of participants allocated at baseline to intervention or control group was 43, but the authors reported that the number of participants with baseline characteristics whose total number of sessions was measured was 42. It is unclear whether 42 or 43 participants' engagement measures were reported; however the risk on engagement measure is still low
Free of selective reporting?	LOW	• Engagement outcome analysis was mentioned in the analysis section "The effect of reminder condition on session completion was evaluated using a linear regression with total number of sessions regressed onto group condition." • No protocol reported
Other source of bias	LOW	• Baseline differences were compared: 'the two randomized groups were compared with respect to baseline values of the outcome measures and demographic variables'. • No source of bias was identified

Schneider et al., 2012– Journal article	
Participants	3448 were randomised and included in the review.
Study designs and arms	RCT (2 arms). **Included arms:** no prompting (n = 1658), prompting (n = 1790).
Digital Intervention	**Name:** Not mentioned **Target health behaviour/health condition:** multiple health behaviours: physical activity, fruit and vegetable intake, smoking cessation and alcohol consumption. The Computer Tailored (CT) program used a dual approach to guide people toward behaviour change. The first part consisted of a health risk appraisal and was aimed at increasing participants' awareness of their health behaviour status and second part provided assistance in changing participants' health behaviour by offering five separate CT modules. The modules used a fixed, gradual approach consisting of four steps, guiding people toward behaviour change. The website was regularly updated.
Engagement strategy	**Engagement strategy arm: prompting** **Mode of delivery:** email **Content:** an email was sent to prompt users to revisit the programme. This email opened with a personalised greeting and reminded people about their first visit to the programme. Subsequently, people were invited to revisit the programme to obtain information on their health status and to monitor their progress. Participants were also informed of the opportunity to receive additional, iterative health advice on the health behaviours selected at baseline or on a new behaviour. The email also contained details on personal login information (user name and password). The email concluded with greetings from the research team and contact information. **Frequency, duration and timing:** email was sent three months from the baseline visit.
Comparator	**Comparator arm: no prompting** This group did not receive any engagement strategy.
Risk of Bias	

Item	Author's judgement	Description
Adequate sequence generation?	LOW	'A computer software randomization device to determine random allocations at the respondent level'
Allocation concealment?	LOW	Randomisation was done by software
Blinding?	HIGH	Protocol mentions that blinding was not possible since participants will take notice of the fact that they received additional email prompts but unclear whether researchers were blinded.
Incomplete outcome data addressed?	LOW	No source of bias was identified
Free of selective reporting?	UNCLEAR	• Protocol was reported • Time spent on the website was mentioned in the protocol but not reported • Protocol describes the engagement strategy as an email sent every three months for the 18 months (study period). Data presented in this study was from November 2013 until August 2010, and only one email was sent in this study, and usage was monitored for four months (three months before the email was sent and one month after), so it is not clear whether they deviate from the protocol or whether they just limited their analysis to the effect of one email.
Other source of bias	LOW	• There was no difference at baseline: 'A randomization check revealed no significant differences between respondents in the prompting and no-prompting condition'. • No source of bias was identified

Schneider et al., 2013b – Journal article

Participants	240 were randomised and included in review.
Study designs and arms	RCT (7 arms). **Included arms:** control condition - no prompt (NP)(n = 34), 6 experimental conditions: 3 groups sent prompt with standard content (SP) at 2 weeks (n = 34), at 4 weeks (n = 34), at 6 weeks (n = 35) and 3 groups sent prompt with standard prompt and additional content (SP+) at 2 weeks (n = 36), at 4 weeks (n = 35) and at 6 weeks (n = 32).
Digital Intervention	**Name:** Internet-Delivered Computer-Tailored Lifestyle Program **Target health behaviour/health condition**: five health behaviours: Physical activity, fruit and vegetables intake, smoking cessation and decreasing alcohol consumption. Website with computer tailored (CT) lifestyle program embedded in it. The programme used a dual approach to guide people toward behaviour change. First, awareness of participants' current health behaviour status was increased by comparing their status to the Dutch public health guidelines set for these health behaviours. Second, assistance was provided in changing participants' health behaviour by using CT modules available per behaviour. The modules used a fixed, gradual approach consisting of four steps, guiding people toward behaviour change. The website was regularly updated.
Engagement strategy (1)	**Arms 1, 2 and 3: standard prompts** **Mode of delivery:** email **Content:** participants received an email that contained a reminder about user previous visit to the CT programme and an invitation to visit it again to monitor their behaviour change progress and obtain additional feedback and advice. This standard email opened with a personalised greeting and reminded people about their first visit to the programme. Participants were also given the opportunity to receive additional iterative health advice on the health behaviour(s) selected at baseline or on a new behaviour. To facilitate logging in to the programme, the email also contained details about their personal login information (username and password). The email concluded with greetings from the research team and contact information.

	Frequency, duration and timing: one email was sent to each group either on the second or fourth or the sixth week from baseline.
Engagement strategy (2)	**Arms 4, 5 and 6: standard prompt and additional content (SP+)** **Mode of delivery:** email **Content:** participants received the same email content as SP with additional content. Additional content consisted of new information that was placed on the programme website since they last visited it. This information referred to nutrition and provided examples of healthy food alternatives that were available for that current season (e.g. spring/summer). **Frequency, duration and timing:** one email was sent to each group either on the second or fourth or the sixth week from baseline.
Comparator	**Comparator arm: no prompt** This group did not receive any engagement strategy.

Risk of Bias

Item	Author's judgement	Description
Adequate sequence generation?	LOW	'Randomization occurred at the respondent level by means of a computer software randomization device'
Allocation concealment?	LOW	Randomisation was done by a software
Blinding?	UNCLEAR	Insufficient information to decide
Incomplete outcome data addressed?	LOW	No source of bias was identified
Free of selective reporting?	LOW	• Engagement outcome measures were pre-specified

		• Non-significant results when comparing different prompt groups to control group were not reported • No protocol was reported
Other source of bias	LOW	• There was no difference at baseline for gender only 'a randomization check revealed that females were equally distributed'. • No source of bias was identified
Simon et al., 2011 – Journal article		
Participants	118 were randomised and included in the review.	
Study designs and arms	Pilot RCT (2 arms). **Included arms:** programme only (n = 54), coaching (n = 64).	
Digital Intervention	**Name:** My Recovery Plan **Target health behaviour/health condition:** bipolar disorder An interactive online programme to support people living with bipolar disorder in creating and using personal recovery plans. Participants received online coaching support from certified peer specialists; however, communication with those coaches was done within the website to protect participants' privacy.	
Engagement strategy	**Engagement strategy arm: coaching** **Mode of delivery:** email **Content:** emails were sent to the participants alerting them every time they received a new message from their coaches. Emails did not contain sensitive information. **Frequency, duration and timing:** email notifications were sent when coaches sent private messages on the website so frequency varies for different users; however, those notifications were related to coaches messaging users which was for one year (the duration of the digital intervention). **Sender:** automated	

Comparator	**Comparator arm: program only** This group did not receive any engagement strategy.	
Risk of Bias		
Item	**Author's judgement**	**Description**
Adequate sequence generation?	UNCLEAR	Insufficient information to decide
Allocation concealment?	UNCLEAR	The authors mentioned that they took measures to conceal allocation of participants "To prevent contamination, discussion groups and chat rooms for the program-only and coaching groups were separated." No information about whether allocation was concealed from investigators
Blinding?	UNCLEAR	insufficient information to decide and the design of the study might make it not possible to blind participants or researchers
Incomplete outcome data addressed?	LOW	No source of bias was identified
Free of selective reporting?	LOW	• Engagement outcome measures were pre-specified • no protocol was reported
Other source of bias	LOW	• They reported significance level for the intervention and control group • No source of bias was identified
Titov et al., 2009 – Journal article		
Participants	168 were randomised, 163 were included in review	
Study designs and arms	Pragmatic RCT (2 arms). **Included arms:** computerised cognitive behaviour therapy (CCBT) (n = 82) and CCBT + Telephone (n = 81).	

Digital Intervention	**Name:** Not mentioned but study name was Shyness 4 **Target health behaviour/health condition**: social phobia A computer-delivered treatment that consisted of six online lessons, a summary/homework assignment for each lesson, comments by prior participants about each lesson. All participants were asked to complete the six lessons within eight weeks of starting.
Engagement strategy	**Engagement strategy arm: CCBT + Telephone** **Mode of delivery:** telephone + emails + text messages **Content:** participants were telephoned each week by a research assistant, at a time specified by the participant, when they were commended and encouraged to persevere, but no clinical advice was offered. Each participant received four text messages and an average of 15 automated emails, which were sent at specific stages of the programme (the criteria for sending an email included a participant completing a lesson, not completing a lesson within a specified time frame, or to alert participants to additional material that had been made available in relation to a specific lesson or issue). **Frequency, duration and timing:** weekly telephone calls, fortnightly text and variable emails for eight weeks. **Sender:** Research assistant made the calls
Comparator	**Comparator arm: CCBT** **Mode of delivery:** emails + text messages **Content:** each participant received four text messages and an average of 15 automated emails, which were sent at specific stages of the programme (the criteria for sending an email was similar to the intervention arm). **Frequency, duration and timing:** fortnightly text and variable emails for eight weeks.

Risk of Bias

Item	Author's judgement	Description

Adequate sequence generation?	LOW	'randomized by NT via a true randomization process (www.random.org)'
Allocation concealment?	LOW	Randomisation was done by a website
Blinding?	UNCLEAR	Blinding was not possible: 'Self-report measures precluded blinding'
Incomplete outcome data addressed?	LOW	No source of bias was identified
Free of selective reporting?	UNCLEAR	• Some Engagement outcome measures were not pre-specified (logging in) while others were mentioned(completers and non-completers) • No protocol was reported
Other source of bias	LOW	• Power calculations were done and target sample size met • Baseline differences were measured for certain variables "No between-group differences on pre-treatment measures or pre-treatment expectations were observed" • No source of bias was identified
Titov et al.,2013 – Journal article		
Participants	257 were randomised, 206 were included in the review	
Study designs and arms	RCT (3 arms). **Included arms:** treatment group (n = 106), treatment Plus Automated Email Group (n = 100). **Excluded arm:** control group (n = 51).	
Digital Intervention	**Name:** Wellbeing course **Target health behaviour/health condition**: anxiety and depression The digital intervention was a five lesson transdiagnostic online intervention model based on models of cognitive behavioural and interpersonal therapies. It is a structured intervention where participants are instructed to read lessons in order over eight weeks. Lessons 1,2,3,4 and 5 are available at the beginning of weeks 1,2,4,5, and 7 respectively.	

Engagement strategy	**Engagement strategy arm:** treatment Plus Automated Email Group **Mode of delivery**: emails **Content: b**oth participants groups received an email at the start of the Course providing guidelines and a recommended timetable to get the most out of the Course Some emails were triggered based on participant behaviour: specifically, emails were triggered when (1) participants completed each Lesson during the Course, and (2) if participants had not completed a Lesson within seven days of it becoming available. Emails were also triggered (1) at the beginning of each week when new Lessons became available or, if no new Lessons became available, to suggest some tasks for the week, and (2) at set times when participants were known to experience increases in symptoms or to have increased difficulties practicing skills. The emails were written and designed to (1) make sure participants always new about new content available on the site, (2) remind participants about unread materials, (3) reinforce progress and skills practice, (4) 'normalise' the challenges of learning new skills, and (5) emphasise and explain that symptom reduction required gentle, but consistent, practice of the skills over time. Each email was brief and was comprised of two to three paragraphs containing three or four concise sentences. Each email used the participant's first name and was written to convey a warm and supportive tone. No emails contained personal or detailed clinical information. **Frequency, duration and timing:** at least two emails per week and some emails were triggered based on participants' behaviour. The duration of these emails was based on the digital intervention sessions, which was eight weeks.
Comparator	**Comparator arm**: treatment group Treatment group only received one email at the beginning of the digital intervention similar to treatment Plus Automated Email Group.
Risk of Bias	

Item	Author's judgement	Description
Adequate sequence generation?	LOW	'A colleague in another country used the website www.random.org to create a list of 300 randomly generated numbers. These were numbers were sorted by size and the highest 20% and lowest 40% were marked to indicated they referred to the control group and the treatment group, respectively. The remainder were marked to indicate they belong to the treatment Plus Automated Email Group. The list was then returned to its original order and was used to automatically assign applicants to a condition."
Allocation concealment	LOW	"Randomisation was done by software."
Blinding?	UNCLEAR	Insufficient information to decide, and the design of the study might make it not possible to blind participants or researchers
Incomplete outcome data addressed?	LOW	No source of bias was identified
Free of selective reporting?	LOW	• Engagement outcome measure was pre-specified • Protocol was reported
Other source of bias	UNCLEAR	• Power calculations were done • There was a significant difference in age and medication intake (baseline variables) between the groups.

Table 3: Characteristics of study participants included in the review

Study	Female, %		Age, mean years(SD)		Highest education, %[1]	
	Intervention	Control	Intervention	Control	Intervention	Control
Berger et al., 2011a	53.1	-	37.2(11.2)	-	University: 25.9	-
Berger et al., 2011b	68.0	72.0	38.2(15.1)	38.6(14.2)	University: 48.0	32.0
Clarke et al., 2005	83.8	72.0	44.4(10.5)	50.3(10.8)	College graduate: 38	38.7
Couper et al., 2010	69	69	46.4(10.9)	46.5(10.8)	Post bachelor education: 26	22
Farrer et al., 2011	82	86	41.7(12.1)	37.5(12.0)	-	-
Greaney et al., 2012	-	-	-	-	-	-
McClure et al., 2013	63.16	-	-	-	College degree or higher: 21.23	-
Mohr et al., 2013	73.5	71.4	47.6(12.4)	48.9(14.6)	Advanced Degree: 32.4	40
Munoz et al., 2009	-	-	-	-	-	-
Proudfoot et al., 2012	73.1	66.9	-	-	Tertiary education: 69.4	69.1
Santucci et al., 2014	69.77	-	23.0(4.2)	-	-	-
Schneider et al., 2012	47.2	-	43.61(12.60)	-	High education level: 42.11	-
Schneider et al., 2013b	73.3	-	50(14.99)	-	High education level: 6.3	-
Simon et al., 2011	72	-	-	-	-	-
Titov et al., 2009	52	-	41.2	-	-	-
Titov et al., 2013	77	73.6	40.31(10.13)	40.71(9.07)	Degree/Diploma: 59	68.9

[1]Category with the highest percentage was extracted

2.5.3 Aim of studies

Seven studies aimed to evaluate the effect of adding the engagement strategy on improving the effectiveness of the digital intervention (Berger et al., 2011a, Berger et al., 2011b, Clarke et al., 2005, Greaney et al., 2012, Muñoz et al., 2009, Titov et al., 2009, Titov et al., 2013). Four studies were about evaluating the effect of the strategy on engagement specifically (McClure et al., 2013, Mohr et al., 2013, Santucci et al., 2014, Schneider et al., 2012). Two studies aimed to evaluate the effect of the strategy on digital intervention outcomes and engagement (Farrer et al., 2011, Proudfoot et al., 2012). One study evaluated the effect of the strategy's timing and content on engagement (Schneider et al., 2013b), another study evaluated the effect of adding online peer coaching on increasing participation with a digital intervention (Simon et al., 2011), and one study explored the level of engagement and factors associated with it measured by auxiliary data that captures details about the process of interaction with a digital intervention (Couper et al., 2010).

2.5.4 Characteristics of study participants

Most of the studies with reported participant characteristics had more females than males, except for one study (Schneider et al., 2012); mean age ranged from 23 to 50 in the intervention groups (Berger et al., 2011a, Berger et al., 2011b, Clarke et al., 2005, Couper et al., 2010, Farrer et al., 2011, Mohr et al., 2013, Santucci et al., 2014, Schneider et al., 2012, Schneider et al., 2013b, Titov et al., 2009, Titov et al., 2013); and the percentage of participants in the highest education category ranged between 6.3 and 69% (Berger et al., 2011a, Berger et al., 2011b, Clarke et al., 2005, Couper et al., 2010, McClure et al., 2013, Mohr et al., 2013, Proudfoot et al., 2012, Schneider et al., 2012, Schneider et al., 2013b, Titov et al., 2013) (see Table 3 for characteristics of study participants included in the review).

2.5.5 Digital interventions

Conditions addressed

The digital interventions targeted different health behaviours or conditions. Two studies targeted social phobia (Berger et al., 2011a, Titov et al., 2009), six studies targeted depression (Berger et al., 2011b, Clarke et al., 2005, Farrer et al., 2011, Mohr et al., 2013, Santucci et al., 2014, Titov et al., 2013), two studies targeted bipolar disorder (Proudfoot et al., 2012, Simon et al., 2011) and two studies targeted anxiety (Santucci et al., 2014, Titov et al., 2013). The rest of the studies targeted different health behaviours including smoking cessation (n = 4), decreasing alcohol consumption (n = 2) self-monitoring of healthy behaviour (n = 1), physical activity (n = 2) and healthy diet (n = 3) (Couper et al., 2010, Greaney et al., 2012, McClure et al., 2013, Muñoz et al., 2009, Schneider et al., 2012, Schneider et al., 2013b).

Content and structure

Two of the studies described their digital interventions as self-help guides with modules presented in a sequential order and not provided gradually; thus, participants can complete the whole programme at once (Berger et al., 2011a, Berger et al., 2011b). Seven digital interventions were composed of sessions that were presented in a sequential and phased order (Couper et al., 2010, Farrer et al., 2011, Proudfoot et al., 2012, Santucci et al., 2014, Schneider et al., 2012, Schneider et al., 2013b, Titov et al., 2013). Two studies updated their website with new information (Schneider et al., 2012, Schneider et al., 2013b), and two studies described their digital interventions as interactive (Clarke et al., 2005, Simon et al., 2011).

2.5.6 Engagement strategies

The characteristics of the engagement strategies differed amongst the included studies, and the following is a list of the characteristics identified and the definition used for each category.

Timing-when was the strategy used?

Two studies reported using engagement strategies early during the study; one study used engagement strategies on the second and third week from baseline (Greaney et al., 2012), and the other used it for the first two months post-enrolment (McClure et al., 2013). One study reported using a strategy on the third month from baseline and measured engagement until the fourth month from baseline (Schneider et al., 2012). One study used strategies during variable time points: second, fourth or sixth week from baseline (Schneider et al., 2013b).

Frequency-how many times was the strategy used?

Most of the studies reported using engagement strategies on a regular basis. Eight studies reported that an engagement strategy was used at least once per week (Berger et al., 2011a, Berger et al., 2011b, Farrer et al., 2011, McClure et al., 2013, Mohr et al., 2013, Santucci et al., 2014, Titov et al., 2009, Titov et al., 2013). One study used the strategy for two weeks (Greaney et al., 2012). One study used a strategy three times on the second, eighth and thirteenth week after enrolment (Clarke et al., 2005), and one study used an engagement strategy every time a user initiated one of the digital intervention sessions (Couper et al., 2010). Three studies reported variable frequencies (Muñoz et al., 2009, Proudfoot et al., 2012, Simon et al., 2011). Two studies only used an engagement strategy once during the whole study period (Schneider et al., 2012, Schneider et al., 2013b).

Duration-for how long was the strategy used?

11 out of the 16 studies used an engagement strategy for the duration of the digital intervention (Berger et al., 2011a, Berger et al., 2011b, Couper et al., 2010, Farrer et al., 2011, Mohr et al., 2013, Muñoz et al., 2009, Proudfoot et al., 2012, Santucci et al., 2014, Simon et al., 2011, Titov et al., 2009, Titov et al., 2013), while in the other studies participants received them at specific times (Clarke et al., 2005, Greaney et al., 2012, McClure et al., 2013, Schneider et al., 2012, Schneider et al., 2013b).

Content-what did the strategy contain?

Six studies used strategies that offered assistance with the digital intervention (Berger et al., 2011a, Berger et al., 2011b, Clarke et al., 2005, Farrer et al., 2011, Greaney et al., 2012, Mohr et al., 2013), three studies used strategies that advertised digital intervention content (Schneider et al., 2012, Schneider et al., 2013b, Titov et al., 2013), and one study's strategy described digital intervention features (Clarke et al., 2005). Strategies in four studies linked users to specific digital intervention pages or sections (Mohr et al., 2013, Muñoz et al., 2009, Proudfoot et al., 2012, Simon et al., 2011), and in six studies strategies reminded or invited users to complete their digital intervention sessions (McClure et al., 2013, Santucci et al., 2014, Schneider et al., 2012, Schneider et al., 2013b, Titov et al., 2009, Titov et al., 2013). Six studies used strategies to provide support and feedback on the health behaviour/health problem or on engagement with the digital intervention (Berger et al., 2011a, Berger et al., 2011b, Couper et al., 2010, Mohr et al., 2013, Proudfoot et al., 2012, Titov et al., 2013).

Behaviour change techniques

Some studies described their strategies' content in a way that enabled coding them as BCTs (see Appendix 3: Behaviour Change Techniques definitions used by study). The most commonly used BCTs were social support (unspecified), which was used by five studies (Berger et al., 2011a, Berger et al., 2011b, McClure et al., 2013, Proudfoot et al., 2012, Titov et al., 2009) and Prompts/cue, which was used by five studies, where they explicitly prompted the users to revisit the digital intervention (McClure et al., 2013, Muñoz et al., 2009, Santucci et al., 2014, Schneider et al., 2012, Titov et al., 2013). Three studies provided feedback on digital intervention engagement (Berger et al., 2011a, Berger et al., 2011b, Greaney et al., 2012). Three studies used social reward in the form of written encouragement and praise on participants' progress in the digital intervention (Berger et al., 2011a, Berger et al., 2011b, Titov et al., 2009), and two studies provided feedback on the outcome of digital intervention engagement in terms of the improvement in their health (Berger et

al., 2011a, Berger et al., 2011b). One study provided instructions on how to engage with a digital intervention, such as how to log in (Clarke et al., 2005). One study used strategies to set goals of engagement (Mohr et al., 2013) Four studies were not explicitly described, so techniques could not be easily coded (Couper et al., 2010, Farrer et al., 2011, Schneider et al., 2013b, Simon et al., 2011). For example, one study described their strategies as study staff or therapists offering assistance and help with problems faced by participants in using the digital intervention, but there was not enough information to code them as problem solving as it was not clear whether by 'offering assistance' the authors meant the problem was analysed and solutions offered to facilitate engagement (Farrer et al., 2011). For one study that described their strategies as an email sent to alert users of internal message received in digital intervention, there was not enough information to code it as prompt/cue (Simon et al., 2011); however, after contacting the author, an explicit description of the content was provided which enabled coding the content as prompt/cue.

Sender/provider-who sent the strategy or provided it?

Nine studies used human-supported strategies. Of these nine studies, four used therapists or counsellors (Berger et al., 2011a, Berger et al., 2011b, Couper et al., 2010, Farrer et al., 2011), one study used non-clinician staff (Clarke et al., 2005), three used research staff who only encouraged participation and provided no clinical advice (Mohr et al., 2013, Santucci et al., 2014, Titov et al., 2009), one used trained peers (Proudfoot et al., 2012), and one used trained coaches (Greaney et al., 2012). Two studies used automated strategies (Muñoz et al., 2009, Simon et al., 2011), and four studies did not mention the sender or provider of the engagement strategy (McClure et al., 2013, Schneider et al., 2012, Schneider et al., 2013b, Titov et al., 2013).

Type of mode of delivery-which modes of delivery were used?

Out of the 16 studies, ten used emails only (Berger et al., 2011b, Couper et al., 2010, McClure et al., 2013, Muñoz et al., 2009, Proudfoot et al., 2012, Santucci et al., 2014, Schneider et al., 2012, Schneider et al., 2013b, Simon et al., 2011,

Titov et al., 2013) and three studies used phone calls (Clarke et al., 2005, Farrer et al., 2011, Mohr et al., 2013). The other three studies used more than one delivery mode: two used phone calls in addition to emails (Berger et al., 2011a, Greaney et al., 2012), and one used phone calls, emails and text messages (Titov et al., 2009).

Use of theory-were strategies based on a theory?

No study mentioned using a theoretical framework for engagement strategies.

Tailoring-were the strategies tailored according to users' engagement or characteristics?

Three studies explicitly described their strategies as tailored: in one study, participants received tailored reports about the frequency of their usage of the digital intervention via emails (Greaney et al., 2012), and two studies sent emails with personalised greetings (Schneider et al., 2012, Schneider et al., 2013b). Six studies described strategies that can potentially be labelled as tailored: four studies provided feedback about progress in the digital intervention usage to their participants (Berger et al., 2011a, Berger et al., 2011b, Titov et al., 2013, Mohr et al., 2013), one reported using peer coaches to provide advice via email to participants on how to use the materials provided in through the digital intervention (Proudfoot et al., 2012), and the last one sent emails to users keyed to their smoking quit dates (Muñoz et al., 2009). For one study, the author replied explaining that participants received non-tailored phone calls, although if the participants did not complete the weekly module when phoned, they were encouraged to complete it and offered a follow-up phone call once they had done that (Farrer et al., 2011).

2.5.7 Comparators

Technology-based engagement strategy compared to no strategy

Out of the 16 studies with full information, 13 studies compared technology-based engagement strategy to no strategy (Berger et al., 2011a, Berger et al.,

2011b, Couper et al., 2010, Farrer et al., 2011, McClure et al., 2013, Mohr et al., 2013, Muñoz et al., 2009, Proudfoot et al., 2012, Santucci et al., 2014, Schneider et al., 2012, Schneider et al., 2013b, Simon et al., 2011, Titov et al., 2013).

Technology-based engagement strategy compared to non-technology based strategy

One study compared a technology-based engagement strategy to a non-technology based strategy (post) (Clarke et al., 2005).

The third comparator group was intended to measure the relative effectiveness of the different characteristics of engagement strategies, but data was not available, and a sub-group of the studies was included in the 'multiple strategies' group that included similar technological-based strategies on both study arms, but one arm had an additional strategy.

Multiple strategies

The effect of multiple strategies refers to studies that have two arms, with both arms receiving similar technology-based strategies but one receiving an additional one. Three studies reported an additional strategy, which was a phone call-delivered strategy. Berger et al. (2011a) had additional phone calls to the original email-delivered strategy; this additional strategy was optional, with participants opting for it if they chose. Greaney et al. (2012) also had two additional phone calls providing technical assistance with the email strategy, and Titov et al. (2009) had technical assistance phone calls in addition to the original email and text message delivered strategies.

2.5.8 Outcomes

Primary outcome

Seven studies reported dichotomous outcomes only, five studies reported continuous outcomes only, and three reported dichotomous and continuous

outcomes. One study's outcome type was unclear. The following details the type of outcomes that were measured.

Dichotomous engagement outcomes

Four studies measured number of participants who visited the digital intervention (McClure et al., 2013, Schneider et al., 2012, Schneider et al., 2013b, Simon et al., 2011), and six studies measured the number of participants who completed digital intervention sessions or lessons (Berger et al., 2011b, Farrer et al., 2011, Greaney et al., 2012, Proudfoot et al., 2012, Santucci et al., 2014, Titov et al., 2013).

Continuous engagement outcomes

Two studies measured number of digital intervention visits/ logins (Clarke et al., 2005, Titov et al., 2009). Four studies measured number of lessons/sessions completed by participants (Berger et al., 2011a, Berger et al., 2011b, Farrer et al., 2011, Santucci et al., 2014). One study measured time devoted to the digital intervention by minutes (Couper et al., 2010) and one study measured the number of days logged in during the study period (Mohr et al., 2013).

Secondary outcomes

Adverse outcomes

No study reported any adverse outcomes.

Economic outcomes

No study reported any economic outcomes.

Timing of follow-up

Timing of follow-up in most of the studies was related to the effect of the digital intervention on the health outcome rather than the engagement strategy, but there were three exceptions. In Schneider et al. (2012), engagement was measured for one month after the strategy was sent and three months before it was sent. In Greaney et al. (2012), engagement was observed for up to 13

weeks following the last engagement strategy sent to participants. Schneider, et al. (2013b) also measured visits/logins to the digital intervention two weeks after receiving the engagement strategy and compared it to baseline visits. Outcomes were measured post- intervention for the rest of the studies.

2.5.9 Risk of bias

The studies differed in the way they were conducted, and some did not provide sufficient information to judge their quality. All studies reported randomisation, but only 11 reported adequate sequence generation process (Berger et al., 2011a, Berger et al., 2011b, Clarke et al., 2005, McClure et al., 2013, Mohr et al., 2013, Muñoz et al., 2009, Schneider et al., 2012, Schneider et al., 2013b, Titov et al., 2009, Titov et al., 2013, Proudfoot et al., 2012). 12 studies had adequate allocation concealment (Berger et al., 2011a, Berger et al., 2011b, Clarke et al., 2005, Farrer et al., 2011, McClure et al., 2013, Mohr et al., 2013, Muñoz et al., 2009, Proudfoot et al., 2012, Schneider et al., 2012, Schneider et al., 2013b, Titov et al., 2009, Titov et al., 2013). One study reported that participants and researchers were blinded (Proudfoot et al., 2012). Engagement measures were pre-specified in 13 studies (Berger et al., 2011b, Couper et al., 2010, Farrer et al., 2011, Greaney et al., 2012, McClure et al., 2013, Mohr et al., 2013, Muñoz et al., 2009, Santucci et al., 2014, Schneider et al., 2012, Schneider et al., 2013b, Titov et al., 2013, Proudfoot et al., 2012, Simon et al., 2011); however, out of these, three studies did not report some engagement outcomes for the intervention and control group separately (Couper et al., 2010, McClure et al., 2013, Muñoz et al., 2009). Engagement measures were measured objectively so no bias was identified for any of the studies in terms of incomplete outcome data except for one study where engagement measures were not reported for six participants who dropped out (Berger et al., 2011a). Protocols were only reported in five studies (Farrer et al., 2011, McClure et al., 2013, Mohr et al., 2013, Schneider et al., 2012, Titov et al., 2013)(see Figure 3: Risk of bias summary and Figure 4: Risk of bias graph).

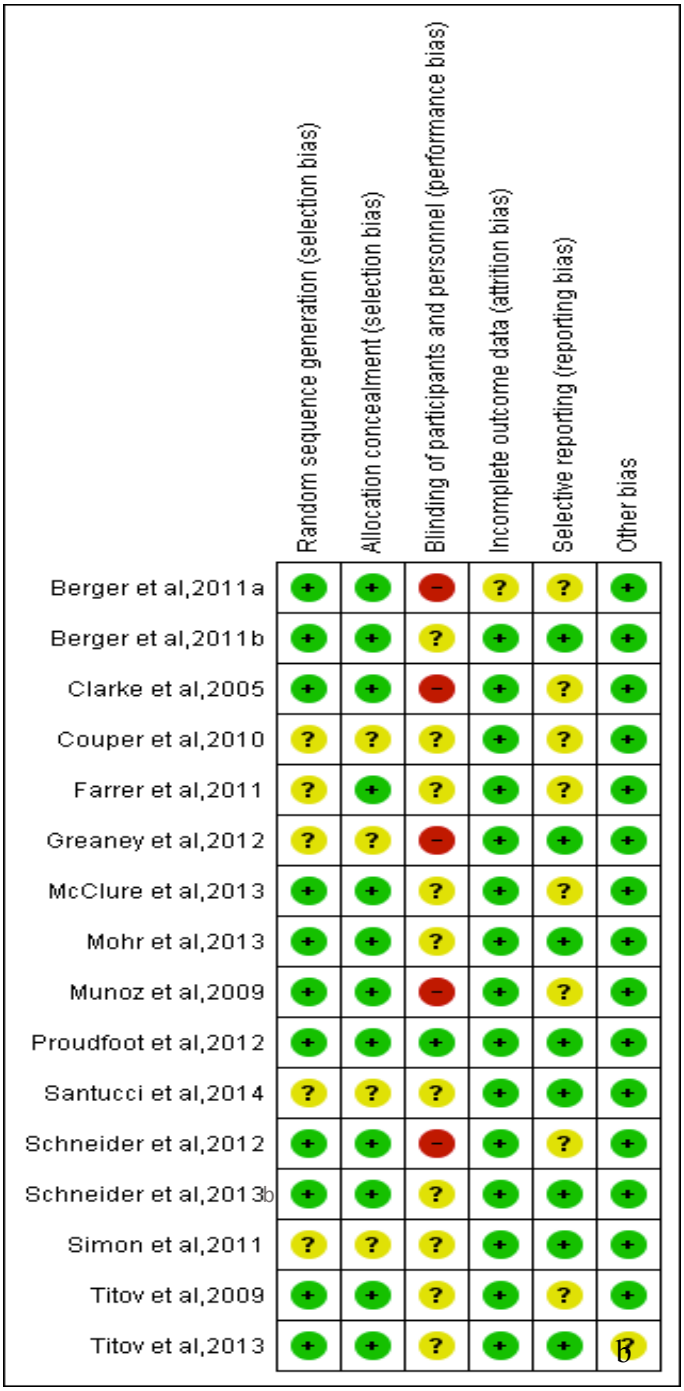


Figure 3: Risk of bias summary: judgements about each risk of bias item for each included study

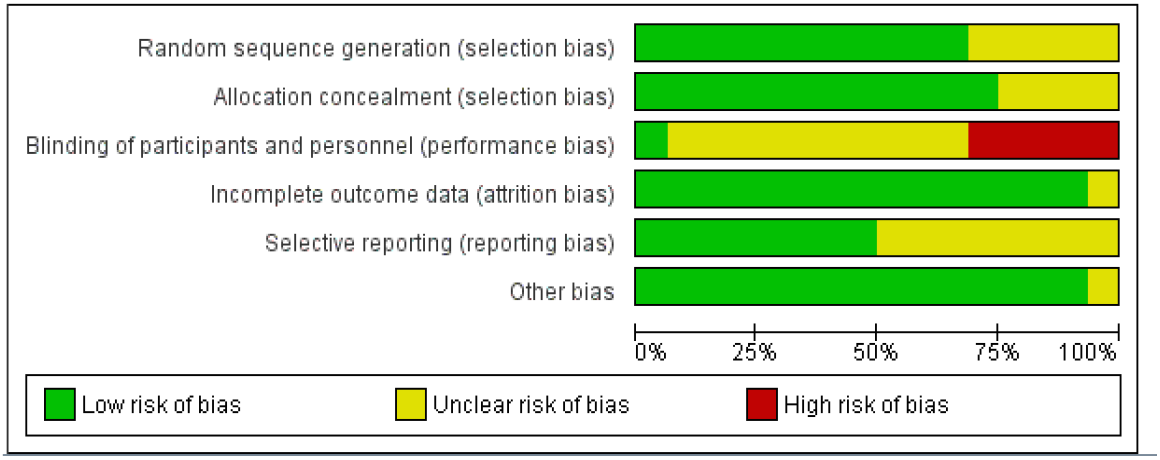


Figure 4: Risk of bias graph: judgments about each risk of bias item for each included study

2.5.10 Effects of engagement strategies

Technology-based engagement strategies compared to no strategy

Data suitable for meta-analysis were only available for the comparison of a technology-based engagement strategy with no strategy. Two meta-analyses were performed, using dichotomous and continuous outcomes. The outcome measures of the studies included in the meta-analyses were number of digital intervention modules/sessions/lessons completed, number of participants who completed digital intervention modules/sessions/lessons, and number of participants who logged in/visited the digital intervention. The outcome measures for rest of the studies can be found in Table 4.

Nine studies with 6,326 participants reported sufficient data to be included in the meta-analyses, comparing a technology-based engagement strategy to no strategy using dichotomous outcomes (see Figure 5). This analysis showed that participants using digital interventions who receive technology-based strategies were found to be significantly more likely to engage with the digital interventions compared

to those who do not receive any strategy (RR = 1.34; 95% CI: 1.07 to 1.67). However, the analysis demonstrated substantial heterogeneity between the findings of the included trials (I^2 = 74%), implying that the results from the included studies differed more than would be expected by chance. Visual inspection of the forest plot suggested that Schneider et al. (2012) was an outlier. This trial had a single email prompt at three months, which was much later than strategies used in other studies. Sensitivity analysis, excluding Schneider et al. (2012) from the forest plot, reduced the heterogeneity to I^2 = 58% and the effect of the technology-based strategy to RR =1.25; 95% CI:1.06 to1.48 as shown in Appendix 4.

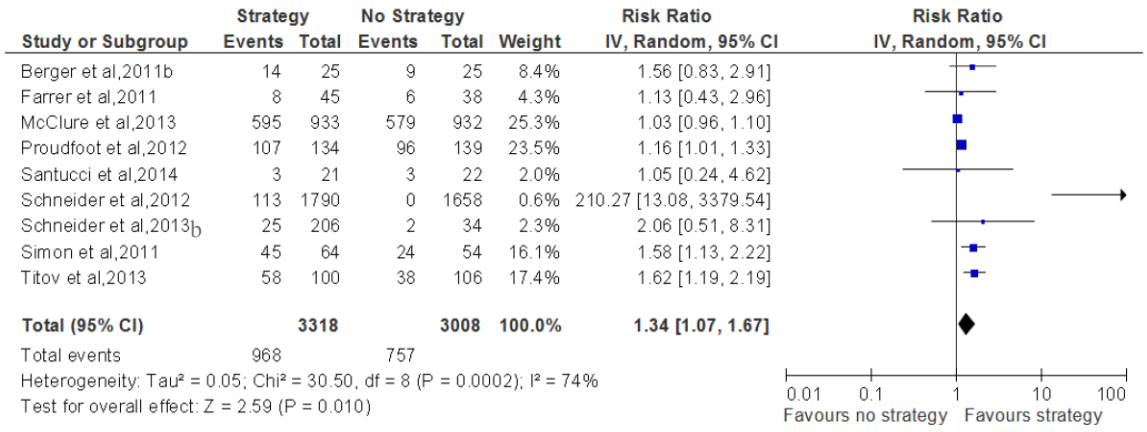


Figure 5: Analysis 1.1: Technology-based engagement strategy compared to no strategy-dichotomous outcomes

Figure 6 shows the results of the meta-analysis for technology-based engagement strategy compared to no strategy using continuous outcomes. Four studies were included, three of which were included in the previous meta-analysis, with 226 participants and found no statistically significant difference in engagement with a digital intervention between participants who received technology-based strategies compared to those who did not receive any strategy (SMD = 0.19; 95% CI: -0.11 to 0.48). Heterogeneity was low (I^2 = 20%).There is an overlap in these meta-analyses as three out of the four

studies in Analysis 1.2 were also included in Analysis 1.1; however, the direction of effect in both meta-analyses was similar.

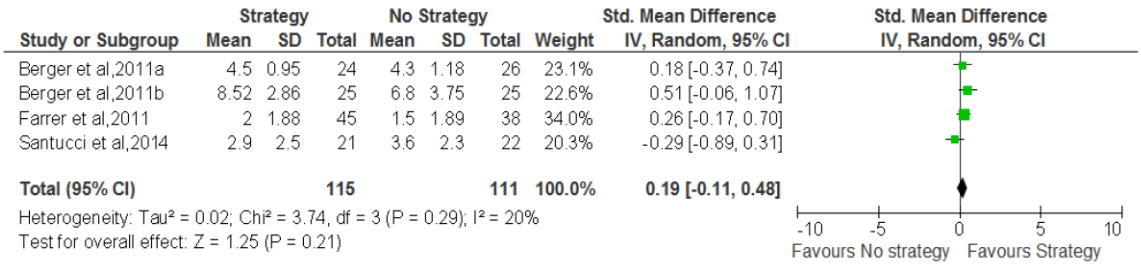


Figure 6: Analysis 1.2: Technology-based engagement strategy compared to no strategy-continuous outcomes

Technology-based engagement strategies compared to non-technological strategies and multiple strategies

For the other comparator types (for which meta-analysis was not performed), one study compared technology-based engagement strategies to non-technological means of engagement (comparing phone calls to postal mail). The postal mail group had an average of 5.9 visits, and the phone call group had an average of 5.6 visits (mean difference = 0.3 visits, *P* = .65), suggesting no statistically significant difference in outcome between the groups (Clarke et al., 2005).

Three studies had two arms with the same technology-based engagement strategy, and one of the arms receiving an extra strategy delivered through phone calls. None of the studies reported a significant difference in the effect of using multiple strategies on engagement (Titov et al., 2009, Berger et al., 2011a, Greaney et al., 2012).

However, no conclusions can be drawn for either comparator type, as meta-analysis was not possible due to the low number of studies.

2.5.11 Engagement strategies' characteristics

One study compared the effects of timing and content of strategies on engagement with a digital intervention.

Timing

Schneider et al. (2013b) looked at the effect of sending emails at different time points from baseline. One email was sent to different groups on either the second, fourth or sixth week from baseline. When the authors examined the effect of timing on visits, they found that participants receving a prompt email two weeks from baseline logged-in significantly more often than those receving the email on the sixth week (OR = 16.356; 95% CI: 2.071 to129.196, *P* = .008), while there was no significant difference in the number of times users logged in between those receiving a prompt email on the fourth week and either second and sixth week.

Content

Schneider, et al. (2013b) compared emails with two different types of content. The first group of emails were tailored to username and contained a reminder to visit the website, and the second group's email content was similar to the first group, but in addition contained a preview of the new content that was placed on the website. The second group, with the additional new content, showed higher number of visits; however, according to the authors the difference was not staistically significant (OR = 2.286; 95% CI: 0.892 to 5.856, *P* = .09).

Summary-Characteristics of engagement promoting strategies

No conclusions can be made about the differential effectiveness of engagement strategy characteristics as only one study compared different characteristics.

Table 4: Main engagement outcomes and findings reported in included studies

Study (author name, year)	Included study arms: *n*	Dichotomous outcomes		Continuous outcomes	
		Outcome	Result, *n* (%)	Outcome	Result, *M* (SD)
Berger et al., 2011a	Pure self-help: 26 Guided self- help: 24 Step-up of support on demand: 25			Mean lessons completed = 5	Pure self-help: 4.3 (1.18) Guided self-help: 4.5 (95) Step-up of support on demand: 4.6 (0.98)
Berger et al., 2011b	Unguided self-help: 25 Guided self- help: 25	No. participants completed 10 lessons	Unguided self-help: 9 (36) Guided self-help: 14 (56)	Mean lessons completed = 10	Unguided self-help: 6.8 (3.75) Guided self- help: 8.52 (2.86)
Clarke et al., 2005	Mail reminders: 75 Telephone reminders: 80			Mean logins	Mail reminders: 5.9 (6.2) Telephone reminders: 5.6 (5.8)
Couper et al., 2010	Tailored: 839 Tailored + human online behavioural intervention (HOBI): 838			Mean total minutes devoted to intervention website	Tailored: 44.1 Tailored + HOBI: 46.7
Farrer et al., 2011	Web only: 38 Web with tracking: 45	No. participants completed all five Moodgym modules	Web only: 6 (15.8) Web with tracking: 8 (17.8)	Mean no. participants completed five MoodGYM programme modules	Web only: 1.5 (1.89) Web with tracking: 2.0 (1.88)

Greaney et al., 2012	Automated assistance (AA): 36 Automated assistance + calls (AAC): 50	No. participants reached minimum threshold of self-monitoring (at least one behaviour three or more times per week during the prompting periods - week two and three)	During week 2: AA: 3.6 (10), AAC: 7.92 (22) During week 3: AA: 7 (14), AAC: 13 (26)		
McClure et al., 2013	No proactive email reminder: 932 Proactive email reminders: 933	Proportion participants viewing content who logged in/visited the digital intervention	No proactive email reminders: 579 (62.12) Proactive email reminders: 595 (63.88)		
Mohr et al., 2013	Self-directed: 35 Coach assisted: 34			Median and range of number of days logged in during the study period of 12 weeks	Self-directed: Median=13; range 0–100 Coach assisted: Median=6; range 1–24
Munoz et al., 2009[1]	Guia: 247 Guia + Individually Timed Educational Messages (ITEMs): 251		Utilisation of a cigarette counter and online journal		
Proudfoot et al., 2012	Bipolar Education Program (BEP): 139 BEP + Informed Supporters (IS): 134	No. participants completed and returned four or more sessions of the eight session programme	BEP: 96 (69.1) BEP+ IS: 107 (79.9)		
Santucci et al, 2014	No reminder: 22 Reminder: 21	No. participants completed all eight sessions	No reminder: 3 Reminder: 3	Mean no. sessions completed = 8	No reminder: 3.6 (2.3) Reminder: 2.9 (2.5)

Schneider et al., 2012	No prompting: 1658 Prompting: 1790	No. participants visited programme during the one- month follow up	No prompting: 0 (0) Prompting: 113 (6.3)		
Schneider et al., 2013b	No prompt (NP): 34 Standard prompt (SP) at two weeks: 34 SP at four weeks: 34 SP at six weeks: 35 Standard prompt and additional content (SP+) at two weeks: 36 SP+ at four weeks: 35 SP+ at six weeks: 32	No. participants logged in/visited digital intervention	NP: 2(5.9) SP at two weeks: 6(17.6) SP at four weeks: 1(2.9) SP at six weeks: 1(2.9) SP+ at two weeks: 10(27.8) SP+ at four weeks: 7(20) SP+ at six weeks: 0(0)		
Simon et al., 2011	Program only: 54 Coaching: 64	No. participants returned after initial sign-up at anytime	Program only: 24 (44) Coaching: 45 (71)		
Titov et al., 2009	Computerised cognitive behaviour therapy (CCBT): 82 CCBT + Telephone: 81			Mean no. logins	CCBT + Telephone: 23 CCBT: 23
Titov et al., 2013	Treatment group:106 treatment Plus Automated Email Group:100	Percentage who completed the five lessons	Treatment group: 38(35.8%) treatment Plus Automated Email Group: 58 (58%)		

[1]The results were not reported separately for each arm

2.5.12 Unpublished data

All authors were contacted to provide and confirm information about missing or unclear engagement outcome information or characteristics of strategies, and four authors replied. Farrer et al. (2011) provided the mean and standard deviation of BluePage visits and time spent, and more information about the strategy including the fact that it is not tailored. McClure et al. (2013) provided the exact number of people allocated to the strategy and the fact that the strategy was used for 12 months. Two studies confirmed the accuracy in categorising their strategies' characteristics (Clarke et al., 2005, Simon et al., 2011).

2.5.13 Changes after the original paper was published

Two papers were identified (Mohr et al., 2013, Titov et al., 2013) after publishing this systematic review when a re-run of the electronic database search was conducted. These two papers met the inclusion criteria, and they were published online before 13 September 2013; however, they were both published in *PLoS One* and there was a very high number of studies published through this journal, which caused a delay in including the studies in the electronic databases such as MEDLINE. The original paper's result show that RR=1.27, 95% CI 1.01 to1.60, I^2=71% while after the addition of one of the studies (Titov et al., 2013) the meta-analysis results changed to RR = 1.34; 95% CI: 1.07 to1.67, I^2 = 74%.

2.6 Discussion

Technology-based strategies to promote engagement are an emerging field of research as shown by the relatively small number of included studies and their dates of publication. Generally, studies report borderline small to moderate positive effects of technology-based strategies on engagement compared to using no strategy, which support the use of technological strategies to promote engagement. However, this result should be treated with caution due to the high heterogeneity, small sample sizes and the lack of statistical significance

in the analysis of continuous outcomes. There were insufficient studies to effectively explore reasons for heterogeneity. No firm conclusions were drawn about which characteristics of strategies were associated with effectiveness, and due to the absence of data, no conclusions could be drawn about costs or cost-effectiveness. Although the review aimed to investigate the cost-effectiveness of engagement strategies, none of the included papers reported cost data.

This review was the first to include a meta-analysis of continuous and dichotomous engagement measures for technology-based engagement-promoting strategies compared to using no strategy; it raised important questions about the complexity of engagement strategies research and complex interventions in general. The review also included an attempt to code BCTs depending on the descriptions provided by the authors. Coding these techniques can help identify how the intervention works and allows for a theory-based explanation of how to develop prompts that can be effective in promoting engagement, as it has been reported that an intervention based on theory is more effective than one that is not (Noar, 2008).

2.6.1 Summary of findings

What engagement-promoting strategies have been used before?

This review included 16 studies of different engagement strategies and overall, eight studies only reported positive significant outcomes (Muñoz et al., 2009, Proudfoot et al., 2012, Schneider et al., 2012, Schneider et al., 2013b, Simon et al., 2011, Titov et al., 2013, Couper et al., 2010, Mohr et al., 2013). Five studies reported no difference (McClure et al., 2013, Titov et al., 2009, Berger et al., 2011a, Berger et al., 2011b, Farrer et al., 2011). Two studies reported a non-significant negative effect of technology-based engagement strategy (Clarke et al., 2005, Santucci et al., 2014), and for one study, the effect was difficult to judge based on the graph provided by the author (Greaney et al., 2012).

How effective were technology-based strategies in promoting engagement?

Ten studies contributed to two separate meta-analyses (one analysis had nine studies and the other analysis had four) of the effect of technology-based strategies compared to no strategy on engagement. Conclusions about the size of effect cannot be made. The direction of effect indicates for both dichotomous and continuous outcomes that strategies can potentially promote engagement; however, the results should be interpreted with caution, as mentioned above.

What are the characteristics of engagement promoting strategies?

The review focused on eight characteristics and identified common categories amongst the 16 included studies.

Which characteristics are associated with effectiveness in promoting engagement?

Although most of the studies reported a variety of characteristics, the majority of the studies compared the engagement-promoting strategy to no strategy, which makes arriving at definitive conclusions about the different characteristics impossible. Only one study compared different characteristics using different arms. It looked at content and timing and reported that email prompts that were sent advertising updated digital intervention content were more likely to encourage users to visit the digital intervention compared to emails that did not advertise new content. This result was also found in the think aloud interviews in Chapter 5, where users preferred including news and updates in emails, which led to developing prompts with news and testing them in Chapter 6. Coding the content of Schneider et al. (2013b) strategy proved futile, as the description provided by the authors was not sufficient to meet the definition of prompt/cue for a BCT, which specifies that in order for behaviour to occur, a stimulus is introduced to prompt the behaviour. In the case of engagement strategies delivered by email, a link directing the users to the digital intervention can be the stimulus needed to prompt them to log in, which was not described

in this paper but was described in another paper by the same author that used a similar email prompt (Schneider et al., 2012).

One study showed that sending engagement strategies when users start using the digital intervention will increase visits compared to later on (Schneider et al., 2013b). However, it has been suggested that users engage more when they first start using a digital intervention even without receiving engagement strategies (Brouwer et al., 2011, Eysenbach, 2005), and one study found the number of participants who logged in when they first register was higher than those who revisited the digital intervention (Schneider et al., 2012). These results suggest that in order to find out whether strategies influence engagement, visits to the digital intervention have to be measured and compared as soon as users register and throughout the duration of the digital intervention. This was tested in Chapter 5 to find out whether prompts can promote engagement with HeLP-Diabetes regardless of the users' registration date.

Some studies used a mixture of engagement strategies but did not provide separate outcome results; for example, one study compared the effect of having a coach or a clinician as a provider of an engagement strategy, but used a mixture of strategies including chat rooms, forums and emails, and reported the effect of those combined strategies. Although that study would have provided information about one specific characteristic of engagement strategies (sender/provider), not all engagement strategies met the definition, and thus the study was excluded (Johnston et al., 2011).

How cost-effective were technology-based engagement strategies?

Conclusions cannot be made about the cost-effectiveness of engagement-prompting strategies, as no study reported any cost-effectiveness data.

2.6.2 Bias assessment

For most of the studies, the description provided was not sufficient to be able to judge the different aspects of trial quality. The current Cochrane bias assessment guidelines (Higgins and Green, 2011) might be more suitable for generic drug trials as opposed to digital interventions. For example, sequence generation is not an issue, as it is made easier with the use of online randomisation programmes; blinding of staff might not be possible, as the control and intervention groups will receive prompts sent by the staff; and the criteria for outcome assessment might not be suitable, as this has to be tailored to how engagement is measured by automatic website metrics.

Authors and developers of digital interventions can benefit from using the enhanced CONSORT-EHEALTH reporting guide published by Journal of Medical Internet Research, as it can help with clarifying what authors need to report and describe in their studies to be able to judge its quality (Eysenbach, 2011), and to understand what digital interventions, or in the case of this systematic review, what technology-based strategies work for specific digital interventions and why.

2.6.3 Overall completeness and applicability of evidence

Search end date and sensitivity

The current review included studies up to and including those published on 13 September 2013, and there were no language and publication type restrictions when the search was conducted in the different e-databases.

The search also included protocols or conference abstracts, but those that were not published after September 2013 were not included. Authors of all the protocols and conference abstracts were contacted, and three mentioned publishing in 2014 or 2015 (Christensen et al., 2010, Hebden et al., 2013, Kavanagh et al., 2012). However, the only author of the previously mentioned protocols who provided a full text was Christensen et al. (2010) who published the full text in 2014 (Christensen et al., 2014). This study would have been

included if the search date did not end on 13 September 2013, as the study compared email-delivered strategies to phone-delivered strategies and found that those delivered by phone had more users finishing their modules than those receiving emails, but as with other studies included in the review, the study had some methodological limitations (Christensen et al., 2014).

Two studies meeting the inclusion criteria were added after submitting the paper (Mohr et al., 2013, Titov et al., 2013).The electronic database search would have identified these papers if there was not a delay from MEDLINE's archiving team due to the huge amount of publishing done in *PLoS One*, the journal that published both studies.

Santucci et al. (2014) was first published in 2013 online and then in paper journal in 2014, hence its inclusion.

The inclusion criteria was designed to be sensitive by including any RCT regardless of the population's gender or health condition; however, limiting the digital interventions to only web- or computer-based interventions might have lowered the number of included studies, but this was deemed necessary as some digital interventions might be used as prompts. For example, smartphones can be used as a platform for sending text message- or email-prompts. Also, this thesis's context is HeLP-Diabetes, a web-based intervention (see Chapter 3).

Timing of follow-up

In this review, follow-up is important for measuring the effect of strategies across time and losses to follow-up as in other studies is not expected since engagement outcome measures are recorded automatically, unlike other trials where self-reported measures are collected from participants at different time points. Only three studies reported timing of follow-up, and it ranged from two to

13 weeks (Greaney et al., 2012, Schneider et al., 2012, Schneider et al., 2013b).

Heterogeneity

There was a substantial level of statistical heterogeneity, which is to be expected as the studies grouped in the meta-analysis used different outcome measures. However, attempts to explore clinical and methodological heterogeneity were not possible because the number of studies included and their characteristics were not deemed enough to produce reliable results if included in a sub-group analysis.

Quality of evidence

Complexity of technology-based engagement-promoting strategies research

Researching engagement strategies is challenging, as for most of the studies, the main aim was to assess the effectiveness of the digital intervention and whether the addition of the strategy would influence the effectiveness of the digital intervention rather than affecting engagement. That led to poor definition, description and selection of outcome measures.

In some studies, there was not a clear distinction between engagement with the digital intervention and adherence to the trial; for example, authors would use the term ‘dropout’ to describe both those who did not complete follow-up assessment and those who did not complete digital intervention sessions.

Quality of engagement measures

For engagement-promoting strategies, the aim is to reach users and prompt them to visit the website; thus, number of visits or participants who logged in would be the preferred measure. However, authors used a variety of measures, which produced in certain cases mixed results (Couper et al., 2010, McClure et al., 2013, Titov et al., 2009). Engagement researchers have to consider which measure will provide a clear picture of whether strategies are promoting engagement or not. This can be done by selecting the type of measure that is

most suitable according to the digital intervention and prompt characteristics; for example, one study used a prompt for the duration of a modular digital intervention and measured engagement by analysing the number of modules completed, which is more appropriate than measuring the number of visits (Berger et al., 2011a), and another study measured the number of visits when they sent a prompt once (Schneider et al., 2013b).

Researchers also need to consider the engagement phases (Brouwer et al., 2008) when selecting engagement measures. As discussed in Chapter 1, in a three-round systematic Delphi-experiment done by Brouwer et al. (2008), engagement was conceptualised into three phases: (1) the first visit to the digital intervention where a user decides to visit a digital intervention to determine what it offers and whether he/she can benefit from it; (2) prolonging the first visit in which a user extends his/her first visit and is exposed to part of the digital intervention; and (3) revisiting the digital intervention in which the user returns to the digital intervention after the first visit. This systematic review targets the third phase by exploring the use of technology-based strategies to promote revisiting digital interventions after the first visit. The strategies identified in the review work on the third engagement phase, which is the continuous use of the digital intervention. Therefore, to be able to measure whether users are engaging due to receiving the strategies or not, authors have to provide engagement measures when users first register, during different follow-up times and post-intervention, and not only provide a post-intervention summary of engagement.

The issue of systematic review for complex intervention

The current available gold-standard guidance for performing systematic reviews is more suitable for reviews of drug trials rather than complex interventions. Methodology researchers are still debating different issues related to gathering the evidence and analysing them to produce reliable results about complex interventions. Some of these issues were encountered in this review, and below is a list of the decisions made:

- There is a debate about ‘lumping’ or ‘splitting’ data when it comes to meta-analysis. A lumping approach was used as the main question of whether technology-based strategies can engage users regardless of their different characteristics, while for drug trials a splitting approach would be used to assist health professionals in making the right decisions about what drugs to use for individual patients by matching the patients characteristics with those included in the meta-analysis (Bailey et al., 2011, Gotzsche, 2000)
- Authors of complex interventions are advised to outline the pathway of their researched intervention with the possible immediate and final outcomes (Burford et al., 2013). In this thesis a simple pathway was outlined (see Figure 1: Engagement prompt logic model, Chapter 1, Section 1.2.4). Engagement has to be explored further so authors can understand what the effect of engagement strategies is on health outcomes of digital interventions. This systematic review did not attempt to answer this question as another review attempted to do that, but could not synthesise the evidence and provide a clear conclusion due to the heterogeneity of the studies (Donkin et al., 2011).
- The use of both random and fixed effect models in the synthesis of complex interventions is recommended as consensus regarding which effect model is preferable has not been reached yet (Pigott and Shepperd, 2013). The results of both models when used were similar (see Appendix 5: Data and Analysis-additional data analysis figures for fixed effects model).

Potential biases in the review process

- Choosing only medical- or health-related databases and not including computer-based research databases could produce a biased search, but this was done because the digital interventions needed to be health-related.
- Selection of studies for inclusion: Deciding on whether the study met the definition of technology-based engagement strategy was relatively easy,

although for Simon et al. (2011) discussion between the authors was necessary to decide on which strategy to include, as the study described sending two types of messages to users. One type that was sent from peer coaches internally and another sent automatically to users' emails to notify them that they had received internal messages and prompted them to log in and view it. The latter was chosen as the engagement strategy.

- Grey literature: Not including enough grey literature databases could introduce potential bias to the review, although evidence shows excluding them might magnify the effect size (Hopewell et al., 2007). Conference abstracts and theses were also researched, but not extensively. The decision to not include more grey literature databases was taken because the bias introduced by excluding them, which is showing greater treatment effect, is a more serious issue for treatment interventions than for interventions aimed at promoting the use of treatment interventions, as is the case for this review. A funnel plot was planned to estimate the degree of publication bias. However, this was not possible due to the low number of studies, and the possible appearance of funnel plot asymmetry regardless of the existence of publication bias, due to the different methodological quality of the studies (Higgins and Green, 2011).
- Ongoing RCT databases: Due to time limitations, ongoing and recently completed RCT databases were not searched; had time allowed, both the International Standard Randomised Controlled Trial Number Register (www.controlled-trials.com/mrct) and the World Health Organisation International Clinical Trials Registry Platform (www.who.int/trialsearch) would have been searched.
- The use of the current Cochrane guidance (Higgins and Green, 2011) for performing this systematic review was challenging, as this guidance is designed for use in drug trials. Cochrane was working on developing a methodology for conducting reviews of complex interventions at the time

of my embarking on the review and, the agenda for research and development by other reviewers was being discussed (Noyes et al., 2013). Some reviewers were encouraged to use a new method used in social policy research called 'realist review', but not many have performed it, and no clear guidance was available (Gough, 2013).

- Quasi RCTs were excluded from the review because of the higher level of bias in such studies as opposed to RCTs.

Agreements and disagreements with other studies or reviews

To my knowledge this is the first systematic review that evaluated engagement-promoting strategies using website metrics as outcome measures. Other systematic reviews (De Leon et al., 2014, Fry and Neff, 2009, Webb et al., 2010) investigated the effect of prompts of digital interventions on behaviour change, and some looked at engagement-enhancing features of digital intervention, including the use of emails and phone calls, on the change in website metrics (Brouwer et al., 2011). All of these systematic reviews reported a potentially positive effect of prompts on changing health behaviour and engagement. However, Brouwer et al. (2011), who used similar outcome measures, did not do a meta-analysis due to the heterogeneity of the outcome measures.

There has always been substantial heterogeneity reported by systematic reviews evaluating engagement with digital interventions, and most of these reviews preferred to conduct narrative synthesis rather than meta-analysis because of the heterogeneity in the outcome measures (Brouwer et al., 2011, Christensen et al., 2009a, Donkin et al., 2011, Schubart et al., 2011). In this systematic review the measures were categorised into continuous and dichotomous outcomes, and two meta-analyses were done. Although the effect size cannot be used with confidence as the number of studies is low, the direction of effect in both meta-analyses can be explored further with the addition of more studies in the future.

The other systematic reviews of engagement reported that one of the most common reasons for excluding studies is lack of reported engagement outcome (Brouwer et al., 2011, Kelders et al., 2012), which was also one of the findings in this systematic review.

Issues for specific studies:

Due to the poor description of many of the studies, all authors were contacted for further information but in some cases, decisions were made in consultation with other authors about the inclusion of studies in the meta-analysis and the review:

- Greaney et al. (2012) was only included in the review and not the meta-analysis because participants received an email or a phone call to encourage them to visit a digital intervention and enter their self-monitoring data, they had an option to provide their self-monitoring data when contacted, but the number of participants who did that was not available in the study.
- In Farrer et al. (2011), the program was composed of six weeks but a only the MoodGYM modules (week two to six) were considered and not the BluePages (week one) as continuous and dichotomous outcomes for engagement with MoodGYM were available and the engagement strategy (phone calls) encouraged the users to complete the modules, thus they were more interested in MoodGYM which consists of modules as opposed to BluePages.

2.7 Conclusion

Generally, studies report borderline small to moderate positive effects on engagement by technology-based strategies compared to using no strategy. However, the results have to be interpreted with caution as the results were heterogeneous. Researchers are encouraged to include in their studies a proper description of the characteristics, context, measures and other features

(factors) that contribute to heterogeneous results to ensure researchers develop a better understanding of what works and why. Identifying the categories of the strategies' characteristics, as reported in this review, can help by contributing to the design of studies that test the effectiveness of different characteristics and can contribute to future systematic reviews by helping to plan analysis and heterogeneity investigation (Pigott and Shepperd, 2013).

The field of engagement strategies is an emerging field, as indicated by the dates of the studies, and more research is needed to understand what strategy characteristics are effective and how cost-effective are they. Below is a list of proposed further areas for research:

- Researchers need to reach an agreement with regards to what outcome measures would be most suitable for evaluating the effectiveness of engagement strategies and their characteristics.
- Researchers need to study the different characteristics of engagement strategies in order to be able to attribute the effect of specific or combinations of characteristics on engagement. In Chapter 6, two characteristics (content and delivery mode) were tested instead of testing a prompt versus no prompt.
- Researchers need to consider theory when developing engagement strategies.

Chapter 3 The methodology for developing and testing HeLP-Diabetes email and text message prompts

3.1 Abstract

In this chapter, I describe the methodology of developing and testing the HeLP-Diabetes email and text messages prompts. The chapter starts with an introduction to the importance of providing a detailed description of the development of any intervention within the eHealth field. This is followed by the objectives of this chapter, and a step-by-step description of the sources and resources used, and the application of the Medical Research Council guidance for complex interventions. I conclude the chapter with a discussion of the applicability of the framework and the lessons learned from using it.

3.2 Background

3.2.1 Importance of this chapter in relation to other chapters

Chapter 1 introduced the aim and objectives of this thesis and the potential for technological prompts, specifically emails and text messages, to engage users of digital interventions. Chapter 2 presented data to support the suggestion that technological prompts may promote engagement. However, the poor description of some of the prompts in the studies identified during the systematic review, and the way they were evaluated, did not allow for a clear picture of which characteristics of prompts might promote engagement.

Until recently, authors of digital interventions have tended not to describe the process of developing their engagement prompts in detail, nor have they reported on the characteristics of such prompts in enough detail to allow for subsequent development to benefit or build upon their experience. Recently there have been calls to publish reports specifically on the development of digital interventions, including a step-by-step description that outlines, for example, the theoretical frameworks used and user and expert feedback (Bradbury et al., 2015, Michie et al., 2012, Webster et al., 2015). However, to my knowledge there has not been any detailed reporting of how an engagement prompt was developed and the methodologies involved in the design.

Thus, in this chapter I present a detailed and transparent description of the process of development of the email and text message engagement prompts developed for use with HeLP-Diabetes. By doing this, I present the work that I have done to achieve the second objective of this thesis: to identify the methodological and practical challenges of developing engagement prompts, and integrating them with HeLP-Diabetes.

The development and evaluation of the prompts followed the Medical Research Council (MRC) guidance for complex interventions mentioned in Chapter 1, Section 1.2.6 (Craig et al., 2008). The guidance provided the pathway by which I was able to decide on the sources of evidence and guidance, resources and methodologies to use for this thesis. The sources included:

- Scientific evidence from the systematic review in Chapter 2;
- A clear and well-described context for the prompts (i.e. HeLP-Diabetes-a digital intervention for people with Type 2 Diabetes);
- Feedback and support from an experienced research team that was involved in developing, maintaining, evaluating and implementing HeLP-Diabetes;
- Input from people living with Type 2 Diabetes about prompt characteristics including content and delivery mode; and
- Context-specific evidence through the conduction of empirical studies in Chapters 5 and 6.

3.3 Objectives

This chapter is arranged in sections that follow the stages of the MRC guidance for complex interventions and aims to describe the evidence, sources and resources, and context for HeLP-Diabetes email and text message prompts, through the following objectives:

- Describe the steps taken to develop the prompts through the use of the MRC guidance for complex intervention.
- Describe how other sources of information regarding development of prompts were used and their importance, including systematic review findings, public patient involvement (PPI) and expert opinion.

- Describe the COM-B ('Capability', 'Opportunity', 'Motivation'– 'Behaviour') model and associated Behaviour Change Wheel (BCW).
- Describe HeLP-Diabetes as the context for the prompts.
- Describe the resources needed to develop engagement prompts such as applications or programmes, human resources and time.

3.4 Methodology

3.4.1 Medical Research Council guidance

'*Developing, piloting, evaluating, reporting and implementing a complex intervention can be a lengthy process. All of the stages are important, and too strong a focus on the main evaluation, to the neglect of adequate development and piloting work, or proper consideration of the practical issues of implementation, will result in weaker interventions, that are harder to evaluate, less likely to be implemented and less likely to be worth implementing "* – MRC (MRC, 2008, p.4)

The MRC guidance advises that in order to develop an intervention that can be potentially effective, the stages in Figure 7 must be undertaken.

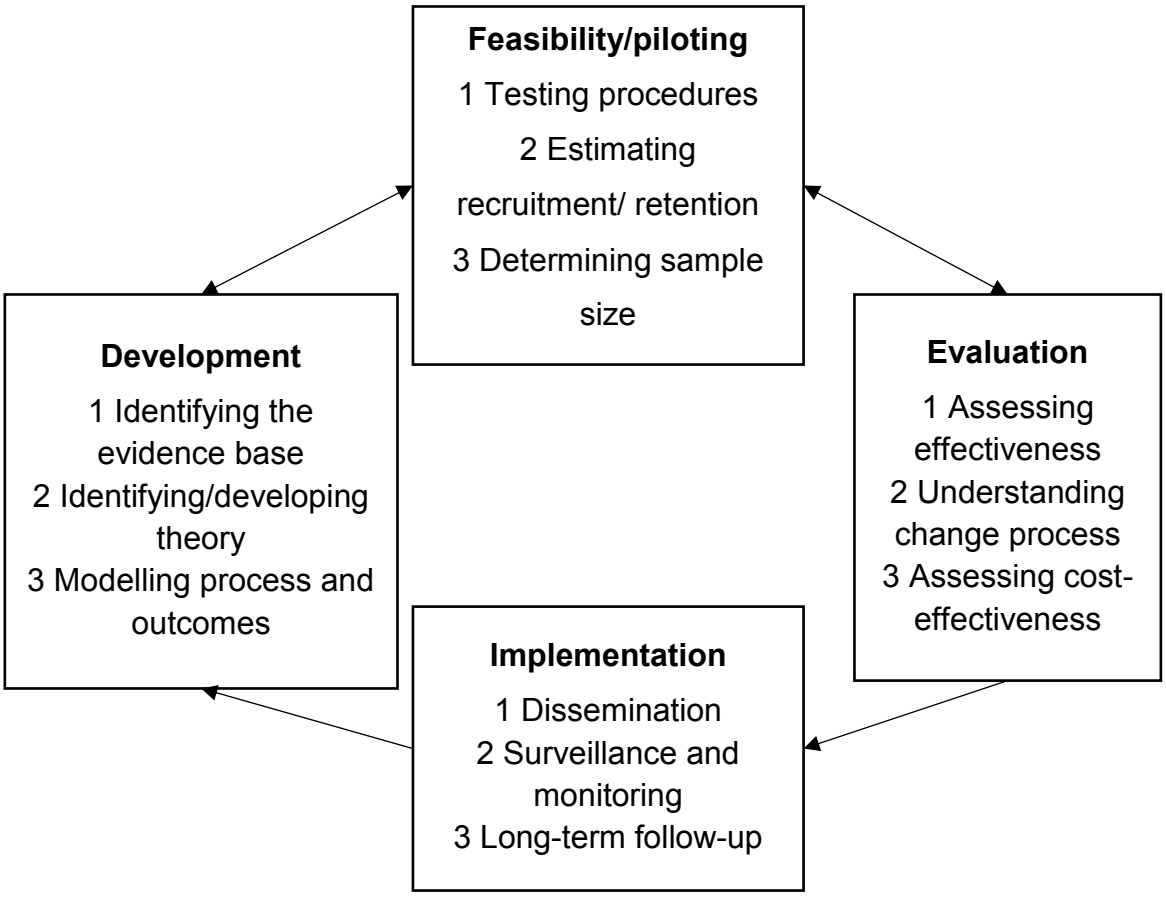


Figure 7: MRC framework for complex interventions

Each stage of the framework is equally important, and the process is not necessarily linear; rather, the stages can be conducted simultaneously and iteratively.

3.4.2 Developing a complex intervention

Development of a complex intervention contains three elements: identifying the evidence base, identifying/developing a theory, and modelling process and outcomes. These three elements are interlinked and can be approached at the same time rather than progressing in a linear way. This stage of the framework is one of the most important ones for the prompts, as it is the one that provides the basis for the rest of the stages in terms of evidence and appropriate methods to use.

Identifying the evidence base

The three types of evidence

The National Institute for Health and Care Excellence (NICE) is England and Wales' source for the most effective and evidence based guidance for the treatment and management of health conditions and prevention of illnesses (National Institute for Health and Care Excellence, 2013, Lomas et al., 2005). NICE uses three types of evidence for the production of their guidance. The first evidence type is context-free scientific evidence, which includes evidence about the general potential of interventions in ideal circumstances; it assumes that evaluated objects are measurable, objective and are not affected majorly by context (although this is being debated as no scientific evidence is completely free from context). This type of evidence is usually produced from systematic reviews and meta-analyses of quantitative evidence or primary empirical studies that evaluate efficacy or effectiveness of interventions. The second type of evidence is context-sensitive scientific evidence, and this concerns what works in particular real-life circumstances or specific contexts. This type of evidence is

what NICE deliberates the most when producing guidance. Such research includes social and behavioural science studies, whether qualitative or quantitative. Context-sensitive scientific evidence complements context-free evidence, and if combined can produce practical recommendations for NICE guidance users to implement and tailor to their specific contexts and needs. Both of these two types of evidence were used in this PhD. The third type of evidence is colloquial evidence (National Institute for Health and Care Excellence, 2012, Sharma et al., 2015). Colloquial evidence informs or supplements scientific evidence and provides insight into contexts; this type of evidence is used to augment the evidence landscape, but by itself it is not enough. It includes the opinions of experts, stakeholders and patients. Information gained from this type of evidence includes practical considerations (i.e. available resources, level of expertise, traditions and habits) and interests (i.e. specific interests of patient groups or stakeholders) (National Institute for Health and Care Excellence, 2012).

Best practice in health research is to begin the research process by conducting a systematic review (context-free scientific evidence) and find generalisable findings. This is highlighted in the MRC guidance when they specify the identification of existing, relevant and recent evidence for an intervention by conducting a systematic review.

Systematic reviews: context-free scientific evidence:

Systematic reviews can be thought of sitting at the top of a hierarchy of evidence, with the hierarchy structured according to the quality of evidence (Guyatt et al., 1995). This hierarchy of evidence is a tool that classifies the potential quality of evidence depending on the study design, with systematic reviews of randomised controlled trials (RCTs) and meta-analyses being on top of the hierarchy, followed by RCTs, other trial designs, and then observational studies. The reason systematic reviews of RCTs sit at the top of the hierarchy is

because this method combines all the relevant studies (specifically RCTs) about a specific intervention and compares them in a rigorous and systematic way against pre-specified quality criteria. Comparison with pre-specified criteria reduces bias that could result during collection, appraisal and synthesis of the studies. A meta-analysis (quantitative synthesis of studies) can also be used if enough studies are found. One specific quality criteria and guidance for systematic reviews is the Cochrane methodology guidance (Higgins and Green, 2011) used in the conduct of the systematic review described in Chapter 2. The Cochrane methodology is the most thorough, transparent and internationally acclaimed guidance for reviews.

Given this hierarchy of evidence, I started my PhD with the conduct of a systematic review and meta-analysis of the effectiveness of prompts, which helped in understanding the potential effectiveness of prompts and their characteristics. Doing this review as my initial study allowed me to identify the challenges involved in developing prompts and conducting trials for evaluating them and led me to pilot and test the prompts in the studies described in both Chapters 5 and 6.

Identifying/developing theory- context-sensitive scientific evidence:
After looking at the evidence on prompts, the next step in the MRC framework is to Identify or develop an appropriate theory, which can also translate to acquiring the second type of evidence: context-sensitive scientific evidence. The MRC guidance emphasises that in order to understand how prompts might work and produce a significant effect on engagement, a theoretical understanding is needed. However, even when theory is used or reported to be used, it does not necessarily lead to an effective intervention (Gardner et al., 2011, Kinmonth et al., 2008, Prestwich et al., 2014). This ineffectiveness might be due to poor application or selection of inappropriate theories. Selecting the right theory depends on the experience of the researcher in behavioural

theories and the available evidence; although, even when an appropriate theoretical basis is used, the intervention might still prove ineffective (Kinmonth et al., 2008). For my PhD, as with conducting the systematic review, I wanted to use a framework or guidance that would aid me in developing or identifying a theory that would explain the mechanism of action of prompts in promoting engagement with a digital intervention in a transparent and reproducible way, and that would reduce the chance of selecting an inappropriate or incomprehensive theory. Therefore, I planned to use the BCW and COM-B model to guide the design and development of the prompts (Michie et al., 2014, Michie et al., 2011).

The Behaviour Change Wheel – A description:

The BCW is a theoretical framework produced from the synthesis of 19 behaviour change intervention frameworks. The BCW provides a systematic method of understanding the factors that influence behaviour and the appropriate techniques /intervention components that can facilitate behaviour change within a specific context. BCW is an operationalisation of the COM-B model of behaviour change (Michie et al., 2011). The COM-B model posits that to perform a behaviour, an individual must have the capability, motivation, and opportunity to do it. Behaviour change requires a shift in one or more of these determinants, and a shift in one may affect another (e.g. a shift in capability may influence motivation) (see Figure 8: The COM-B Model).

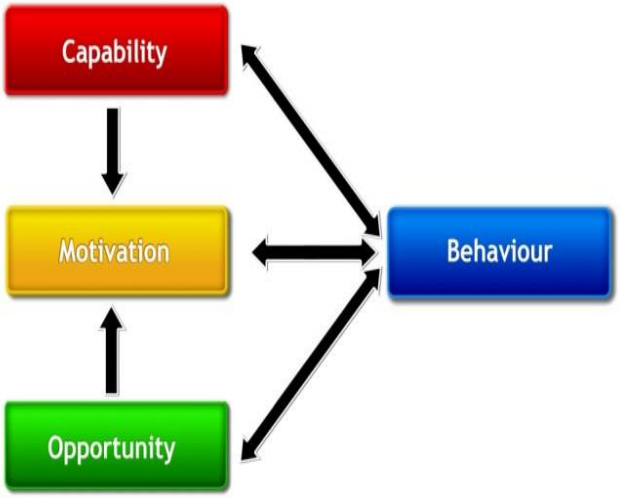


Figure 8: The COM-B model

Reprinted from "The behaviour change wheel: a new method for characterising and designing behaviour change interventions." by Michie et al, 2011, Implementation Science, 6(42), 4. Copyright Michie et al; licensee BioMed Central Ltd. 2011.

These three determinants are also expanded into six subdivisions. For the first determinant, an individual must have the **physical** or **psychological** skills, strength, stamina and knowledge to perform the behaviour (i.e. capability). For the second determinant, **social** or **physical** external factors may influence behaviour (i.e. opportunity). The final and third determinant is composed of the conscious (**reflective** e.g. conscious decision making) or reflexive/impulsive (**automatic** e.g. habitual processes) brain processes that influence behaviour (i.e. motivation). These three components influence and are influenced in turn by behaviour; however, while capability or opportunity can influence motivation, motivation cannot directly influence capability or opportunity (Michie et al., 2014, Michie et al., 2011). The six determinants can also be expanded to include specific determinants by linking the COM-B model to the theoretical domains framework (Cane et al., 2012) which defines 14 domains of theoretical

constructs including, but not limited to, knowledge and skills (for full list of domains and mapping the domains to the BCW COM-B model refer to (Cane et al., 2012).

The BCW is therefore composed of three main layers, as seen in Figure 9:

- Behaviour layer: Identifies determinants or sources of behaviour mentioned above in the COM-B Model.
- Intervention layer: Identifies intervention functions that can be used to change the behaviour determinants.
- Policy layer: Identifies policy categories that can be targeted to support or enable interventions.

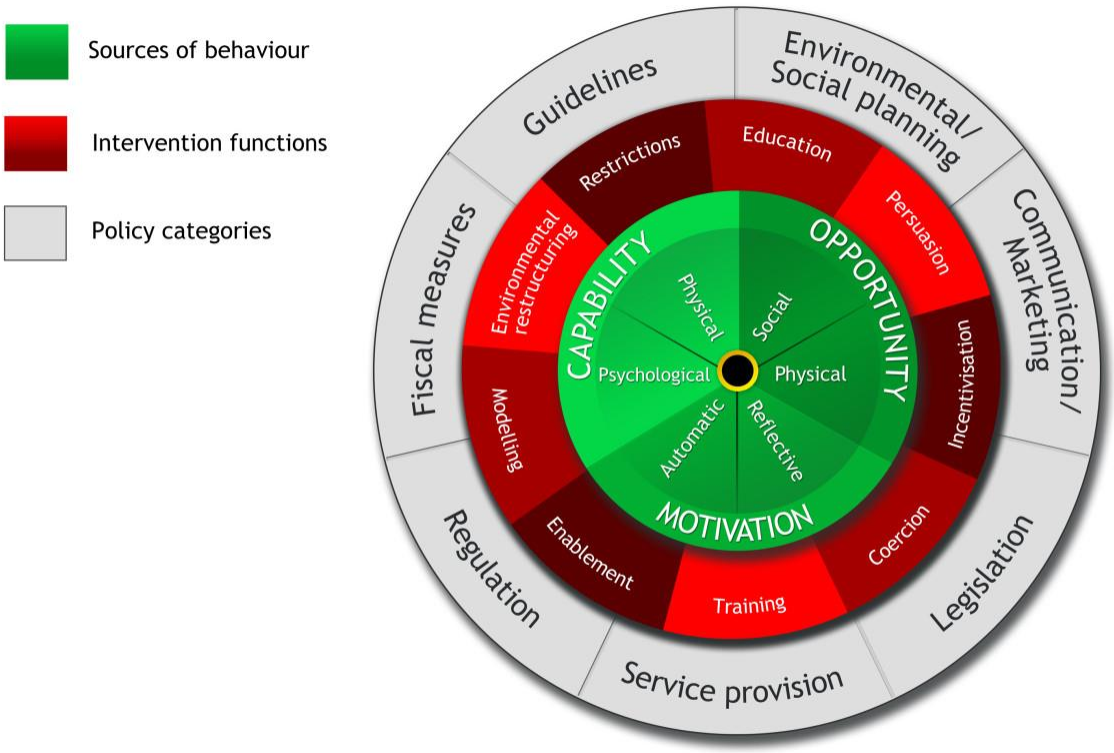


Figure 9: Behaviour Change Wheel

Reprinted from "The behaviour change wheel: a new method for characterising and designing behaviour change interventions." by Michie et al, 2011, Implementation Science, 6(42), 1. Copyright Michie et al; licensee BioMed Central Ltd. 2011.

The behaviour layer components helps to identify the behavioural determinants that need to be targeted, using the prompts to promote engagement (see Figure 1: Engagement prompt logic, Chapter 1, Section 1.2.4) through an analysis of the COM-B model determinants of behaviour (Capability, Motivation and/or Opportunity), which forms the core of the BCW (see Figure 8: the COM-B Model).

For the intervention layer, once determinants of engagement behaviour are identified, intervention functions are chosen, then delineated into specific

behaviour change techniques (BCT), defined as “observable, replicable, and irreducible components of an intervention designed to alter or redirect causal processes that regulate behaviour” (Michie et al., 2013, p.82).

The policy layer of BCW is beyond the scope of this thesis and I did not consider it, because choosing the appropriate policy to support the delivery of the intervention would be more suitable for HeLP-Diabetes with the prompts as a whole package, rather than the prompts by themselves.

The rationale for selecting the Behaviour Change Wheel:

The BCW development was a transparent and comprehensive process. The process started with a literature review conducted by Michie et al. (2011) to identify any behaviour change intervention framework that met three criteria: it has to be comprehensive, meaning that the a framework can be applied to any behaviour change intervention; it has to be coherent, in that all its categories fit together well and are all on the same level of specificity; and finally the framework has to be linked to a model of behaviour that takes into consideration the conscious and unconscious behaviours and other external and internal influences of behaviour. Michie et al’s literature review identified 19 framework and synthesized them to produce the BCW. The intervention functions identified in those frameworks were linked to the components of the COM-B model (i.e. Capability, Opportunity and Motivation) producing the BCW. To ensure the applicability and reliability of the BCW, it was used to code components of behaviour change-related policy strategies (e.g. 2006 NICE obesity guidance). The coders’ inter-rater agreement was subsequently measured and found to be high (79%) (Michie et al., 2011). The BCW simplifies the process of intervention design and development by linking together internal and external determinants of behaviour, broad intervention functions, as well as small, clear and replicable BCTs. This improves the usability of the model for

non-behavioural change experts and inexperienced intervention developers, as they can more easily link the mechanism of action of behaviour change interventions to the desired or possible outcome. In this way it enables an accurate assessment of why an intervention worked or did not work (Michie et al., 2014). Hence, the main reasons why I selected the BCW were the systematic and inclusive process of the BCW development, and the framework's clear and specific steps to follow.

How the behaviour Change Wheel was used:

To determine the sources of behaviour (Capability, Opportunity and Motivation) to be targeted, I planned to use the COM-B model to analyse engagement using data from qualitative interviews with HeLP-Diabetes users and in reference to studies that used theory in developing their prompts identified in the systematic review. However, neither data source was available because I could not conduct the interviews due to recruitment issues, as discussed in Chapter 4, and the systematic review did not identify any study that used theory for development of prompts (see Chapter 2).

Hence, I was not able to get information that would have enabled me to tailor the BCW to the context of this PhD (i.e. I was not able to identify the determinants of behaviour to specifically target then select the appropriate functions (Persuasion, Modelling, Environmental restructuring…etc) that would increase the chance of the prompts being effective), and time constraints did not allow me to consider other possible theoretical options. However, I was able to use a range of functions based on the three different determinants of behaviour, through coding BCTs used in the prompts identified in the systematic review (Chapter 2, Section 2.5.6). This was followed by testing these BCTs and others, when possible, in the prompts used for HeLP-Diabetes (see Section 3.4.4, Table 5 for the prompts with BCTs).

Modelling process and outcomes

The final suggested elements in the development part of the MRC framework is to model processes and outcomes. This step is about understanding the possible pathway of change for interventions with a higher degree of complexity than the prompts used in this PhD (see Figure 1: Engagement prompt logic model, Chapter 1, Section 1.2.4). It is about theorising the process and outcomes for the intervention. The MRC guidance describes one way of modelling as doing a pre-trial economic evaluation or a theoretical one to explore the casual pathway. Both methods would not have been possible within the limits of my PhD; the systematic review did not yield enough information about theory or cost-effectiveness data. Furthermore, the analysis of prompts I did in Chapter 5 produced enough evidence to enable me to conduct pilot trials (see Chapter 6) and choose the appropriate outcome measure within HeLP-Diabetes.

3.4.3 Describing the context as part of the development stage of the Medical Research Council guidance

The development stage of the MRC guidance does refer to an important step that, although not explicitly written in the guide, is much needed for any intervention, and that is the description of the context of an intervention. The MRC guidance recommends that when developing an intervention it is preferable to tailor it to a specific setting or context rather than to standardise it (Moore et al., 2015, Craig et al., 2008, Medical Research Council, 2008). Understanding the context of where the intervention will be used is crucial to develop, evaluate and implement it, as it helps to identify the outcome measures that can be used, confounders that may affect the results, issues that can affect the performance of the intervention, resources needed to conduct the intervention and how the intervention will work (Moore et al., 2015). This allows other researchers to decide how relevant the results are and whether they are reproducible in other cases.

Context of prompts development - HeLP-Diabetes: The digital intervention

I used a digital intervention targeting self-management for people living with Type 2 Diabetes called Healthy Living for People with Type 2 Diabetes (HeLP-Diabetes, https://www.help-diabetes.org.uk) as the context for prompt development and testing. The digital intervention was developed by a research team at University College London funded by National Institute for Health Research (NIHR). The aim of HeLP-Diabetes is to provide the tools and information to improve self-management among people living with Type 2 Diabetes (HeLP-Diabetes, 2016).

HeLP-Diabetes was developed because diabetes is one of the most common chronic diseases in the United Kingdom (UK), affecting around four million people and causing substantial morbidity and mortality (Diabetes UK, 2015a). Around ten percent of the total health resources spending (National Health Service (NHS) budget) is allocated to diabetes, but a substantial amount of the cost is attributable to potentially preventable complications (Hex et al., 2012). Structured education for patients with Type 2 Diabetes on how to better manage their condition and prevent complication is one way of reducing the burden of diabetes on the patients and the NHS; however, in 2015 only 5.3% of patients attended structured education (National Diabetes Audit, 2016). Thus, a digital intervention that includes tools and information that patients need, and is accessible regardless of time or geographical constraints can potentially improve the self-management behaviour of many diabetic patients. It can also provide health professionals with a convenient and cost effective education and behaviour change tool. HeLP-Diabetes was a five-year- funded program with the first and second year spent on developing the digital intervention through a participatory design approach. This approach included interviews and focus groups with patients, their family and friends, as well as health professionals to explore their perspectives on the essential and desirable features that would

make up HeLP-Diabetes, as well as its usability. I joined the team at the start of the third year, at which point the team was just starting two parallel studies to evaluate and implement HeLP-Diabetes. One study was a RCT that evaluated the impact of HeLP-Diabetes on clinical outcomes and quality of life and the other study was an implementation evaluation study that looked at the uptake and usage of HeLP-Diabetes within NHS practices and the resources needed to implement it. It should be noted that throughout this PhD, HeLP-Diabetes users were not a fixed number, rather users started to register from 2013 and continued to do so up until the project concluded in 2016.

Rationale for choosing HeLP-Diabetes

As detailed in Chapter 1, Section 1.2.3, engagement is multidimensional. In order for a context to be conducive to developing and testing prompts, the context has to be well-prepared in terms of having some proven engagement-promoting features in terms of user, targeted health condition or behaviour, and digital intervention characteristics. Thus, HeLP-Diabetes was an appropriate context for developing and testing the prompts for the following mixture of theoretical, scientific and pragmatic reasons.

Theoretical and scientific reasons for choosing HeLP-Diabetes as the context for developing and testing the prompts: HeLP-Diabetes is based on a strong foundation of behavioural theory and was developed with the patients' and health professionals' needs and preferences in mind. It is composed of comprehensive sections that cover the main elements of chronic disease management, which are role management, behavioural management, emotional management and social support, as well as a comprehensive educational component based on the NICE guidance for diabetes and behaviour change (Ross et al., 2014). The developers of HeLP-Diabetes also took into account the different engagement domains, such as the characteristics of an engagement-promoting digital intervention and constructed the digital

intervention out of elements designed to make it engaging, including interactivity and component tailoring (Pal et al., 2013a, Pal et al., 2013b). Also, within the context of HeLP-Diabetes, there was evidence through focus groups conducted during development that prompts sent via email and text messages could potentially promote users' engagement (Pal et al., 2013a).

Pragmatic or practical reasons for choosing HeLP-Diabetes as the context for developing and testing the prompts: The previous reasons for using HeLP-Diabetes as the context to develop and test engagement prompts were a mixture of theoretical and scientific reasons, while the main practical reason was that when I started my thesis, HeLP-Diabetes was just launched and was being evaluated in a RCT and implementation study, both of which officially concluded in February 2016. The development and testing of prompts ran parallel with these two studies, which allowed for testing of the intervention on all users from registration until conclusion of the studies and the availability of the team and patient representatives who developed HeLP-Diabetes to provide feedback on the prompts. Another pragmatic reason is that ethical approval for sending prompts was available as part of the HeLP-Diabetes ethics approval and consent of participants to receive email and/or text message prompts was part of the registration procedure.

HeLP-Diabetes description

HeLP-Diabetes has eight main sections; these sections can be accessed easily from the homepage (see Appendix 6: Screenshot of HeLP-Diabetes home page). The following is a brief description of each section:

- **Understanding diabetes:** This section is aimed at increasing users' knowledge about Type 2 Diabetes and how to properly manage it. It includes the most common questions about Type 2 Diabetes (i.e. What is

it? How can it affect my body? What can I do to look after myself while managing my diabetes?). It contains 15-minute-quick guides about medication, eating and quitting smoking.

- **Staying healthy:** This section was designed to support users to change their Type 2 Diabetes-related health behaviours. It emphasises the essential and significant role of the patient in managing their diabetes. It includes pages on the importance of lifestyle, looking after one's self, physical activity, taking medicines, eating and drinking, alcohol, smoking and working with a diabetes team. It includes many tools (e.g. goal setting).

- **Treating diabetes:** This section was designed to increase users' knowledge about information regarding tests, medication, surgery, vaccination and services provided by the NHS.

- **Living and working with diabetes**: This section was designed to assist patients to manage their Type 2 Diabetes to fit with their life and work and how to deal with diabetes in everyday life; such as with travelling and eating in social occasions. It also includes advice and tips to support patients and their families, as well as the type of financial support available for patients.

- **Managing my feelings:** This section aims to increase users' knowledge and skills in understanding the different moods and feelings they might experience such as depression or sadness and how to cope with them. It also includes a personalised computerised cognitive behavioural therapy course called Living Life to the Full that helps users cope with their feelings.

- **My health record:** This section provides the users with lots of tools to record information about the different aspects of their diabetes

management (e.g. appointments and test dates, care goals and plans, test results, screening checks and medicines list). This section also allows the users to print and share the information with their health professionals to facilitate better communication and decision-making.

- **News and research:** This section includes a summary of the latest news and research articles related to Type 2 Diabetes as well as an archive of the newsletter issues sent by me. This section was one of the most regularly updated sections of HeLP-Diabetes.
- **Forum and help:** This section includes a forum to facilitate communication and experience sharing between users. It also includes threads where users can post questions to health professionals and dieticians. In addition, it includes videos from www. Healthtalk.org of patients talking about their experience with Type 2 Diabetes as well as other useful external online resources (e.g. location of libraries with free internet access).

HeLP-Diabetes prompt recipient groups

HeLP-Diabetes had three user groups. The groups differed depending on their recruitment procedures, locations and study design. However, they all had access to the same website pages and could interact in the forum and internal messaging system. I was not actively involved in recruiting participants to any of the three groups.

The three main groups were:

- **HeLP-Diabetes RCT participants:** This group of users were recruited from different practices across England, not only London; the trial manager recruited practices then lead clinicians in each practice

recruited patients. The aim of the trial was to evaluate the effectiveness and cost-effectiveness of HeLP-Diabetes in improving glycated haemoglobin A1c (HbA1c) and diabetes-related emotional distress as measured by the 'Problem Areas In Diabetes' questionnaire. It compared HeLP-Diabetes to a website with text-based basic information; users of the latter group did not receive any prompts. This Trial started recruitment of practices in 2013, then participant recruitment in March 2014, and the 12-month follow-up for all participants concluded in February 2016.

- **Implementation study participants:** This group of users were recruited from the London boroughs of Camden and Islington to evaluate the implementation of HeLP-Diabetes and describe the uptake and usage of HeLP-Diabetes among patients as well as the resources needed for a widespread implementation. This study used different recruitment methods including distributing leaflets for patients to sign-up or sending a person trained on facilitating registration and use of HeLP-Diabetes to recruit patients (Ross et al., 2014). This group of participants included 19 participants who were also included in a psychological sub-study that ran for six weeks that aimed to evaluate the impact of HeLP-Diabetes on the participants' psychological well-being (Hofmann et al., 2016). Recruitment of these implementation study participants started in 2013; the research study finished at the end of August 2015, but patients in Islington are still allowed to register.

- **Diabetes Modernisation Initiative participants:** This was not treated as a research study but as service delivery. It was a rollout of HeLP-Diabetes conducted in mid-2014 in South London borough of Lambeth. The rollout was at first intended to be done by patient volunteers with no health professional involved, but this method of recruitment was abandoned, and patients were recruited via post letters sent to them by

the Lambeth intermediate care team. This group was targeted to recruit for the interview study for my PhD (see Chapter 4, Section 4.2 for more details about this group)

The prompt-related consent procedure of all the groups was the same: all registered users were asked to agree to the terms and conditions of HeLP-Diabetes before using it. The terms and conditions included the following conditions regarding emails and text messages:

> *"We may use the information that you provide or that is obtained by us (that is not part of your confidential personal or* general practitioner (GP) *medical record) in the following ways: a) We may use the information you provide to us to keep you informed of the activities of and the services provided by us by any of the following methods: e-mail, telephone (including automated calls), SMS text messages and other electronic messages such as picture messaging, post, fax."* (HeLP-Diabetes, 2016)

Participants could also choose whether they would like to receive text messages from HeLP-Diabetes and were given the option to opt-out. They could also unsubscribe from email prompts.

HeLP-Diabetes experts and patient representatives - colloquial evidence

HeLP-Diabetes also offered the opportunity to acquire colloquial evidence, the third type of evidence following context-free and context-sensitive scientific evidence mentioned in Section 3.4.2 of this chapter. I used this type of evidence to assist with prompts development, as the systematic review identified significant evidence gaps, and there was no context-specific evidence as HeLP-Diabetes was a newly formed digital intervention, and I was not able to acquire a theoretical understanding of the engagement behaviour of HeLP-Diabetes users and their preference for prompts. The most common source of this type of

evidence is experts (i.e. experts in the targeted health condition, population and intervention) and patient representatives.

HeLP-Diabetes Experts: A team of experts were consulted regarding the development of prompts. This team of experts consisted of two GPs and two psychologists (who led the development, evaluation and implementation of HeLP-Diabetes); two diabetes specialist nurses; a dietician; and project and data managers. Experts were selected for their knowledge of HeLP-Diabetes, digital interventions and the wider context of eHealth. Clinical experts also brought experience of working with patients living with diabetes. The team provided feedback and information that was informed by the ongoing evaluation and implementation of HeLP-Diabetes that coincided with the development of prompts. The team advised on appropriate topics, wording and language style to use in prompts, their layout and the links of HeLP-Diabetes section to embed in the prompts.

Patient Public Involvement: In addition to the experts, patient representatives were consulted on each and every prompt developed. These patient representatives were people living with Type 2 Diabetes who were involved in the development of HeLP-Diabetes. Their role was essential to the development and testing of the prompts as PPI is currently considered an essential element of any well-conducted health-related research.

Definition of patent public involvement and why it is important: PPI is a prerequisite for many funders of health research as it reflects the UK government's commitment to encourage individuals to take a greater role in their health and social care services (Department of Health, 2004). The UK Research Governance Framework for Health and Social Care states clearly that the active involvement and participation of service users, patients and carers is

a feature of quality research culture in the NHS and Social care (Department of Health, 2005).

There are many definitions for PPI, but for my PhD I used the INVOLVE definition. INVOLVE is a national advisory group funded by the NIHR; its mission is to support active PPI in NHS and research. They define the process of PPI in research as research being performed “with” or “by” patients or the public rather than “to”, “about” or “for” them (Wilson et al., 2015, INVOLVE, 2015)

Importance of Patient Public Involvement: The importance of PPI in research can be explained using three arguments (van Thiel and Stolk, 2013, Boote et al., 2015).

The first argument is an epistemological one; patients and the public are more aware of their own health condition and health service experience than researchers. If researchers focus on what they believe patients and the public need, this might result in certain biases; for example, research favouring one topic over others, focusing on chronic conditions instead of acute ones or focusing on improving interventions or services instead of focusing on engaging and improving access of patients to these services and interventions. Indeed, research continues to show that health professionals prioritise areas of research that do not align with patients’ needs (Welfare et al., 2006, van Thiel and Stolk, 2013). Thus, PPI is seen as a way to prioritise research questions and agendas and identify common ground between policy makers, researchers and the public (Wilson et al., 2015).

The second argument is a moral and ethical one. Within a democratic society it is only fair for members of the society to be involved in research funded by the public, especially if the research has a direct or indirect impact on their health

status and services. For that reason, policy makers and funding bodies are increasingly, in the UK and worldwide, demanding the inclusion of PPI at the grant application stage (van Thiel and Stolk, 2013, Department of Health, 2005, Wilson et al., 2015).

The final argument is a consequentialist one, and it concerns the potential positive impact of PPI. The NIHR states that PPI in research can improve outcomes and enable quicker uptake of new evidence (NHS Choices, 2014). Patients' or the public's experiential knowledge (i.e. knowledge that stems from their experience with the health services or condition) is valuable and is believed to contribute to improvement in health outcomes and services in the short and long term. A systematic review that looked at the impact of PPI found that involving patients in research led to the design of research objectives and questions focused on the patients' needs; design and writing of more user-friendly information, questionnaires and interview schedules; the use of more appropriate recruitment strategies for studies; a more patient-centred interpretation of data; and better dissemination of study results (Brett et al., 2014a). Another systematic review found that patients and public representatives involved in research reported feeling empowered and appreciated, and acquired self-confidence and new life skills. Researchers developed a better understanding and awareness of their research area and established good rapport with their target population. But, there were some challenges, as some patients felt unprepared or untrained to share their experience or overwhelmed with the work involved with the research team, and some researchers felt that they did not have enough resources to incorporate PPI at the appropriate research stages (Brett et al., 2014b).

How Patient Public Involvement has been used so far and Patient Public Involvement roles: A bibliographic review showed the different health areas that had used PPI, and they included mental health, cancer, sexual health, children

and parenting, diet, obesity and diabetes, drug and alcohol addiction, people with learning difficulties, older peoples' and vulnerable groups' health and well-being, stroke and other neurological disorders, spinal cord injuries, burns, cardiovascular problems, and dermatological problems (Boote et al., 2015). The types of groups who have been involved include black and minority ethnic groups and people from indigenous populations, patients of specific health problems, children and parents, and vulnerable adults (Boote et al., 2015). PPI occurred at different or multiple stages of the research process including identification of questions and objectives, designing research, collecting data, reviewing ethical proposals and other documentation (e.g. patient information sheets, questionnaires, invitation letters), commissioning and/or funding of research, analysing data and interpretation, and disseminating results (Boote et al., 2015).

3.4.4 Assessing feasibility and piloting methods

This *assessing feasibility and piloting methods* stage according to the MRC guidance aims to address all uncertainties before a large-scale evaluation study. This stage is needed to identify any challenges likely to arise in the study and to assess the potential impact of the intervention. The guidance clarifies that a pilot or feasibility study should address some of the uncertainties in the development work rather than running as a small-scale study of the main evaluation study, if possible. According to the NIHR glossary, a feasibility study is defined as research conducted prior to the main study to find out if the main study is possible to conduct. Feasibility studies are used to estimate important parameters that are needed to design the main study (NIHR Evaluation, Trials and Studies Coordinating Centre, 2016). Such parameters include the information needed to calculate the sample size (e.g. number of participants willing to participate), information needed to characterise the outcome measure or define it (e.g. the availability and usefulness of the databases recording the outcome measures), and time needed to complete and analyse the data and

recruit the participants (NIHR Evaluation, Trials and Studies Coordinating Centre, 2016).

A pilot study is defined as a small-scale version of the main study done to assess if the main study's components work together. Pilot studies are used to identify the potential challenges of a main evaluation study in terms of recruitment, randomisation and follow-ups (NIHR Evaluation, Trials and Studies Coordinating Centre, 2016). It resembles the main study in many aspects; it can even include an assessment or testing of outcome measures, and in some cases data from a pilot study contributes to the results of the subsequent main evaluation study in the final analysis (NIHR Evaluation, Trials and Studies Coordinating Centre, 2016). In such a case, a pilot study would be classed as an internal pilot. However, it can never replace the main evaluation study in determining the effectiveness of the intervention (NIHR Evaluation, Trials and Studies Coordinating Centre, 2016). Pilot studies can also be used when it is not possible to conduct a fully powered evaluation trial because the intervention is too costly to evaluate or the sample size is too small. An insufficient sample size was the issue for the pilot trials discussed in Chapter 6. A pilot study ensures a smooth process of evaluation by identifying any difficulties or barriers and solving them. Feasibility and pilot studies can be interchangeable and can answer similar questions (Medical Research Council, 2008, Craig et al., 2008). In my PhD, feasibility was evidenced in the actions I took to test the prompt as described in this section, and the results are available in Chapter 5.

Prompts within HeLP-Diabetes

Process: The process for piloting the prompts was iterative and constantly integrated new evidence from the systematic review and tested on all HeLP-Diabetes users at the same time. Email prompts were first sent in November 2013. I developed the email prompts every month and the content changed depending on current events and news or suggestions by the HeLP-Diabetes

team and the patient representatives. I drafted the content of the emails and included ‘universal record locators’ linking to relevant HeLP-Diabetes sections. The emails were tailored to each user’s username, proofread then sent to the patient representatives for comments and feedback on the tone and content of the emails. Finally, their comments were discussed in a team meeting before I edited and sent the revised emails to the rest of the HeLP-Diabetes users. I used the same procedure for the text message prompts starting from October 2014.

The process for piloting the prompts was not significantly changed throughout the PhD period. However, as a result of frequent discussions and emerging data, characteristics such as frequency and content evolved with time. Figure 10 shows the timeline for prompt design and other decisions.

Prompts characteristics and decisions

Frequency, duration and timing: Out of the three prompt characteristics of frequency, duration and timing, frequency was the one that I mostly discussed and debated with the HeLP-Diabetes team, as there had to be a balance between achieving positive engagement and ‘harassing’ users. The systematic review in Chapter 2 showed that most studies used weekly prompts, but it was not possible to do a meta-analysis to find out if using prompts weekly can promote engagement. Another systematic review that looked at frequency of prompts for interventions targeting different health behaviours found that high intensity and low intensity or irregular prompts both yielded positive engagement (De Leon et al., 2014). As for changing health behaviour rather than engagement, a meta-analysis showed that text message prompts were more effective at changing health behaviour if they were sent daily compared with if they were sent less frequently (Orr and King, 2015). Thus, I decided to base the frequency of the prompts on two elements. The first element was the patient representatives’ preference, as it was the only source of evidence

related to HeLP-Diabetes in particular. Hence, the email prompts started as one email per week, then patient representative feedback gained stated it would be better to have three prompts per month, including one text message. The second element was the restricted resources that did not allow me to send prompts more regularly; for example, sending daily prompts instead of weekly ones, would require automation, and the resources available did not allow for that.

Controlling duration (i.e. send the prompts in the early or late stages of using HeLP-Diabetes), was not possible because HeLP-Diabetes is not a session-based digital intervention. Users were registered from the launch of HeLP-Diabetes until the conclusion of the project, and the application for sending the prompt did not contain an algorithm that tailors the prompts to time length of users' registration. Thus, it was not possible to test the difference in user engagement between those users who received a prompt just after registering and those who had been registered for some time.

Mode of delivery: Two modes of delivery of the prompts were available through HeLP-Diabetes: emails and text messages. Emails were available from 2013, while text messages were available from late 2014. The patient representatives liked both delivery modes.

Tailored: The option of tailoring prompt content to users was the topic of much discussion. I even met with another technology company to discuss acquiring a program that could tailor prompts; however, it was not possible to do that as the expenses were high, and I was only able to send generic prompts with usernames being the only element tailored to users.

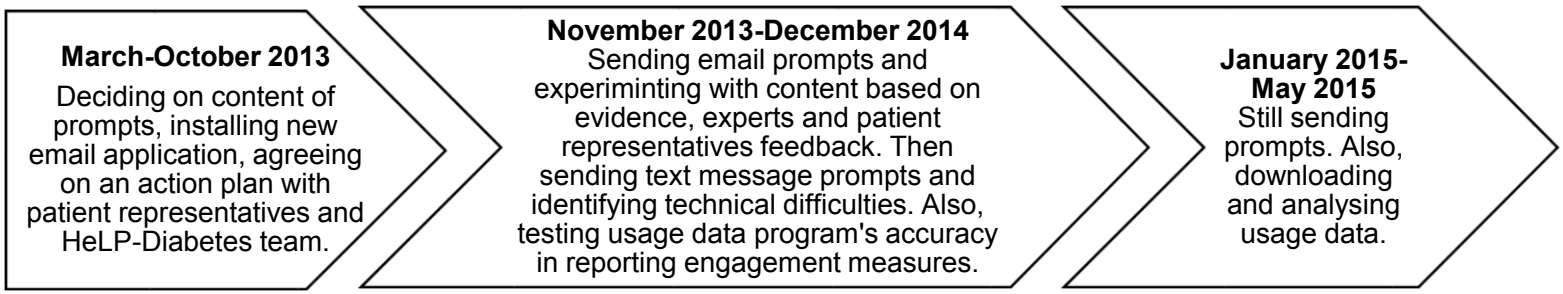


Figure 10: Timeline for prompts decisions

Content: The content of the prompts was one characteristic that I significantly worked on compared to the others. Before gathering the evidence from the systematic review and working with the patient representatives, HeLP-Diabetes experts suggested using generic email prompts to remind users to visit HeLP-Diabetes if they did not visit it within one-to-two weeks. However, such a reminder needs to be tailored to users' engagement behaviour, which requires special algorithms programmed into the email application. This capability was beyond what the HeLP-Diabetes developers (SoftForge) could offer.

The content of the prompts, then, focused on seasonal topics and suggestions from patient representatives with links to different sections of HeLP-Diabetes. The patient representatives suggested inclusion of this prompt content as non-newly diagnosed diabetic patients are familiar with the usual information regarding self-management and maintaining healthy behaviour, as this is received in group education sessions when they are newly diagnosed and through regular clinical visits. Therefore, the patient representatives suggested that users would be more interested in new and seasonal information or refreshers. Furthermore, a plethora of systematic reviews suggest that regular updates or new content may promote engagement (Fry and Neff, 2009, De Leon et al., 2014, Brouwer et al., 2011) (see Table 5: list of prompts details).

Use of theory: See this chapter, Section 3.4.2 for this characteristic.

Table 5: List of prompts details (delivery mode, title, date, content)

Prompt No.	Type of prompt	Prompt title	Date	Content
1	Email	How are your New Year's resolutions going?	06/02/2014	The email listed various tips and advice on how to maintain and achieve new year's health-related resolutions. The BCT in this email was "prompt/cue"; it included links to different sections of HeLP-Diabetes.
2	Email	HeLP-Diabetes Newsletter 6-Medication	14/02/2014	The newsletter described tools and tips to help with taking medications, video about diabetic patients and their experience with medication, the Sharing Data Saves Lives Campaign and the encouragement to use the Ask the Expert thread. The BCT in this email was "prompt/cue"; it included links to different sections of HeLP-Diabetes.
3	Email	Boosting your health during winter	20/02/2014	The email listed advice for boosting health during winter including beating winter blues, flu vaccination and looking after feet health. The BCT in this email was "prompt/cue"; it included links to different sections of HeLP-Diabetes.
4	Email	Best diet advice!	27/02/2014	This email introduced the dietician thread in the forum for any diet questions, the practical diet advice page in HeLP-Diabetes and user recommended

				recipe thread. The BCT in this email was “prompt/cue”; it included links to different sections of HeLP-Diabetes.
5	Email	Share your personal experience with us!	07/03/2014	This email encouraged users to share their personal experience of any aspect of Type 2 Diabetes and introduced the people stories section. The BCT in this email was “prompt/cue”; it included links to different sections of HeLP-Diabetes.
6	Email	How do I lose weight and feel better?	14/03/2014	This email discussed why losing weight is healthy and who should lose weight, as well as tips on how to do that. The BCT in this email was “prompt/cue”; it included links to different sections of HeLP-Diabetes.
7	Email	Designing your care plan	21/03/2014	This email introduced the diabetes care plan tool and how using it helps with managing Type 2 Diabetes. The BCT in this email was “prompt/cue”; it included links to different sections of HeLP-Diabetes.
8	Email	HeLP-Diabetes Newsletter 7- Making changes	28/03/2014	The newsletter contained tips for small increases in physical activity, a description of the reminder tools, quick guides and physical activity experience videos of diabetic patients, update on Sharing Data Saves Lives Campaign and a news article about chocolate and red wine. The BCT in this email was “prompt/cue” as it included links to different sections of HeLP-Diabetes, “information about health consequences”, and “information about environmental consequences”, of using specific sections and tools of HeLP-

				Diabetes and how it can help improve or bring change to their health and lifestyle.
9	Email	It's Springtime	03/04/2014	This email coincided with the beginning of Spring and included tips on exercising in the nice weather and how food can affect mood. The BCT in this email was “prompt/cue”; it included links to different sections of HeLP-Diabetes.
10	Email	Happy Easter	10/04/2014	This email described HeLP-Diabetes content related to Easter Holiday such as shopping for food and resisting chocolate, and travel tips for the holiday. The BCT in this email was “prompt/cue”; it included links to different sections of HeLP-Diabetes.
11	Email	Shopping for food	16/04/2014	This email focused on food labels and information to consider when shopping for food. The BCT in this email was “prompt/cue”; it included links to different sections of HeLP-Diabetes.
12	Email	Achieving your goals	24/04/2014	This email discussed how achieving goals can help with raising confidence, how to achieve goals, and what to do if they are not achieved, including dealing with emotions. The BCT in this email was “prompt/cue”; it included links to different sections of HeLP-Diabetes.
13	Email	HeLP-Diabetes Newsletter 8-	30/04/2014	The newsletter focused on personal experiences of diabetic patients and described the personal stories section of HeLP-Diabetes, available resources

		Personal experiences		for family and friends, a forum post of personal experience of gastric band surgery written by one of our users and a news article about how Cognitive Behaviour Therapy can improve outcomes for people with Type 2 Diabetes. The BCT in this email was “prompt/cue” as it included links to different sections of HeLP-Diabetes and “social support (unspecified)” as it provided information about support resources and help groups.
14	Email	How many meals do you eat per day?	08/05/2014	This email included recommendations spacing out and choosing meals and healthy snacks. The BCT in this email was “prompt/cue”; it included links to different sections of HeLP-Diabetes.
15	Email	Keeping your bones healthy	16/05/2014	This email discussed the importance of Vitamin D and exercises to keep the bones healthy. The BCT in this email was “prompt/cue”; it included links to different sections of HeLP-Diabetes.
16	Email	What you need to know about hypoglycaemia!	21/05/2014	This email included advice and information about hypoglycaemia (low blood glucose). The BCT in this email was “prompt/cue”; it included links to different sections of HeLP-Diabetes.
17	Email	HeLP-Diabetes Newsletter 9-Anxiety	29/05/2014	The focus of this newsletter was on coping with anxiety, describing the online Cognitive Behavioural Therapy programme and the quiz for ‘emotion diagnosis’, as well as a news article on exercise protecting from the effects of overeating. The BCT in this email was “prompt/cue” as it included links to

				different sections of HeLP-Diabetes and “information about emotional consequences” of using the Cognitive Behavior Therapy programme to improve emotional health.
18	Email	Are you a complementary therapy user?	03/06/2014	This email discussed alternative therapy. The BCT in this email was “prompt/cue”; it included links to different sections of HeLP-Diabetes.
19	Email	Sexual health-let's talk about it!	20/06/2014	This email included advice about sexual health and how diabetes can affect it and what do it if experiencing problems. The BCT in this email was “prompt/cue”; it included links to different sections of HeLP-Diabetes.
20	Email	HeLP-Diabetes Newsletter 10-break a sweat this summer!	27/06/2014	The newsletter contained tips for staying motivated with a physical activity routine and exercising in the heat; a reminder tool; a quiz with answers providing personalised tips on maintaining physical activity; and two news articles, one about eating large meals and weight loss, and the other about the link between incretins and pancreatitis. The BCT in this email was “prompt/cue” as it included links to different sections of HeLP-Diabetes and “information of environmental consequences” of using tools to change lifestyle routine.

21	Email	Fasting during Ramadan	30/06/2014	This email introduced Ramadan (fasting month for Muslims). The BCT in this email was “prompt/cue”; it included a link to the Ramadan section in HeLP-Diabetes.
22	Email	HeLP-Diabetes Newsletter 11-Holiday preparations	16/07/2014	The newsletter contained tips and things to do before traveling and during the trip; a tool for keeping track of medication; and two news articles: one about an initiative by Diabetes UK, and the other about the NHS rating as a top health service in the developed world. The BCT in this email was “prompt/cue”; it included links to different sections of HeLP-Diabetes.
23	Email	How to handle the summer heat	04/08/2014	The email included tips to avoid heat exhaustion such as exercising in cool locations and keeping hydrated. The BCT in this email was “prompt/cue”; it included links to different sections of HeLP-Diabetes.
24	Email	HeLP-Diabetes Newsletter 12-Your diabetes is in your hands	21/08/2014	This newsletter focused on empowering diabetic patients by pointing out that the skills they need to improve their diabetes management, a brief description of diabetes care plan tool, and a video featuring discussion between health professionals and patients about self-management, and two news articles: one on aerobic and strength training and the other on how Metformin helps people live longer. There was also a Member Spotlight on a user sharing his diet journal on the HeLP-Diabetes forum. The BCTs in this email were “prompt/cue”, as it included links to different sections of HeLP-Diabetes;

				“social comparison”, as it drew attention to one of our members posts in the forum about his journey with a new type of diet in the member spotlight section; and “information about health consequences”, where the positive consequences of using the diabetes care plan tool were listed.
25	Email	HeLP-Diabetes Newsletter 13-Get rid of your medication worries!	05/09/2014	This newsletter focused on dealing with worries related to receiving new medications specifically and taking medications in general. It included common questions and experts answers, and a news article about NICE considering expansion of criteria relating to acceptance for weight loss surgery. The BCT in this email was “prompt/cue” as it included links to different sections of HeLP-Diabetes and “information about health consequences” of using the tools on HeLP-Diabetes.
26	Email	Smile - You're on Camera!	17/09/2014	The email focused on oral care tips including using the health profile and medicine list tools to take to the dentist and when to brush the teeth. The BCT in this email was “prompt/cue”; it included links to different sections of HeLP-Diabetes.
27	Email	Autumn health reminder	02/10/2014	This email focused getting the flu vaccine. The BCT in this email was “prompt/cue”; it included links to different sections of HeLP-Diabetes.
28	Email	HeLP-Diabetes Newsletter 14-	17/10/2014	This newsletter included tips on how to enjoy special occasions without over-indulging in terms of food and drinks, the smoking alcohol cessation

		What's happening this October?		campaigns, HeLP-Diabetes layout update, a news article about low carbohydrate diet and a teaser about a news article for next month's issue. The BCT in this email was "prompt/cue"; it included links to different sections of HeLP-Diabetes.
29	Text message	Flu jab reminder	31/10/2014	This text stated: Do you need the flu jab? Visit https://www.help-diabetes.org.uk for more information. If you want to unsubscribe update your profile. The BCT in this text message was "prompt/cue"; it included a link to HeLP-Diabetes..
30	Email	World Diabetes day	09/11/2014	This email contained the three key messages for World Diabetes Day campaign for 2014 and links to HeLP-Diabetes that facilitate actions to support the campaign. The BCT in this email was "prompt/cue"; it included links to different sections of HeLP-Diabetes.
31	Text message	Home exercises	24/11/2014	This text stated: Feeling the cold? Why not warm up with some simple home exercises at https://www.help-diabetes.org.uk/. If you want to unsubscribe update your profile. The BCT in this text message was "prompt/cue"; it included a link to HeLP-Diabetes.
32	Email	HeLP-Diabetes Newsletter 15-	29/11/2014	This newsletter contained tips on planning meals and shopping for food, and tools to help with this, such as for setting goals and using reminders; there was also a news article about a cure for Type 1 Diabetes and an

		Shopping done the right way		achievement of one of our users reaching his weight loss goal and sharing his journey in the forum. The BCT in this email was “prompt/cue” as it included links to different sections of HeLP-Diabetes and “information about environmental consequences” of using the tools on HeLP-Diabetes.
33	Email	HeLP-Diabetes Newsletter 16-Eye care	09/12/2014	This newsletter focused on eye health and included tips for eye care, videos about diabetic patients who experienced eye problems, using the diabetes care plan tool, an announcement about subscribing to text messages, a guide for quitting smoking and a news article about Metformin. The BCT in this email was “prompt/cue” as it included links to different sections of HeLP-Diabetes and “information of health consequences” of using HeLP-Diabetes tools.
34	Text message	Eating and drinking on holidays	18/12/2014	This text stated: Would you like to enjoy your festive meals and drink safely during the holiday period? Read our guide at https://www.help-diabetes.org.uk/. If you want to unsubscribe update your profile. The BCT in this text message was “prompt/cue”; it included a link to HeLP-Diabetes.
35	Email	Happy Holidays	22/12/2014	This email included tips for enjoying the holidays in terms of eating without feeling guilty, encouraged users to share their recipes, included a link about social life and a teaser for next newsletter. The BCT in this email was “prompt/cue”; it included links to different sections of HeLP-Diabetes.

36	Email	New Year Tips	12/01/2015	This email focused on real tips from researcher and author Brian Wansink on slimming down and making being healthy easier. The BCT in this email was “prompt/cue”; it included links to different sections of HeLP-Diabetes
37	Text message	January blues	20/01/2015	This text stated: Are you feeling the January blues? Then visit our happiness and well-being page for steps to overcome this feeling that can affect everyone. https://www.help-diabetes.org.uk/. If you want to unsubscribe update your profile. The BCT in this text message was “prompt/cue”; it included a link to HeLP-Diabetes.
38	Email	HeLP-Diabetes Newsletter 17-Change for 2015	27/01/2015	This newsletter highlighted how HeLP-Diabetes can assist users who want to make health-related changes as part of their New Year resolutions, a video about the Mediterranean diet and a news article about NICE guidance on weight loss surgery. The BCT in this email was “prompt/cue” as it included links to different sections of HeLP-Diabetes and “instructions on how to perform behavior”, as it described how to use HeLP-Diabetes.
39	Text message	Sharing problems and advice	11/02/2015	This text stated: A problem shared is a problem halved. Are you confused by the different messages about diabetes? Do people offer different advice? Or can you offer some? Check our FAQs to find out which messages to follow or check our Forum to see what other people advice.

40	Email	How to manage your diabetes using the HeLP-Diabetes care plan	18/02/2015	This email advised on how to use the HeLP-Diabetes care plan in consultations or clinic visits. The BCT in this email was “prompt/cue”, as it included links to different sections of HeLP-Diabetes; “instructions on how to perform behaviour”, as it included instructions on how to use the care plan; and “information about health consequences” of using it.
41	Email	HeLP-Diabetes Newsletter 18-Alcohol, love and activity in February	27/02/2015	The newsletter contained tips to succeed in the Dry January Challenge of quitting alcohol and information about that; and information about support and love from family, friends, local support groups and other types of support available for Type 2 diabetic patients. It also contained a news article about physical activity. It was the first newsletter to include pictures. The BCT in this email was “prompt/cue”; it included links to different sections of HeLP-Diabetes.
42	Text message	NHS medical exemption certificate	15/03/2015	This text stated: What do you know about NHS medical exemption certificates? Do you know that there is a fine of £100 if free prescriptions are claimed without a valid exemption certificate? Read more about it on https://www.help-diabetes.org.uk/living-working-with-diabetes. The BCT in this text message was “prompt/cue”; it included a link to HeLP-Diabetes.

43	Email	Get to know HeLP-Diabetes	19/03/2015	This email quoted a user interviewed about HeLP-Diabetes and how he learned something new from HeLP-Diabetes. The BCT in this email was “prompt/cue”; it included links to different sections of HeLP-Diabetes.
44	Email	HeLP-Diabetes Newsletter 19-Spring, delicious recipes and dark chocolate	30/03/2015	The newsletter contained tips for exercises for all levels; tips for outdoor activities; recipe for cookies, scones and fruit kebabs; and a news article about chocolate. The BCT in this email was “prompt/cue”, as it included links to different sections of HeLP-Diabetes; and “instructions on how to perform behaviour”, explaining the right way of using the exercise videos.
45	Email	What HeLP-Diabetes can do for you…	23/04/2015	This email listed why using HeLP-Diabetes can help the user to manage their condition and also included an email address to contact for technical support. The BCT in this email was “prompt/cue”; it included links to different sections of HeLP-Diabetes; and “information about health consequences” of using HeLP-Diabetes different tools.
46	Email	HeLP-Diabetes Newsletter 20-What can you eat?	29/04/2015	This newsletter focused on tips about having a balanced diet, the using a dietician thread and a news article about exercise and reducing waistline.The BCT in this newsletter was “prompt/cue”; it included links to different sections of HeLP-Diabetes.

47	Email	Making HeLP-Diabetes easier	15/05/2015	The BCTs in this email were “instructions on how to perform behaviour”, as it included instructions on how to use HeLP-Diabetes, such as logging in; and “prompt/cue”, as it included links to different sections of HeLP-Diabetes.
48	Text message	Specialist and technical support	21/05 /2015	This text stated: Hello [username]. Visit https://www.help-diabetes.org.uk/forum-help/forum for support from people living with diabetes, diabetes specialists and technical support. The BCT in this text message was “prompt/cue”; the link was to the HeLP-Diabetes forum.
49	Email	HeLP-Diabetes Newsletter 21- Mindfulness, HeLP-Diabetes and fruit sugar	27/05/2015	The newsletter contained a step-by-step guide on how to use an online course on HeLP-Diabetes, description of an activity booklet and one research article about fruit sugar. The BCT in this newsletter was “instructions on how to perform a behavior”; the instructions were on how to use an online course on HeLP-Diabetes.

Notes: Although the development of the prompts was not an easy process, getting the following positive feedback from users who received emails during the testing period was rewarding (Note that this feedback was not formally analysed): “I found your February newsletter very informative and useful - thank you. I also found it very easy to switch from one topic to another to answer some of my queries – great”; “Thanks for your most useful and helpful guidance for healthy eating over the festive season. A very peaceful and prosperous New Year to you all”; “Like this issue - it's well balanced even for a low carber such as myself!“; “Thank for the words of Comfort“.

Technical difficulties

Through this development stage, there were some technical difficulties that would have hindered sending the prompts and analysing them; however, I was able to provide a solution with the support of the developers (SoftForge) and the HeLP-Diabetes team (see Table 6: list of the main technical difficulties and actions taken to solve them).

Analysing test period email and text message prompts

The analysis of the prompts during this stage of piloting the prompts is explained in detail in Chapter 5. Briefly, usage data were not available until later in the PhD and were analysed quantitatively; specific email prompts were selected to be explored further through think aloud interviews with the patient representatives. The analysis discussed in Chapter 5 generated hypotheses about the content and delivery mode of prompts to be tested in the pilot randomised study in Chapter 6. This analysis helped construct the intervention and control arms, the follow-up period and the outcome measures definition, extraction and analysis.

Table 6: List of the main technical difficulties and actions taken to solve them

Technical difficulties	Solutions	My specific action
Original HeLP-Diabetes application used for sending emails was not flexible and difficult to use. It did not provide the number of participants opening emails or clicking links and did not allow filtering emails by groups.	Bought and integrated a new application called Acymail with HeLP-Diabetes that included detailed data about emails and allowed for sending emails separated by groups.	I asked the developers and the team if it was possible to use another application to send the emails with the previously mentioned specifications.
Usage data not recorded properly from 2013 until mid-January 2014.	This was an issue related to the way the system was set up and the developers were able to fix it to record the data properly from mid-January 2014 and onwards.	I used the usage data from February 2014 since the number of participants was very low in the beginning and increased mid-2014.
Choosing which program that records data to use and downloading the data in a usable format.	Used JamoolaWatch, which was not perfect, as it required constant monitoring of data output and testing to ensure accuracy. The output of the data also required cleaning.	I consistently reviewed the usage data and tested it with the support of the HeLP-Diabetes team, specifically the data manager, for accuracy and reported any odd data to team and developers. To clean the

		data, we used Excel and SPSS and the data was ready in early 2015.
Adding a text message-sending application to the front end of HeLP-Diabetes.	Adding the application was easy but it required more work to filter out users who did not want to be contacted by text message and those who added inaccurate mobile phone numbers or only added landline phone numbers.	I manually filtered out the users who did not want to receive text messages or did not provide mobile phone numbers and notified the developers to make the necessary changes and tested the text message application for any possible glitches or technical errors.
Adding images to the email prompts.	Acymail was updated, as the version installed in the beginning was not flexible enough to add images.	I discussed the difficulty of adding images to the current version of Acymail with the team and the need to find a way to fix this, as the patient representatives wanted pictures in the newsletters to make them more attractive.

Text messages application not working when the number of users increased in each of the recipient groups.	The developers had to install an add-on that queued text message prompts, so that a group of five message prompts were sent within a couple of minutes between each group.	I had to manually try sending a group of five messages every two minutes to figure out if that would work.

3.4.5 Evaluation

The MRC guidance describes three types of intervention evaluation:

- **Effectiveness evaluation**, which is outcome evaluation. It requires many considerations to be addressed such as what study design would be most appropriate and the outcome measures that can be used.

- **Process evaluation** can help to provide an explanation as to why an intervention failed or succeeded in achieving its outcomes, as well as clarifying the intervention's mechanism of action and providing insight into the contextual factors that might have resulted in variation in outcomes.

- The final type **is assessing cost-effectiveness**. This can be done by conducting an economic evaluation to produce results than can help decision makers decide whether the benefits generated from implementing the intervention are justified by the costs of developing and delivering it.

All three types of evaluation are necessary and important. However, evaluation of effectiveness is essential for an intervention to be implemented and funded if it produces positive outcomes. The other two types of evaluation complement the study appraisal overall by adding information about the cost and mechanism of action.

In my PhD, I have conducted two consecutive pilot RCTs to test the effect of different prompts on engagement with Help-Diabetes (see Chapter 6). The two main features of effectiveness evaluation are randomisation to reduce the chances of selection bias, which can occur if the samples in the different treatment arms differ in more than the type of intervention they receive; for example, in this PhD such variables include age, sex, length of registration and length of diabetes. The other main feature of effectiveness evaluation is the

consideration given to the outcome, whether it is objective or subjective and the length of follow-up. Most of these issues I considered during the previous stages; Chapter 5 contains more detail about the outcome chosen for measuring engagement due to prompts. The two pilot RCTs described in Chapter 6 were intended as effectiveness evaluation trials but the sample sizes were not powered to detect an effect. This is discussed in detail in Chapter 6.

3.4.6 Implementation

Implementation is an essential stage of the MRC guidance for the continuity of an intervention. Therefore, it was an important stage to consider in this thesis. This stage of the MRC framework encompasses two elements. The first element is effective dissemination of evidence through not only publishing it but getting it into practice i.e. integrating the scientific evidence (e.g. evidence that a specific intervention is effective in changing an unhealthy behaviour) into the real-life setting, context or practice it is intended for. Successful integration of evidence into daily life practice is achieved by identifying and tackling potential barriers and utilising potential facilitators. In the case of successful integration of prompts into HeLP-Diabetes, barriers and facilitators included the identification and solving of technical difficulties to sending them as well as setting a clear and easily followed protocol to send the prompts (Medical Research Council, 2008, Craig et al., 2008). The second element of implementation is the long-term follow up of intervention outcome, to find out if short-term positive results of evaluation study persist over time; it can be done by finding an outcome measure that can be collected routinely, such as what I have used in this thesis to measure engagement (see Chapter 5) (Medical Research Council, 2008, Craig et al., 2008).

Implementation in this PhD ran in parallel with the other stages of the MRC guidance, as the natural context for the prompts was within HeLP-Diabetes and the targeted population was its users.

The protocols constructed for sending the prompts and the solving of technical difficulties that were raised while sending or analysing the prompts can ensure the use of the prompts in the long-term. Also, the results of the development and testing will be published for other prompts developers to benefit from.

3.5 Discussion

3.5.1 Summary of application of Medical Research Council guidance

The original plan for my thesis was to incorporate the results of the systematic review, analysis of usage data of the email and text message prompts in the piloting and feasibility period, and the results of semi-structured interviews that explored the preference of HeLP-Diabetes users (Chapter 4). This synthesis would have produced prompts to test in subsequent randomised studies. The process of development and testing was intended to be iterative with more than one randomised study to test different characteristics.

However, due to technical difficulties with the usage data, it took considerable time to get this in a format clear enough to analyse. The results of the data analysis led me to conduct think aloud interviews with PPI representatives (Chapter 5) in place of the semi-structured interviews originally planned with HeLP-Diabetes users. The quantitative and qualitative data enabled me to test the prompts in two pilot randomised controlled trials (Chapter 6). The steps taken in this PhD also enabled me to modify the MRC framework as shown in Figure 11.

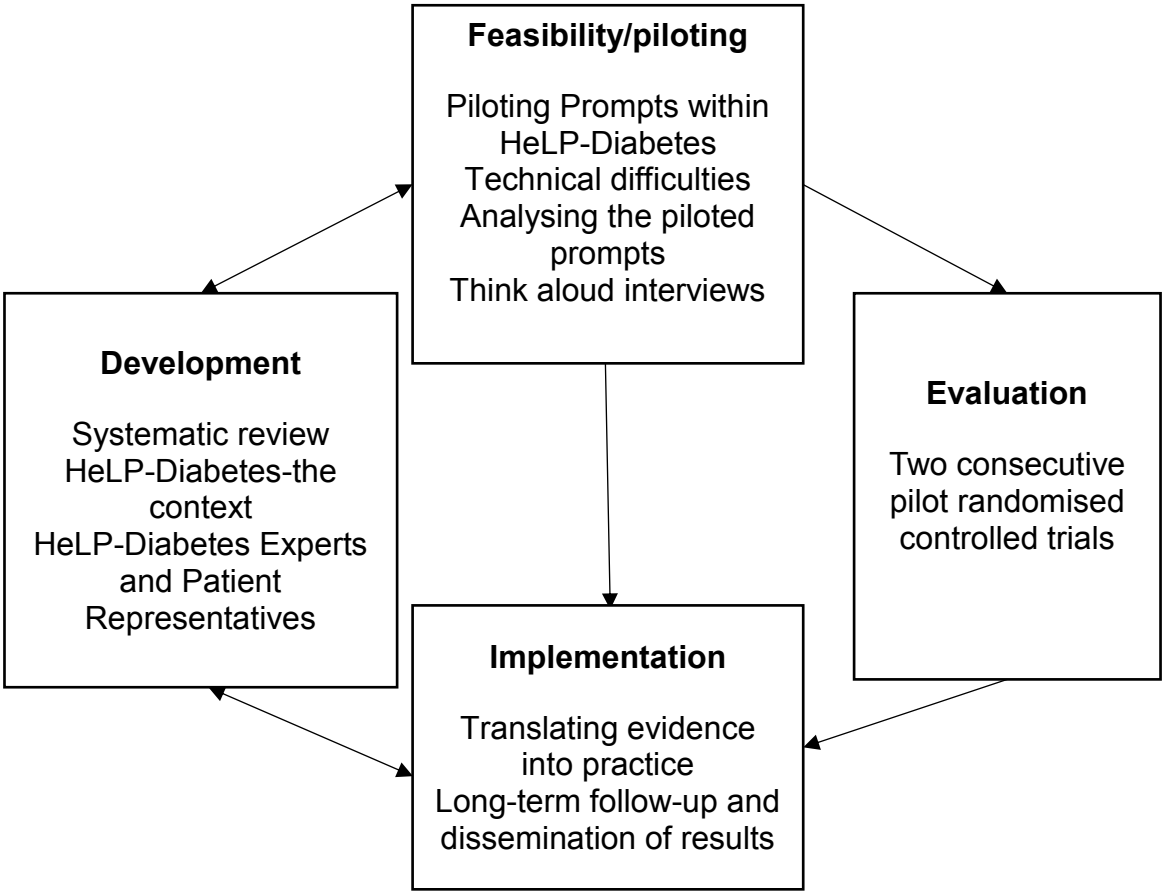


Figure 11: MRC Framework Application

3.5.2 Applicability of the Medical Research Council guidance

The MRC guidance in its current form is the second version (Medical Research Council, 2008, Craig et al., 2008), published after revising the first version and accommodating recommendations from many researchers who used the first version (Campbell et al., 2000). The guidance is flexible and applicable to whole populations, community units and individuals; the latter being the focus of the prompts. I have followed the main stages of the guidance by starting with identifying the evidence in the systematic review to testing the prompts in two pilot RCTs while implementing all of these stages within a defined context (HeLP-Diabetes) on the targeted population rather than a representative sample. This enabled me to produce protocols for sending the prompts and analysing them in the long-term. However, there were some challenges in selecting the recommendations and advice in the MRC guidance. Some of the recommendations can be applied to interventions with a higher level of complexity than the prompts; for example, the *modelling processes and outcomes* element of the development stage was not applicable to the prompts (see Section 3.4.2).

3.5.3 Final thoughts and lessons learned

The use of the MRC guidance helped shape my PhD. Following the steps and recommendations enabled me to start and conclude my PhD in a logical order, although I have made some changes to the guidance, as shown in Figure 11. These changes were made to accommodate the context of the prompts and the available resources. While I faced some challenges in applying the guidance (e.g. not being able to identify or develop a theory), by returning to the main stages in the guidance (i.e. development, feasibility/piloting, evaluation and implementation) I was able to make the necessary changes to ensure I achieve my PhD aim and objectives.

Chapter 4 Experience with a patient-led rollout of HeLP-Diabetes and the use of engagement prompts: providers' and patients' perspectives

4.1 Abstract

In this study, I aimed to explore the acceptability and feasibility of HeLP-Diabetes users receiving engagement prompts via emails and text messages, with a view to optimising the content and patterning (i.e. frequency) of the prompts. I intended to use a semi-structured interview schedule with purposive selection of participants, based on a maximum variation sampling technique. I was planning to analyse the data thematically using the framework method. However, no users volunteered to participate in the interviews, so I was not able to carry out this component of my PhD. In this chapter, I will present the original protocol for this study, describe efforts made to improve recruitment, and include a reflective discussion about the reasons behind not being able to complete this study.

4.2 Background

In Chapter 1, I introduced the problem of low engagement with digital interventions and the potential use of prompts as a solution. In Chapter 2, I summarised what is known about the effectiveness of such prompts from the published literature. However, there is lack of evidence related to users' experiences of, and preference for prompts.

4.2.1 Qualitative research about engagement

Qualitative studies related to engagement with digital interventions have explored users' views regarding facilitators or barriers to engagement with digital interventions (Donkin and Glozier, 2012, Gerhards et al., 2011, Postel et al., 2011, Short et al., 2014). These barriers include lack of motivation to complete the digital interventions, lack of computer skills and dissatisfaction with digital interventions content. Facilitators to engagement with digital interventions include personalised advice provided by the digital interventions, users noticing an improvement in their health or behaviour as a result of using the digital interventions, and the convenience of the digital interventions compared with attending face-to-face therapy sessions. Other studies have explored users' decisions to engage based on the digital interventions content and design and found that digital interventions that are convenient (Khadjesari, 2012), regularly updated (Brouwer W, 2009) and tailored (Morrison et al., 2014b) are more likely to engage users. Some studies specifically suggest that users accept email or other technological prompts to promote engagement with digital interventions (Brouwer W, 2009, Pal et al., 2013a, Postel et al., 2011), but there are also data which suggest that although occasional newsletters are acceptable, weekly emails may be annoying (and counter-productive) (Brouwer W, 2009).

4.3 Context of the qualitative study

HeLP-Diabetes, which I described in Chapter 3, Section 3.4.3, is a web-based self-management programme for people with Type 2 Diabetes that was being evaluated in a randomised controlled trial and an implementation study.

There were three study or service delivery groups using HeLP-Diabetes, with the potential to recruit for the current qualitative study. The groups are described in more detail in Chapter 3, Section 3.4.3; they are the HeLP-Diabetes trial participants, the Implementation study participants and the Diabetes Modernisation Initiative (DMI) participants. My reasons for choosing whether or not to recruit from each of these groups are listed below:

— *Groups I did not recruit from:*

- ***HeLP-Diabetes trial study:*** I considered recruitment from this group, but since the trial was demanding in terms of follow-up procedures (i.e. participants had to submit questionnaires and some blood tests for follow-up at three, six and 12-months follow-up), only those who finished 12 months follow-up would have been available to recruit from for interviews, as requesting interviews can increase the demand on those participants. However, this meant that I could not interview users in this group within the time limits allowed for this study as the majority of the users would reach their 12 months follow-up at the end of 2015 or early 2016.
- ***Implementation study:*** I did not consider recruitment from this group as the researcher conducting the implementation study originally planned to interview 50 users, but could only recruit 15 as users were not interested in participating in the research interviews.

— *Group I attempted to recruit from:*

- ***The DMI group:*** this group was the only appropriate and accessible group to recruit from for the current study, as this group was intended as a service delivery, rather than a research study group. HeLP-Diabetes was provided in order to benefit patients in South London from it, and

because there were not enough resources to conduct a study there. Thus, participants were available for recruitment. Furthermore, the group had not been involved in any previous study, so it was assumed that it would be less burdensome to participate.

4.3.1 Background information about the Diabetes Modernisation Initiative group

The DMI group started when HeLP-Diabetes was chosen in early 2013 as an exemplary project to test a new and innovative implementation method: a patient-led rollout.

This patient-led rollout was endorsed by Improvement Science London, which is an enterprise and a collaboration between Imperial College London, King's College London and University College London (UCL). Improvement Science London aims to promote and apply an evidence-based approach to the organisation and delivery of health services in London. Improvement Science London chose HeLP-Diabetes to try out a new method of implementation because HeLP-Diabetes addresses three policy priority areas:

- Long-term self-management of chronic conditions
- Patient and public involvement in research, and service improvement and delivery
- Using technology to make the National Health services (NHS) more effective

HeLP-Diabetes is also suited for this method of implementation because it is an evidence- based, and theoretically informed, website intervention that can be accessible anywhere, at any time and is acceptable to both patients and health care professionals.

The DMI, which was a three-year initiative by the local Clinical Commissioning Groups of Lambeth and Southwark, was in its legacy phase. The DMI was successful in improving Type 2 Diabetes detection rate, the structured

education attendance rate, and the percentage of patients with Haemoglobin A1c (HbA1c) controlled below 64 mmol/mol in Lambeth and Southwark (Diabetes Modernisation Initiative, 2014). The DMI approached Improvement Science London and wanted to implement HeLP-Diabetes (they did not intend to conduct any research, but merely to deliver a service) in Lambeth and Southwark through the use of patient volunteers, or what they otherwise called 'patient champions', who had participated in other DMI projects. DMI proposed a plan on how to train these patient champions to approach the following two potential groups of participants for HeLP-Diabetes in Lambeth and Southwark:

- People living with Type 2 Diabetes who declined attending the NHS group-based education programme called Diabetes Education and Self-Management for Ongoing and Diagnosed (DESMOND)
- Those completing DESMOND, to encourage them to sign-up and use Help-Diabetes

The patient champions were requested to approach the two groups of patients described above and provide them with an information leaflet about HeLP-Diabetes to encourage them to use the website. The information leaflets also contained separate registration universal record locators to allow for identification of patients signing up from Lambeth and Southwark. It should be noted though that patients from the two HeLP-Diabetes studies mentioned earlier and in Chapter 3, Section 3.4.3, as well as patients recruited through the DMI had access to the same materials and received the same email and text message prompts.

As explained above, in this rollout, health professionals were not intended to be actively involved in recruiting users and guiding them in the use of HeLP-Diabetes. This eliminated an important engagement incentive, as one study showed that users trust websites that have been recommended by health professionals (Jariwala, 2005), and it has been suggested that a successful recrutiment strategy can be one where health professionals are keen to recruit

(Campbell et al., 2007). Given the likely problems with maintaining engagement with digital interventions, as detailed in Chapter 1, Section 1.2.3, it was an ideal opportunity to explore users' views about engagement and engagement prompts, including their frequency, content, mode of delivery (i.e. text messages, email) and other characteristics. Improvement Science London and DMI agreed access to their participants if I could also interview the people involved in the patient-led rollout about this model of delivery, as it was suggested that there was a trend for patients with chronic diseases seeking online peer advice (Fox, 2013) but not whether a patient-led rollout can be successful.

Unfortunately, this patient-led model was not implemented due to the following reasons:

- The DMI patient champions were not available anymore, as they became involved with a "UK diabetes" group, and as the DMI was in its legacy phase, it did not have enough resources to recruit new patient champions.
- Improvement Science London suddenly ceased to exist, which halted the project and did not allow for finding an alternative to the DMI.

Therefore, the only option for recruiting patients to HeLP-Diabetes from Lambeth and Southwark was through the Lambeth intermediate care team, who had been introduced to HeLP-Diabetes by the DMI. However, that team only had funds to send the information leaflets by post to non-DESMOND attendees. This recruitment method led to a very low number of patients registering on HeLP-Diabetes and thereby a very low number of potential participants to recruit for the current study.

4.4 Aims and objectives

In this study, I aimed to explore:

- The acceptability and feasibility of HeLP-Diabetes users receiving engagement prompts via emails or text messages, with a view to optimising the content, patterning (i.e. frequency) and other characteristics of the prompts, through the following objectives:
  - Exploring users' perceptions of their actual usage of HeLP-Diabetes, how this compared with their intended usage, and reasons for any discrepancy.
  - Exploring HeLP-Diabetes users' feelings and thoughts about receiving engagement prompts via emails or text messages.
  - Exploring HeLP-Diabetes users' opinions and perceptions of the characteristics and content of prompts that can promote engagement.
- Participants' personal experiences of the patient-led rollout of HeLP-Diabetes, with a view of optimising this service delivery method for future implementation, through the following objective:
  - Explore participants' views of the usefulness of the patient-led rollout model in facilitating uptake of HeLP-Diabetes.

4.5 Methods

4.5.1 Design

This study adopted a qualitative methodology using semi-structured interview methods. I would have conducted semi-structured interviews within three specific groups of participants; a sample of HeLP-Diabetes users who were recruited for the patient-led rollout, DMI staff who worked on the patient-led rollout and a sample of the patient champions who recruited users to the website.

4.5.2 Pilot phase

I did a pilot interview with one of the patient representatives mentioned in Chapter 3, Section 3.4.4 to identify and rectify any issues with the methodology and the interview guide. I consulted another patient representative in the HeLP-Diabetes team on how to improve the wording of the invitation letter, patient information sheet and consent letter to make them more attractive to participants.

4.5.3 Participants

In qualitative studies, researchers often aim to reach data saturation, and the literature indicates this may be achieved after 15 to 20 interviews, depending on the complexity of the topic and heterogeneity of the sample (Ritchie J., 2014). For the HeLP-Diabetes users, interviewing until we reached saturation might have been possible, as the number of participants was not restricted. However, there were only two possible staff participants, and fewer than 15 patient champions, so, for these two groups, my goal was to obtain as much data as possible.

Therefore, for the staff and volunteer patient champion groups, the number of participants depended on the number of people involved in the rollout. Hence, two participants from the DMI staff group and for the volunteer patient champion group, a sample of three to five participants. As for the HeLP-Diabetes users sample, the number of participants I wanted to interview depended on achieving data saturation.

Purposively selecting users and patient champions based on maximum variation sampling technique is the best method of selection of participants, as this method is used to select specific but diverse people for the information they can give that cannot be received from using another random sample (Maxwell, 2009).

Criteria for selecting participants

I intended to use purposive sampling to select participants (i.e. selecting participants based on a pre-specified criteria).

The most important criteria for selecting users to participate in the interviews were differences in their experiences with HeLP-Diabetes; whether they used HeLP-Diabetes or not and for how long; how long have they had diabetes; and their age and sex, as these factors may contribute to their HeLP-Diabetes experience (Pal et al., 2013a, Ritchie J., 2014). However, for a participant to be interviewed, he/she had to be a registered user in the HeLP-Diabetes DMI rollout group. The user also had to have one or both of the two methods of receiving engagement prompts, which were an active email account or a valid mobile phone number to receive text messages.

To be eligible to participate in an interview, DMI staff had to be involved in leading, planning, supervising or implementing the patient-led rollout of HeLP-Diabetes. Patient champions had to be involved in identifying, recruiting and assisting other people living with Type 2 Diabetes to use the website. They had to be HeLP-Diabetes users themselves or to have been exposed to the content of the website. They also had to have one or both of the two methods of receiving engagement prompts mentioned above.

Recruitment Strategy

My recruitment method depended on the categories of the participants, and these methods are outlined below.

HeLP-Diabetes users: Patients who registered to use HeLP-Diabetes were required to provide an email address during the registration process. I initially invited potential participants to participate in an interview by an email sent from the HeLP-Diabetes website shortly after the user registered to use the website (see Appendix 7: Invitation email). I planned to email a participant information sheet and consent form to users who responded positively to this email

invitation, and invite them to discuss any queries they had with me. I would then have contacted users who agreed to participate in the qualitative study, so I could arrange a convenient time and date for the interview (see Figure 12: original recruitment process of HeLP-Diabetes users).

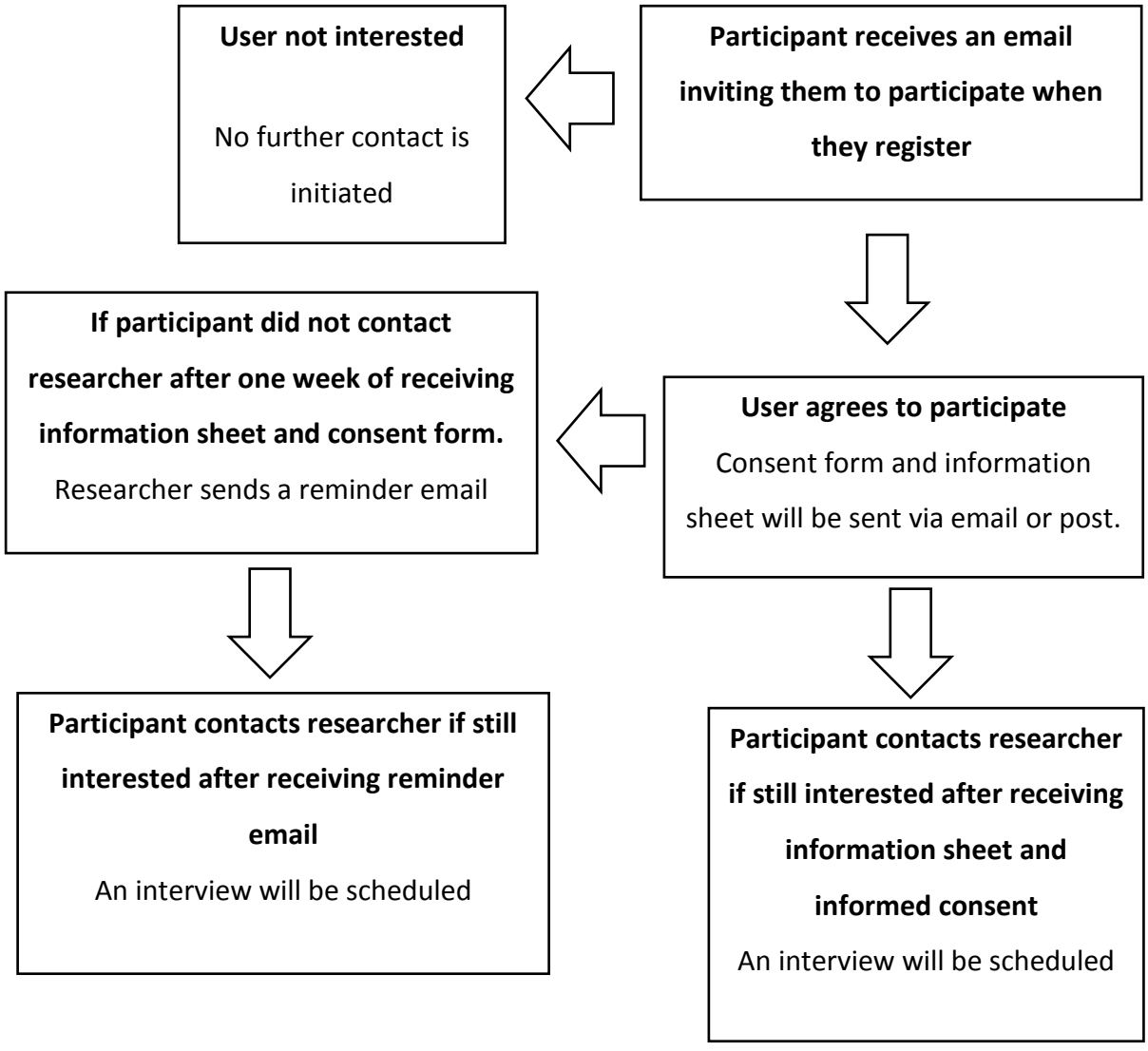


Figure 12: Original recruitment process of HeLP-Diabetes users

DMI staff: DMI staff members were keen to have their innovative service model evaluated and made the initial request for this qualitative study to be done. The HeLP-Diabetes team was working closely with the DMI staff on this patient-led rollout; hence, they already had email addresses of the DMI staff. DMI staff were emailed directly and invited to participate, then sent a consent form and information sheet. The information sheet covered the aims and scope of the study.

Patient champions: Initial contact would have been made by an email from a DMI staff member, with a participant information sheet and consent form attached, and a request to contact me directly if they would like to participate in the study. When they contacted me, I would have had an opportunity to discuss the study, and if they wished to participate, I would then schedule an interview at a time and place that was convenient for the patient champion and at a location safe for me.

As a token of appreciation for the support and help of the interview participants, I intended to give a £20 voucher to each participant, as detailed in their participant information sheet and invitation letter.

4.5.4 Conduct of interview/data collection for HeLP-Diabetes users

I selected interviews as a data collection method because I deemed it an appropriate way to collect data based on participants' experiences with HeLP-Diabetes and the patient-led rollout. Interviews might have helped in providing a detailed explanation of participants' motivations or decisions to use HeLP-Diabetes, the role of engagement prompts in motivating them to use HeLP-Diabetes, and their opinions about the patient-led rollout (Ritchie J., 2014). Each interview would have been conducted by myself.

UCL field research policy procedures have to be followed for each interview; for example, a member of the HeLP-diabetes team has to be informed of the location and expected time and length of the interview.

Upon arrival at the interview location, I would have asked the participant to sign the consent form after re-reading the information sheet. I would then start the interview by taking some basic demographic information from the participant to describe their characteristics. Followed by a semi-structured interview schedule to explore the participant's personal experience of HeLP-Diabetes, the barriers and facilitators to using the website, and what could be done to facilitate better engagement; followed by an exploration of how feasible and acceptable it is for the user to receive prompts to engage them with the website via emails or text messages and their preference for the characteristics of the prompts, while presenting examples of prompts that could be, or were, sent to users during the interview.

Finally, if the patient-led rollout had been implemented, the interview would have concluded with an exploration of the participant's personal experience of the DMI initiative implementing HeLP-Diabetes via trained patient champions, their views as to whether the patient-led rollout is a useful model that should be duplicated elsewhere, and if so, what worked well, what should be improved or modified, and their personal opinion of benefits and disadvantages of this model of implementation.

The interviews would have been recorded, transcribed verbatim and analysed following completion of the first interviews, allowing completed interviews to inform subsequent development and iterations of the topic guide for future interviews. Interviews were expected to last between 30 and 40 minutes.

4.5.5 Data analysis

I intended to do the coding of the data thematically, with a focus on the areas defined by the interview schedule, and any other emergent themes, as in using

a mixture of deductive and inductive coding. I would have analysed the semi-structured interviews using the framework method because this method is most suitable for applied research (Pope et al., 2000). The framework analysis process consists of seven main stages (Gale et al., 2013):

1. Interviews transcribed verbatim and names of people and places replaced so that transcripts and quotations were anonymised
2. Familiarisation with the interviews using the audio-recordings, transcripts and any other field notes
3. Coding the transcripts line by line for the first few transcripts to ensure no important information was missed. At this stage I would use the COM-B model, detailed in Chapter 3, Section 3.4.2, to help me with understanding the determinants of the users' engagement behaviour. I would then code using the Behaviour Change Techniques (BCTs) taxonomy (Michie et al., 2014), the characteristics of the prompts and the content suggested by the users
4. After coding the first few transcripts, I planned to meet with the rest of the team to agree on a set of codes to be applied for the rest of the transcripts. These codes would have been categorised into pre-defined themes (COM-B model and BCT) and any other emerging themes that make up the analytical framework. Emerging themes, if any, would have been probed for in subsequent interviews
5. Applying the agreed analytical framework to the rest of the data
6. Summarising the data by category from each transcript into a matrix to reduce the data and enable interpretation. This step is called 'Charting the data'
7. In the final steps, conclusions are drawn from data interpretation.

I intended to use the program Nvivo 10 to assist with facilitating the coding process.

4.6 Results

I conducted only one pilot interview. Although I continued recruitment for over six months, no participants agreed to be interviewed, and two participants who showed initial interest did not respond after receiving the patient information sheet and consent letter or two reminder emails. As for my study's second aim of exploring the patient-led rollout, only one of the staff was interviewed because this planned mode of service delivery was not implemented.

The original method of recruitment I detailed above (see Section 4.5.3) did not recruit any participants, despite each registered user being sent two email invitations. After further discussion with the patient representative and the HeLP-Diabetes team, I made changes to the invitation email (i.e. timing, content and title) and I used another method similar to that used in the implementation study to identify users willing to participate in research. The method used in the implementation was that each participant would tick a box when registering to HeLP-Diabetes to indicate whether they would like to be included in research. For the current study, users who ticked this box were then sent an email invitation by me with more details of the interview study. However, none of the methods succeeded in recruiting participants for the interviews.

The changes above required that I submit minor amendments to the ethics committee. These amendments included, as mentioned above, notification that patient champions would not be used anymore, changing the title and content of the invitation letter, as well as the content of the patient information sheet and using a similar method to the implementation study to filter out participants who are interested in research (i.e. providing the option of whether users would like to join research or not when they register to use HeLP-Diabetes).

Since the minor amendments were not successful in recruiting participants, I considered substantial amendments such as attempting to recruit HeLP-Diabetes trial participants to the interviews, but at that stage the trial was

suffering from low recruitment, and an extension to the trial recruitment deadline was needed. I also considered recruiting through using phone numbers to either call or text message DMI users. However, choosing emails was the only method where non-identifiable information could be used. In addition, using phone numbers would not have been very helpful, as the number of participants with either phone or mobile phone numbers was low compared with email addresses.

Since both of these options were not possible due to time and ethical limits, I did not submit these substantial amendments. Instead, I interviewed the patient representatives mentioned in Chapter 3, Section 3.4.4, who had helped with developing HeLP-Diabetes and provided consistent feedback on email and text message prompts. However, the data from this group would not have been useful to answer my original research questions, as their involvement with HeLP-Diabetes from the start might not reflect the usage behaviour of the rest of HeLP-Diabetes users. Therefore, I interviewed this group to discuss their thoughts about the content of the prompts. These interviews are analysed and discussed in more detail in Chapter 5. Ethics for interviewing the patient representatives group was granted from UCL rather than the NHS, as the patient representatives were not recruited from general practices.

4.6.1 Time scale of the study

Time constraints acted as a barrier to the success of my study. Ethical approval was granted from the London - City & East Ethics Committee (Experience with a patient-led roll-out of HeLP-Diabetes and the use of engagement prompts: providers and patients perspective, REC reference: 14/LO/0408).It was granted on March 2014 when Improvement Science London and DMI agreed for me to interview any recruited participant (i.e. as they were funding the recruitment and implementation of HeLP-Diabetes in Southwark and Lambeth). However, at that time there were only two users registered in the HeLP-Diabetes DMI group, and they were not recruited through the patient-led rollout model, so I did not start recruitment until more people were registered between August 2014 and early

2015. The deadline for analysis and writing up this study was February 2015, so after discussion with the rest of the team, I halted recruitment to focus on the other studies in this thesis.

4.7 Discussion

4.7.1 Recruitment

Recruitment difficulties were the reason I could not complete this study. Although the period of recruitment was six months, the sample to recruit from was very small. The literature shows that recruitment was a major challenge in numerous studies. The STEPS study that aimed to identify issues relating to recruitment in trials found that out of the 114 studies reviewed, only 38 (31%) were able to reach their original recruitment target. The study also concluded that there is no clear indication of what factors can really predict successful recruitment (Campbell et al., 2007).

The DMI group, as described in Section 4.3.1, was encouraged to recruit participants through patient champions, but this method of recruitment was not successful. Therefore, they started to recruit people living with diabetes who do not attend face-to-face diabetes education sessions in Lambeth by sending these patients' letters via post by the Lambeth intermediate diabetes care team. However, recruiting via post was not a successful method, as shown in the HeLP-Diabetes implementation study (see Section 4.3). An invitation letter was sent to 1000 patients with diabetes in Camden, but fewer than 20 of these responded by registering with HeLP-Diabetes. Therefore, since very few of the patients the Lambeth care team contacted by post registered, the sample to recruit from was very small.

There are a number of reasons why this method of recruitment was unsuccessful. There was no sense of obligation from participants to be interviewed (i.e. they did not join HeLP-Diabetes to be included in research and they only joined it as a service). Also, due to the elimination of patient

champions and DMI, there was no previous link between UCL and Lambeth, so there was no brand identity that the participants were familiar with, and the sample themselves, being non-attendees of DESMOND, would by definition be a difficult sample to recruit from. In addition, the groups conducting the HeLP-Diabetes trial and implementation study were also having difficulty recruiting participants. This might have been due to most people who registered to use HeLP-Diabetes not being newly diagnosed and therefore already being good at self-management. Also, there are many resources in different formats for self-management of Type 2 Diabetes available to patients.

None of the DMI participants agreed to be interviewed; only two showed initial interest but when an email with an informed consent form and information sheet was sent they did not respond, even after sending a reminder email.

I chose emails as the recruitment method because in order to understand participants' usage behaviour and their preference for prompts, they had to be registered on HeLP-Diabetes and have received prompts either via their mobile phones or emails. While developing HeLP-Diabetes, users were asked what they thought might engage them, and prompts were suggested. Interviewing them after they registered on the final version of HeLP-Diabetes and had received some prompts would have provided a better understanding and met the aims of this study, as they would had a chance to engage or disengage with HeLP-Diabetes. Hence, recruiting participants by sending emails was the best option rather than recruiting via general practitioner practices to register on HeLP-Diabetes then asking about the prompts. Using emails was convenient, as the number of users who opened emails could be determined immediately, which helped me in experimenting with the title or the content of the invitation email by changing it and checking to see if those changes increased the opening rate of the invitation emails. Based on this data, I used different strategies to recruit the participants, including using different days to send the emails, using different titles for the emails, shortening the content of the email, filtering users who were willing to join research when they registered on HeLP-

Diabetes and sending two invitation emails with seven to ten days' gap between them. Unfortunately, my efforts were not successful.

4.7.2 Final thoughts and lessons learned

Thoughts about recruitment

One of the research dilemmas I considered while writing the study protocol was that recruitment of participants might be a challenge and my strategy to fix this was to identify the reasons. Since the implementation study was conducted in parallel with the DMI rollout, some similar observations were considered. People signing up to use HeLP-Diabetes as a service were reluctant to take part in research or be interviewed, so, after I consulted with a patient representative in the HeLP-Diabetes team on the amount and type of incentive, I used a £20 voucher as an incentive. Also, to help reduce barriers to participation, I allowed participants to choose a convenient time and location for the interview. While I also consulted with experts and patient representatives prior to writing the protocol, and iteratively applied changes to the recruitment strategy, both efforts did not succeed in recruiting participants.

The main lessons I learned were that one method of recruitment is not enough, especially when recruiting a sample that is very difficult to reach, and that I should have considered longer recruitment time when I planned my PhD timeline. For future studies, I would allow more time for gaining ethical approval and use different recruitment methods, not only emailing registered users or using posted letters to register users on HeLP-Diabetes.

The role of the interviews in the thesis

The interviews were to be an integral part of my thesis because using the COM-B model explained in Chapter 3, Section 3.4.2 to analyse the interviews could have been helpful in understanding what drives people to engage with HeLP-Diabetes and what keeps them away. That information would have been useful to decide on appropriate BCTs to use in developing the prompts. Furthermore,

by exploring users' preferences and opinions related to prompts and their engagement with HeLP-Diabetes, with no engagement incentive apart from the site and their intrinsic motivation, I could have provided better understanding of how the continued use of HeLP-Diabetes can be facilitated over a long period.

Interviews alternatives

Other researchers in the HeLP-Diabetes team were also conducting qualitative research with users about the facilitators and barriers to using HeLP-Diabetes, and such information helped in understanding the engagement outcomes explained in Chapters 5 and 6. Also, the analysis of usage data in Chapter 5 provided hints to what characteristics of prompts can be effective in engaging HeLP-Diabetes users, specifically content and delivery mode. This was enhanced by interviewing the patient representatives in Chapter 5. For future research, trial participants who finished their 12 months follow-up could be asked for their opinion about the prompts that were sent to them while using HeLP-Diabetes.

Chapter 5 Promoting engagement with HeLP-Diabetes using email and text message prompts: a mixed methods study

5.1 Abstract

Background: Digital interventions provide effective and potentially cost-effective models for improving health behaviour outcomes. In Chapter 2, findings from a systematic review led to the conclusion that prompts can potentially promote engagement with digital interventions, but future studies are needed to identify effective prompt characteristics. In Chapter 3, I described the methodology of developing and testing the HeLP-Diabetes email and text message prompts. My original PhD plan was to incorporate results of the systematic review, and analysis of usage data generated from the email and text message prompts sent to HeLP-Diabetes users, with the results of semi-structured interviews that explored the preference of HeLP-Diabetes users (Chapter 4). In order to produce prompts to test in subsequent randomised studies. This iterative process of evidence input, development and assessment was geared to design effective prompts. However, due to the unavailability of usage data until the late stages of my PhD and the unsuccessful recruitment of participants for the semi-structured interview study, this chapter introduces a modified mixed methods study that incorporates both quantitative and qualitative data to design prompts to be tested in two pilot randomised controlled studies in Chapter 6.

Aim: To identify the characteristics of prompts, specifically the content and delivery mode, that have the potential to promote engagement with HeLP-Diabetes.

Method: This is a mixed methods study. Usage data collected for a period of 16 months, including user visits, were extracted from HeLP-Diabetes. I examined the usage data (quantitative data) to identify email and text message prompts associated with higher and lower levels of engagement with the digital intervention. I then analysed the identified email prompts qualitatively by conducting 'think aloud' interviews with six patient representatives to find out what content they liked or did not.

Results: About 48.7% (19/39) of the emails showed a significant association between opening email prompts and visiting HeLP-Diabetes, while none of the text message prompts' analysis showed a significant association between subscribing to receive a text message and visiting HeLP-Diabetes. Think aloud interviews were carried out with six users who preferred email prompts that were clear, short, used non-directive advice, empowering, included health professional references, used personalisation, were visually appealing and most importantly contained news and updates.

Conclusion: Findings of this study contribute to the existing evidence of email prompts being associated with positive engagement. This study showed the content of prompts that may be engaging. However, the results should be interpreted with caution as prompts may be context-specific interventions and the results may not be generalisable across other digital interventions. As for this PhD, the findings were used to test the potential effectiveness of different prompts' contents and delivery modes on engagement in two pilot randomised controlled studies, described in Chapter 6.

5.2 Background

5.2.1 Chapter rationale

Chapter 1 introduced the importance of conducting the research that makes up this PhD. Chapter 2 provided evidence that prompts can potentially promote engagement. Chapter 3 detailed the prompts development plan, including the process of developing and testing email and text message prompts; Chapter 4 described the semi-structured interviews with HeLP-Diabetes users I planned to conduct to elicit their thoughts about receiving prompts. As previously described, the original plan for my PhD, was to utilise evidence from a systematic review, usage data, semi-structured interviews and randomised studies to iteratively design prompts. By incorporating preferences, feedback and suggestions about the characteristics of prompts from interviews, followed by analysing the usage data, this iterative design would have enabled the identification of characteristics of prompts such as content or frequency that can promote engagement. Prompts developed as a result of these findings could then be tested in subsequent randomised controlled trials. However, the plan had to be changed due to two main reasons. The first was that technical issues with usage data unavailable in a meaningful and organised format until early 2015, as previously discussed in Chapter 3, Section 3.4.4, Table 6. The second reason was that I was unable to recruit HeLP-Diabetes users for interviews, and the reasons for this were discussed in Chapter 4. Therefore, this chapter presents the methodology and results of a mixed methods study that combines usage data with 'think aloud' interview results.

5.2.2 Usability study

Usability studies are defined as studies that incorporate techniques to evaluate interventions by testing them on users; the focus in such studies is the intervention rather than the user. Usability studies are used mainly in the field of human-computer interaction (Sharp et al., 2007). They provide a method to identify any problems with the intervention and improve it, as well as determining users' satisfaction with it.

5.2.3 Usage data

Analysis of usage data or measuring engagement using website analytics or metrics is the process whereby parameters that are constructed from digital traces left by users of digital interventions are extracted to be analysed (Lalmas et al., 2014). As mentioned in Chapter 1, there are two categories of engagement measures: intra-session measures, such as number of pages viewed and duration of visit, inter-session measures, such as time between visits and number of visits. The latter category is the focus of this thesis, because it includes measures that look at long-term engagement or returns to digital interventions (i.e. loyalty) (see Chapter 1, Section 1.2.3).

There is no universally agreed measure for engagement with digital interventions that is accepted amongst all eHealth researchers. For this PhD, the number of visits to HeLP-Diabetes per user was selected to measure the effectiveness of prompts. That measure acts as an indicator of whether the prompt motivated the users to visit HeLP-Diabetes or reminded the users of HeLP-Diabetes.

Other measures could not be used to measure engagement for this PhD, including the number of completed sessions per unit of time, because HeLP-Diabetes is not a session- based digital intervention The time between visits (absence time) could also not be used, as this measure assumes that if users find the digital intervention interesting, they will return to it quicker (i.e. have a shorter absence time), thus this measure is more concerned with the digital intervention itself and what makes it engaging (Dupret and Lalmas, 2013), rather than any associated prompts. Another measure that was not useful for this PhD was the time spent on a digital intervention, as this measure is an intra-session measures that again is influenced more by the characteristics of the digital intervention that holds the attention of the user rather than a prompt. An important distinction should be considered when deciding on a type of usage data to measure engagement, which is whether to use continuous or dichotomous outcomes. Choosing either one is based on its fitness for purpose

and the degree to which it can answer research questions. In Chapter 2, Section 2.4.3 a criteria for selecting engagement outcome measures had to be used as some studies used different types of outcome measures without clarifying the justification for their use, and this gave an unexplainable difference in their results (Couper et al., 2010, McClure et al., 2013, Titov et al., 2009). In the case of the prompts, as mentioned previously, number of visits is the most appropriate measure for engagement, but there are two ways to utilise this measure: either by analysing it as a dichotomous outcome-whether the user visited or did not visit HeLP-Diabetes - or as a continuous outcome - how many visits occurred after the users received the prompt. The latter might show a large number of visits by a single user, while the dichotomous outcome will show the number of users who received a prompt and then visited HeLP-Diabetes at least once. Using a dichotomous outcome will help indicate which prompts might have been more engaging, by looking at all the recipients of the prompts to find out if they did or did not visit HeLP-Diabetes after receiving a specific prompt regardless of how many times they visited, while a continuous outcome will look at how many visits occurred after sending a prompt, which can be misleading (i.e. one user visiting multiple times).

Usage data was the preferred measure of engagement for this PhD, because it is an objective measure that is collected automatically and unobtrusively, so bias that can occur in data collection is non-existent. It provides information on all users in real time, unlike other types of collected data such as questionnaires. It is not resource-intensive, as this type of data is stored in server logs that are easily accessible in large volumes. Yet, there are some limitations for using usage data. The most important one is that the large amount of data makes it difficult to determine the most useful data and how to present it meaningfully. Usage data is also limited in the information it provides, as it represents the actions of users, such as visiting a web page, but not the meaning behind it (i.e. the reason behind the action); thus, depending only on usage data to understand digital intervention users actions and behaviour is insufficient and may lead to erroneous interpretations (Atkinson, 2007). One

method of ensuring the accuracy of usage data interpretation is combining it with another type of data, such as self-report measures (i.e. interviews or questionnaires) (Lalmas et al., 2014).

5.2.4 Think aloud interviews

Self-reported measurements are designed to elicit participants' attitudes, knowledge, opinions and/or beliefs. They are subjective measures where participants share experiences, feelings and thoughts (Lalmas et al., 2014). There are two main categories of self-report measures: questionnaires and interviews, as mentioned in Chapter 1, Section 1.2.3. One type of emerging interview technique that is used extensively in the human-computer interaction field as a usability testing method is 'think aloud' interviews. In think aloud interviews, participants vocalise aloud their reactions, thoughts and feelings while, or immediately after, viewing or navigating the digital intervention (Lalmas et al., 2014, Sharp et al., 2007). The difference between an interview and a think aloud interview is that the latter depends on the information stored in the user's short-term memory. Ericsson and Simon, (1980) who were pioneers in the field of think aloud, suggested that all information passes through the short-term memory as it is, then is adapted and changed based on numerous factors related to the recipient's culture, opinions and perceptions (Ericsson and Simon, 1980). Thus, when a researcher uses think aloud interviews, the results are participants' verbalisations of their initial thoughts, reactions and feelings while perceiving the digital intervention or shortly after. However, for retrospective interviews, some time has passed so the information is not stored in the short-term memory anymore and instead what the participants verbalise in their interviews is their analytical description and explanation of what they perceived rather than their first impressions (Nielsen et al., 2002). Thus, I chose think aloud interviews as they provided me with users' immediate thoughts and reactions that are less subject to social desirability and more reflective of immediate processes of thinking.

5.2.5 Combining usage data and think aloud interviews-a mixed methods approach

Mixed methods is defined as exploring a topic through the use of both quantitative and qualitative research methods (Yardley and Bishop, 2015). The Pragmatism approach to evaluation of mixed methods studies aims to preserve the integrity of both quantitative and qualitative components to maximise their contribution to the overall research question (ultimately contributing positively to the world) (Bishop, 2015). There are two main ways of employing a mixed methods design. The first one is a sequential design where a qualitative component is used to explain or contextualise the findings of a quantitative component or vice versa. The second way is a concurrent design where both components are used in parallel. A sequential deign is better for my study than a concurrent one because it makes it easier to separate the two components and their functions as well as evaluate the quantitative and qualitative methods separately according to their respective quality criteria (Bishop, 2015); quality criteria for quantitative research include validity, reliability and generalisability while for qualitative research it includes transferability and credibility (Bryman et al., 2008). The usage data (quantitative data) were available but were insufficient to identify what prompt content was engaging or disengaging. Qualitative data was ideal to provide such insight into the available quantitative data (Ivankova et al., 2006). Thus, I have analysed usage data descriptively in sequential steps, then selected specific prompts and explored their content in think aloud interviews as shown in Figure 13 (i.e. the mixed methods element of the study was used to explore content).

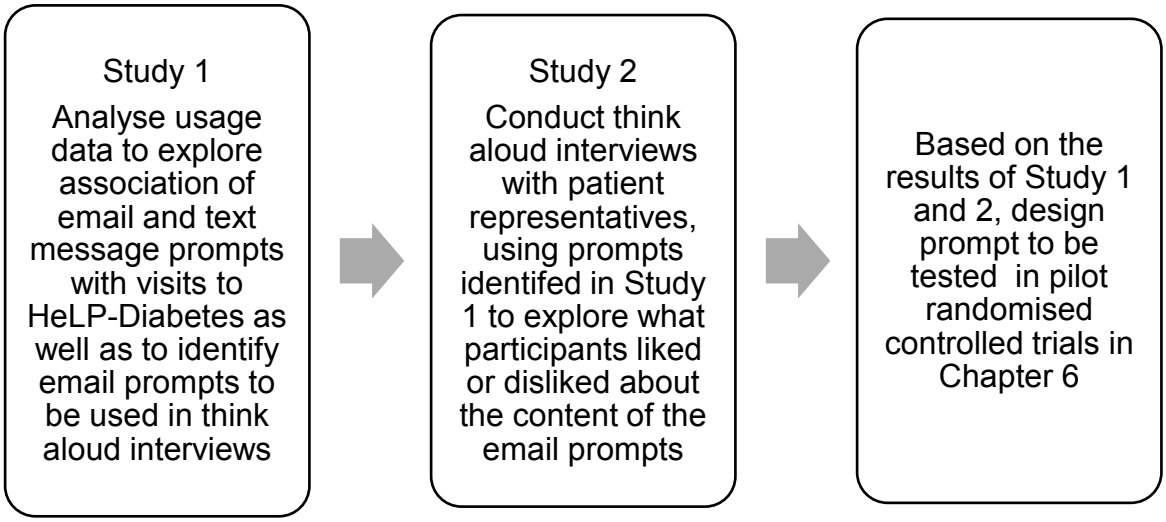


Figure 13: Study steps

This chapter shows the incorporation of two different methods of analysing and collecting data to explore the effects of prompts on engagement with a digital intervention. The integration of the available data resources and the challenging circumstances for data collection, which included limited access to interview participants and a lengthy process of usage data acquisition, are also discussed in this chapter. The chapter concludes with important and useful results that were tested in two pilot randomised controlled trials described in Chapter 6.

5.3 Aim

The main aim of the two studies in this chapter was to identify the characteristics of prompts, specifically the content and delivery mode that have the potential to promote engagement of HeLP-Diabetes users.

5.3.1 Objectives

Study 1- Quantitative component

- Describe the email and text message prompts sent to HeLP-Diabetes users.

- Convert raw data downloaded from HeLP-Diabetes into useful and meaningful usage data that are easier to analyse and interpret.
- Identify proportion of users who opened email prompts and visited Help-Diabetes.
- Determine the time period in which the majority of users visited HeLP-Diabetes after receiving an email prompt.
- Identify the email prompts to use in the think aloud interviews.
- Identify proportion of users who subscribed or did not subscribe to receive text messages and visited HeLP-Diabetes.

Study 2- Qualitative component

- Explore users' reactions to the titles, content and layout of email prompts with a view to determining which content features they liked or disliked.

5.4 Study 1-Quantitative component

5.4.1 Methods

Participants and procedure

This stage of the study took place between November 2013 and May 2015. Participants were registered users of HeLP-Diabetes, who were adults over 18 years old and had clinically diagnosed Type 2 Diabetes. They were recruited through a randomised controlled trial conducted across England or through an implementation study conducted in Islington and Camden boroughs in London and a few were from Lambeth in South London (see Chapter 3, Section 3.4.3 and Chapter 4, Section 4.3 for more information on prompt recipient groups) . Recruitment started in 2013 and continued through to 2015. Each user was assigned a unique identification number when registered on HeLP-Diabetes, and this identification number was used to track users' activities on HeLP-Diabetes.

Data cleaning and validation

The raw data were stored in the server of HeLP-Diabetes and calculated through server logs. The server saves all user-related information, which includes but is not limited to demographics, visits and email opens. When I started downloading the data with the support and guidance of the HeLP-Diabetes data manager, there were three options of data analytics and downloading programmes that organise the data in a comprehensible way: Google Analytics, Content Statistics and JamoolaWatch. Google Analytics did not accurately record individual data produced by HeLP-Diabetes so I did not use it. Then we tested the other two programmes by recording our actions (i.e. visits/logins, web pages visited, and emails opened) on HeLP-Diabetes and checking whether the programmes recorded raw data and downloaded it accurately in organised and clear Excel spread sheets. This testing showed that JamoolaWatch was the best option, as Content Statistics was neither able to capture some of the earlier data nor all of the recorded data in the HeLP-Diabetes server. However, JamoolaWatch still needed a clear definition of the data sets I needed to download and analyse. I had to contact HeLP-Diabetes developers (SoftForge) with a clear definition of the data set I would need, including the type of information it should contain arranged by user identification numbers. To clarify, an example would be “data set number 3”, which I defined as the text message information set. This data set included the identification number and group of the recipient, text message content, the date and time a text message was sent and whether it was successfully sent or not. Defining data sets took considerable time between defining and explaining to SoftForge, validating the accuracy of the data sets, then downloading and cleaning the data to analyse it. The complete data sets used for analysis are listed in Table 7.

Table 7: List of data sets used from JamoolaWatch.

Data set number	Content	Prompt type
Number 1	Information about HeLP-Diabetes visits: user visits, dates and times of visits, user identification numbers and user groups	Email and text message
Number 2	Information about emails: time the email was sent, user identification number of recipient, group of the recipient and time when the email was last opened	Email
Number 3	Information about text messages: time and date the text message was sent, content of the text message, user identification number of the recipient, group of the recipient and status of the text message (sent or not)	Text message
Number 4	Users' information when they registered to HeLP-Diabetes: user identification number and whether the user subscribed to text messages or not, the rest of the information were user characteristics that were not needed within the scope of this study	Text message

Outcomes

The usage data used in this study were downloaded from HeLP-Diabetes. Usage data were recorded on HeLP-Diabetes server using a custom-made programme that ran on the server; it recorded the usage data by user

identification numbers for the duration of the study period. The data included number, date and time of visits, dates and numbers of email and text message prompts sent, email opens, links clicked and users' demographic information (e.g. age, sex) and characteristics (e.g. length of diabetes, knowledge and experience with computer). Although other data such as time spent on HeLP-Diabetes and tools used were recorded, user visits were selected and mainly analysed because they are more likely to indicate whether the emails and text messages prompted the user to engage with HeLP-Diabetes (Brouwer et al., 2011, Tullis T., 2008). For email prompts, there was another measure analysed, 'email opens', i.e. whether the user opened the email or not, as this was a better indicator of whether the user visit was due to receiving an email prompt or not.

Primary outcome measure: HeLP-Diabetes user visits

The HeLP-Diabetes user visits measure was used for both email and text message prompts. HeLP-Diabetes visit refers to the user accessing HeLP-Diabetes by entering his/her username and password. 'Visits' were defined when the data was downloaded as one visit per day per user. HeLP-Diabetes records a new visit if any page is viewed after a period of at least 30 minutes without any activity by the user while he/she is still logged in. The purpose of the latter is to measure engagement with the website rather than the prompt: i.e. for how long does the user stay on HeLP-Diabetes? This information is useful for the HeLP-Diabetes team member evaluating use of the digital intervention itself. However, for my study the results show only one visit per user during a specific time period. For example, a user may have visited HeLP-Diabetes twice after receiving an email prompt (before the next prompt was sent), but only one visit is counted for that user as the first visit could be due to the prompt but subsequent visits are more likely to be due other reasons (e.g. HeLP-Diabetes characteristics, user's motivation etc.).

Secondary outcome measure: Email opens

The 'email opens' measure is for email prompts only. An email open is counted if the user's email client (e.g. gmail, yahoomail, outlook) downloaded the images embedded in the email (i.e. all emails were HTML so they were image-based, if the images were not downloaded the individual open would not be calculated); thus, this metric may miscalculate the actual number of email opens if a user's email client does not load images. This measure also shows only the time for the last email open, so if the user opened the email on the day he/she received it then reopened it next day, it records the latter. Only one open per user during a specific time period is calculated; for example, if a user opened an email prompt two times before receiving the next email prompt, only one open is counted for that user. Text message prompts did not have a measure of whether they were opened or not, as that type of function was not available, and therefore the text message results might be less accurate than the emails. Thus, in summary there were two end points for email prompts: when email is sent, user opens it or not (first end point) and then after reading it, user decides to visit HeLP-Diabetes or not (second endpoint).

Analysis

Email prompts analysis

Examining email prompts: The data sets number 1 and 2 from HeLP-Diabetes were used to analyse email prompts data (see Table 7). The two sets of data were matched using SPSS version 22 to get usage data about each email prompt sent from February 2014 until end of May 2015 (detailed steps for downloading and analysing the data are in Appendix 8). Descriptive analysis using graphs and tables started with calculating the percentage of users who received an email prompt and visited HeLP-Diabetes, followed by calculating the percentage of users who opened or did not open an email prompt and visited HeLP-Diabetes before the next email prompt or was sent (see Figure 14 and 15). This process was followed by standardising the time period between email prompts (see Table 8 for list of email prompts).

Standardising time period between email prompts: Email prompts were sent on random days, hence the time period between each email prompt was different. The reason for that was due to real-life circumstances such as schedules (or availability) of experts and patient representatives whose input was incorporated in each prompt (see Chapter 3, Section 3.4.4 for more information about the process of writing and sending prompts) and topics of prompts coinciding with a specific date, for example World Diabetes Day on the 14th of November. There was a need to standardise the time period between each email prompt, in order to eliminate the possible bias arising from different length of time periods between the email prompts (i.e. if three emails were sent, the time period between the first and the second one was one week while the time period between the second and the third one was two weeks, the second email might have a higher number of visits than the first one because it has a longer period of time).

Two attempts were made to standardise the time period between each email prompt. The initial attempt was to use the shortest time period between any two prompts. By using the shortest time period, I would be able to include and analyse all the email prompts that were ever sent to find an association between sending these prompts and visiting HeLP-Diabetes. The shortest period between two prompts was three days (i.e. the period between "HeLP-Diabetes Newsletter 10- break a sweat this summer!" and the next prompt was 27.6.2014 to 29.6.2014). However, there was a chance that some users did not open an email prompt and visit HeLP-Diabetes within these three days (see Appendix 9 for the percentage of users who visited HeLP-Diabetes up to 3 days after an email prompt was sent). Thus, my subsequent attempt to standardise the time period between each email prompt was to calculate the range, median (50%) and interquartile ranges (25% and 75%) for the number of days it took users to visit HeLP-Diabetes. For this, I analysed all the user visits that occurred after an email prompt was sent from the first one in February 2014 until the last one in May 2015. The result of this latter analysis was used for analysing the

association between opening an email prompt and visiting HeLP-Diabetes (see Figure 16).

Association between opening an email prompt and visiting HeLP-Diabetes and email prompt selection for think aloud interviews: A Chi-square test of dichotomous variables (open email vs. did not open email) and (visited HeLP-Diabetes vs. did not visit HeLP-Diabetes) for each email prompt was conducted to investigate any significant association. An alpha of <0.05 was used to indicate statistical significance (i.e. *P*-value <0.05 is the probability of an event occurring if there was really no true effect). The null hypothesis was that there was no difference in the percentage of user visits to HeLP-Diabetes (within a specific time period of receiving an email prompt) between users who opened an email prompts at least once and those who did not.

The Chi-square test is a statistical test for categorical data that produces 2x2 contingency tables. It compares observed data with expected data for each observation according to the hypothesis. The expected data (i.e. frequency) is calculated by the following formula:

$$\frac{\text{Row total x Column total}}{\text{Grand total}}$$

If the expected data is similar to the observed data, then the null hypothesis of no difference is true.

In order to conduct a Chi-square test, two assumptions have to be met:

1. Independence. Each item analysed, in this case HeLP-Diabetes users, contribute to only one cell of the contingency tables.
2. Cell count. The expected value in any of the cells should not be below 5, otherwise the results would be invalid for a Chi-square test (Howell, 2012, Kirkwood and Sterne, 2003)

I used a Chi-square test to determine an association between opening an email prompt and visiting HeLP-Diabetes, in order to identify the email prompts to use in think aloud interviews (see Figure 17, Table 9), then selected email

prompts with the highest and lowest number of visits based on data visualisation.

Text message prompts analysis:

Examining text message prompts: The data sets number 1 (information about HeLP-Diabetes visits), 3 (information about text messages) and 4 (Users' information when they registered to HeLP-Diabetes) from HeLP-Diabetes (see Table 7) were downloaded and matched using SPSS version 22 to get usage data about each text message prompt sent from October 2014 until end of May 2015 (detailed steps for downloading and analysing the data are in Appendix 10).

For text messages, there were two groups to compare, unlike email prompts that had one group: subscribers only. The text message prompts groups consisted of those who subscribed to text message prompts and provided their mobile phone numbers and those who did not. This is because users were given the option to enter their mobile phone numbers to receive text messages when they registered, while emails were a prerequisite for registration. However, it should be noted that for both emails and text messages, users could unsubscribe at any time. Having the option to choose whether to receive text messages or not at registration led to fewer text message recipients compared with emails (see Table 8 for list of text message prompts and number of subscribers and non-subscribers).

Association between subscribing to text message prompt and visiting HeLP-Diabetes: A Chi-square test of dichotomous variables (subscriber to text messages/non-subscriber to text messages) and (visited HeLP-Diabetes/did not visit HeLP-Diabetes) for each text message prompt was conducted to find any significant association. An alpha of <0.05 was used to indicate statistical significance. The null hypothesis was that there was no difference in the

percentage of user visits to HeLP-Diabetes (before the next prompt was sent) between users who subscribed to text messages and those who did not.

5.4.2 Results

In the period from 06/02/2014 and 27/05/2015 I sent 49 prompts, seven of which were text message prompts. Table 8 shows a list of all the prompts in chronological order.

Email prompts

Examining email prompts:

The analysis started with Figure 14, which shows the percentage of users who visited HeLP-Diabetes in the time period between receiving any prompt until the day before the next prompt was sent. This graph shows that some emails may have resulted in a higher percentage of HeLP-Diabetes users visiting it such as "World Diabetes Day" that had the highest percentage of user visiting HeLP-Diabetes (20.5%) and "HeLP-Diabetes Newsletter 19- Spring, delicious recipes and dark chocolate" that had around 16%, while other emails did not have any user visits such as "How do I lose weight and feel better?", none of the users who received the email visited HeLP-Diabetes after receiving it (0%). However, there is a high possibility that Figure 14 might show users who visited HeLP-Diabetes not because the email prompt directed them or encouraged them to visit but due to other reasons such as those mentioned in Chapter 1, Section 1.2.3 (e.g. HeLP-Diabetes engagement promoting characteristics). Thus, Figure 15 shows a comparison between the percentage of users who opened the email prompt at least once and those who did not open it and then visited HeLP-Diabetes during the period when they received each email prompt until the day the next email prompt was sent. Figure 15 shows that in general, email opens are associated with a higher number of users visiting HeLP-Diabetes.

Table 8: List of the prompts with available usage data

Type of prompt	Prompt title	Date	No. recipients/ No. total registered users [1,2]
Email	How are your New Year's resolutions going?	06/02/2014	71/72
Email	HeLP-Diabetes Newsletter 6-Medication	14/02/2014	69/69
Email	Boosting your health during winter	20/02/2014	79/79
Email	Best diet advice!	27/02/2014	81/81
Email	Share your personal experience with us!	07/03/2014	69/69
Email	How do I lose weight and feel better?	14/03/2014	83/83
Email	Designing your care plan	21/03/2014	90/90
Email	HeLP-Diabetes Newsletter 7-Making changes	28/03/2014	98/98
Email	It's Springtime	03/04/2014	99/99
Email	Happy Easter	10/04/2014	102/102
Email	Shopping for food	16/04/2014	103/103
Email	Achieving your goals	24/04/2014	106/106
Email	HeLP-Diabetes Newsletter 8-Personal experiences	30/04/2014	108/109
Email	How many meals do you eat per day?	08/05/2014	112/121
Email	Keeping your bones healthy	16/05/2014	127/129
Email	What you need to know about hypoglycaemia!	21/05/2014	130/134
Email	HeLP-Diabetes Newsletter 9-Anxiety	29/05/2014	131/134
Email	Are you a complementary therapy user?	03/06/2014	136/144
Email	Sexual health-let's talk about it!	20/06/2014	145/150
Email	HeLP-Diabetes Newsletter 10-break a sweat this summer!	27/06/2014	167/167
Email	Fasting during Ramadan	30/06/2014	167/177
Email	HeLP-Diabetes Newsletter 11-Holiday preparations	16/07/2014	182/200
Email	How to handle the summer heat?	04/08/2014	213/224
Email	HeLP-Diabetes Newsletter 12-Your diabetes is in your hands	21/08/2014	233/238
Email	HeLP-Diabetes Newsletter 13-Get rid of your medication worries!	05/09/2014	242/249
Email	Smile - You're on Camera!	17/09/2014	249/260
Email	Autumn health reminder	02/10/2014	268/279
Email	HeLP-Diabetes Newsletter 14- What's happening this October?	17/10/2014	286/303
Text message	Flu jab reminder	31/10/2014	172/301

Email	World Diabetes day	09/11/2014	308/327
Text message	Home exercises	24/11/2014	185/327
Email	HeLP-Diabetes Newsletter 15-Shopping done the right way	29/11/2014	333/337
Email	HeLP-Diabetes Newsletter 16-Eye care	09/12/2014	338/343
Text message	Eating and drinking on holidays	18/12/2014	199/350
Email	Happy Holidays	22/12/2014	346/347
Email	New Year Tips	12/01/2015	348/354
Text message	January blues	20/01/2015	190/357
Email	HeLP-Diabetes Newsletter 17-Change for 2015	27/01/2015	358/358
Text message	Sharing problems and advices	11/02/2015	209/370
Email	How to manage your diabetes using the HeLP-Diabetes care plan?	18/02/2015	376/388
Email	HeLP-Diabetes Newsletter 18-Alcohol, love and activity in February	27/02/2015	390/402
Text message	NHS medical exemption certificate	15/03/2015	234/407
Email	Get to know HeLP-Diabetes	19/03/2015	404/406
Email	HeLP-Diabetes Newsletter 19- Spring, delicious recipes and dark chocolate	30/03/2015	407/414
Email	What HeLP-Diabetes can do for you….	23/04/2015	416/416
Email	HeLP-Diabetes Newsletter 20- What can you eat?	29/04/2015	416/418
Email	Making HeLP-Diabetes easier	15/05/2015	428/430
Text message	Specialist and technical support	21/05 /2015	246/426
Email	HeLP-Diabetes Newsletter 21-Mindfulness, HeLP-Diabetes and fruit sugar	27/05/2015	432/433

[1]No. recipients stands for number of users who subscribed to receive a prompt. No. total registered users stands for number of users in total whether subscribed to receive prompts or not.

[2] There are some inconsistencies in the number of recipients and total registered users due to the following reasons: 1) users deregistered or unsubscribed; 2) users at the start of HeLP-Diabetes did not require email verification at registeration, thus emails might be wrong and the users were then deleted 3) there might have been a delay between registering users and subscribing to prompts.

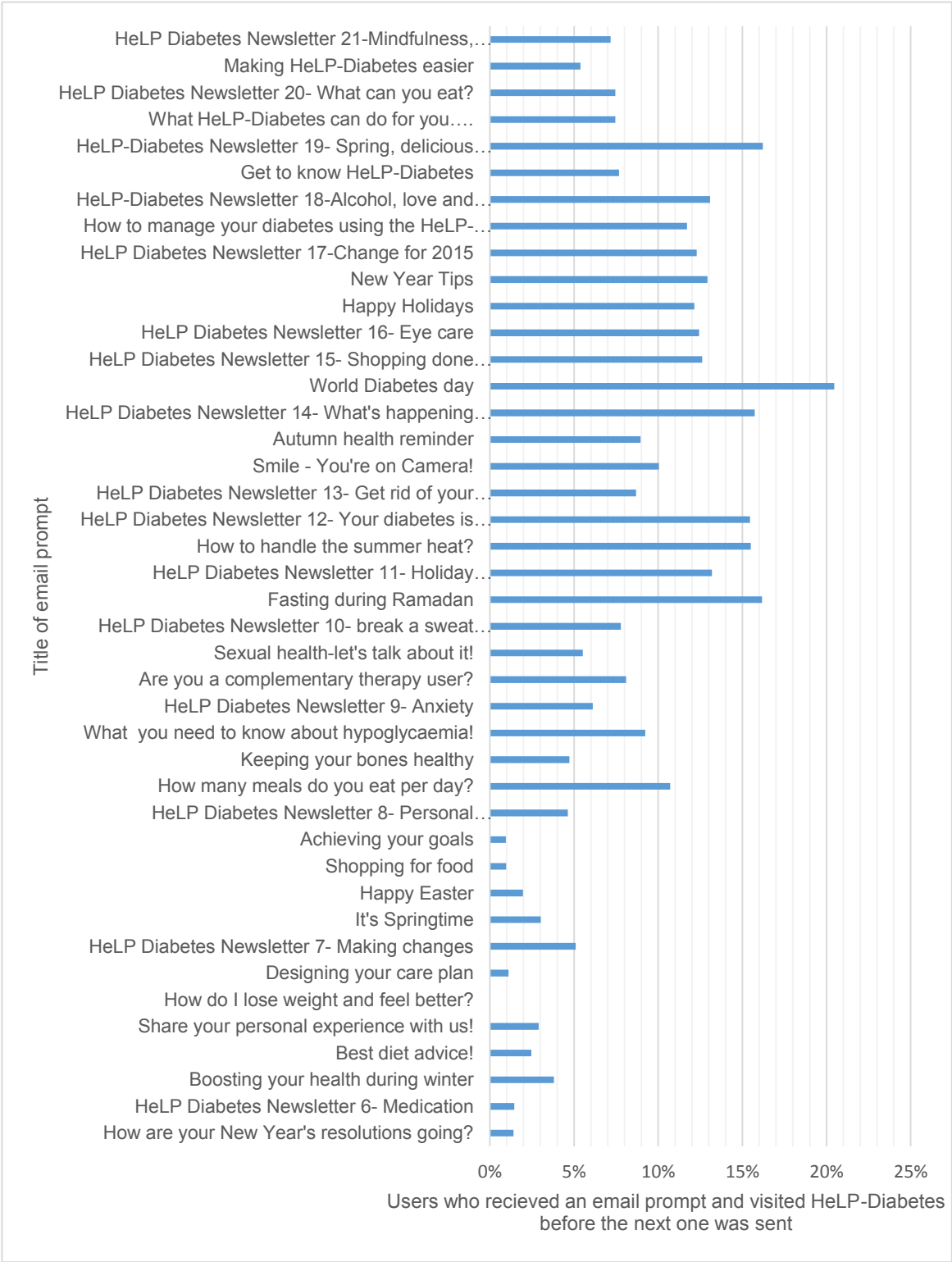


Figure 14: Percentage of users who received an email prompt and visited HeLP-Diabetes before the next one was sent (email prompt dates listed in descending chronological order – most recent emails from top)

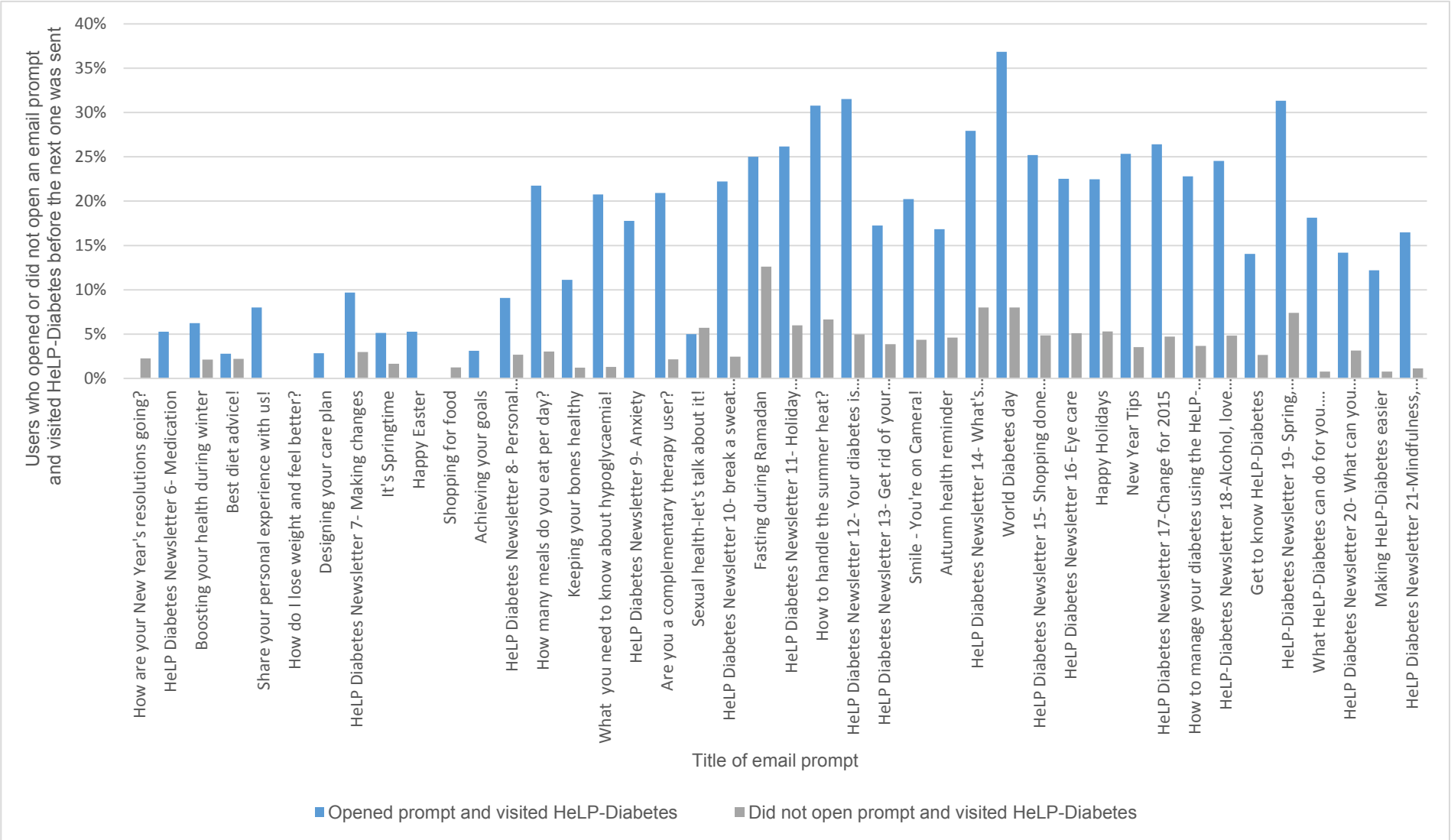


Figure 15: Percentage of users who opened or did not open an email prompt and visited HeLP-Diabetes before the next one was sent

Standardising time period between email prompts:

Of all the user visits (N = 918) that were recorded for all of the email prompts sent from the first one in February 2014 until the last one in May 2015, the time taken for users to visit HeLP-Diabetes after an email prompt was sent ranged from the same day to 23 days, the median of users (50%) visited HeLP-diabetes within one day of receiving an email prompt, 25% did so within the same day of receiving an email prompt and 75% of users visited HeLP-Diabetes within five days of receiving a prompt (including the day the email prompt was sent and five days after).

The percentage of users who opened or did not open an email and visited HeLP-Diabetes up to five days after a prompt was sent is shown in Figure 16 for all the email prompts except for these three email prompts: “Keeping your bones healthy”,” HeLP-Diabetes Newsletter 9-Anxiety” and “HeLP-Diabetes Newsletter 10-break a sweat this summer!” as the time period in these email prompts is less than the other email prompts, so they were not included in the calculation.

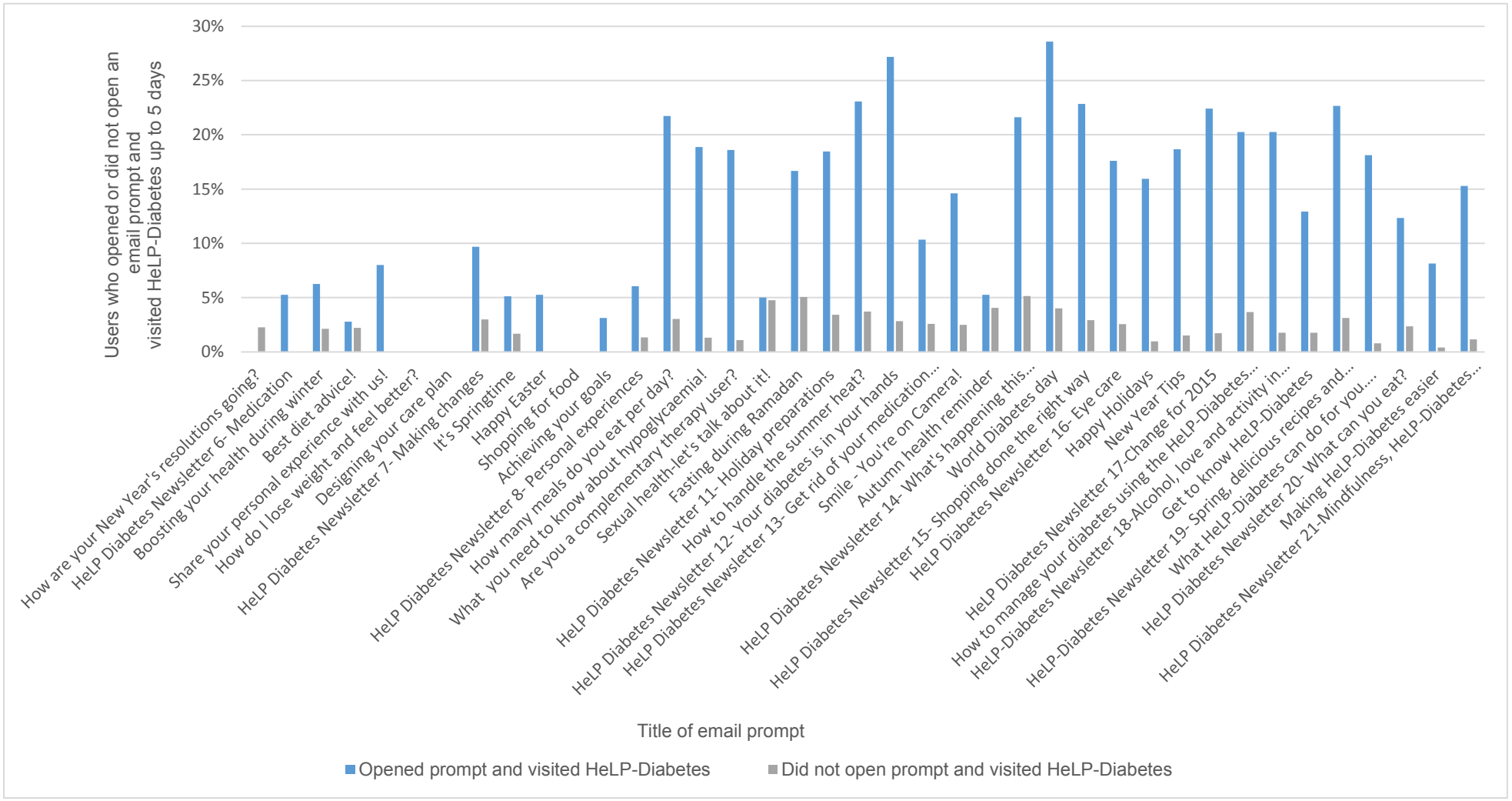


Figure 16: Percentage of users who opened or did not open an email prompt and visited HeLP-Diabetes up to 5 days after an email prompt is sent

Association between opening an email prompt and visiting HeLP-Diabetes and email prompt selection for think aloud interviews

Table 9 shows the Chi-square test results for users who opened or did not open an email prompt and visited HeLP-Diabetes up to five days after an email prompt was sent. The Chi-square test identified the 19 email prompts that showed a statistically significant association (*P<0.05)* out of the 39 analysed email prompts (see Figure 17). From these 19 email prompt, I selected seven email prompts with the highest and lowest number of visits for the think aloud interviews (i.e. seven emails were chosen as the maximum allowed in a 60 minutes interview) (For more details, see Section 5.4.1).

Table 9: Chi-square test results for users who opened or did not open an email prompt and visited HeLP-Diabetes up to five days after an email prompt was sent

Email prompt title	Users who visited HeLP-Diabetes N(%)	Users who opened an email prompt N(%)	Users who opened an email prompt and visited HeLP-Diabetes N(%)	Chi-square result X^2 (df, *N*), *P-value*
How are your New Year's resolutions going?[1]	1(1.4%)	27(38%)	0(0%)	0.62 (1, 71), 0.43
HeLP-Diabetes Newsletter 6-Medication[1]	1(1.4%)	19(27.5%)	1(5.3%)	2.67 (1, 69), 0.10
Boosting your health during winter[1]	3(3.8%)	32(40.5%)	2(6.3%)	0.88 (1, 79), 0.35
Best diet advice! [1]	2(2.5%)	36(44.4%)	1(2.8%)	0.02 (1, 81), 0.87
Share your personal experience with us! [1]	2(2.9%)	25(36.2%)	2(8%)	3.62 (1, 69), 0.06
How do I lose weight and feel better? [1]	0(0%)	32(38.6%)	0(0%)	No user visited HeLP-Diabetes
Designing your care plan[1]	0(0%)	35(38.9%)	0(0%)	No user visited HeLP-Diabetes
HeLP-Diabetes Newsletter 7-Making changes[1]	5(5.1%)	31(31.6%)	3(9.7%)	1.96 (1, 98), 0.16
It's Springtime[1]	3(3%)	39(39.4%)	2(5.1%)	0.96 (1, 99), 0.32
Happy Easter	2(2%)	38(37.3%)	2(5.3%)	3.43 (1, 102), 0.06
Shopping for food	0(0%)	23(22.3%)	0(0%)	No user visited HeLP-Diabetes
Achieving your goals[1]	1(.9%)	32(30.2%)	1(3.1%)	2.33 (1, 106), 0.13
HeLP-Diabetes Newsletter 8-Personal experiences[1]	3(2.8%)	33(30.6%)	2(6.1%)	1.89 (1, 108), 0.17
How many meals do you eat per day?[2]	12(10.7%)	46(41.1%)	10(21.7%)	9.91 (1, 112), <0.001

What you need to know about hypoglycaemia![2]	11(8.5%)	53(40.8%)	10(18.9%)	12.51 (1, 130), <0.001
Are you a complementary therapy user?[2]	9(6.6%)	43(31.6%)	8(18.6%)	14.62 (1, 136), <0.001
Sexual health-let's talk about it![2]	7(4.8%)	40(27.6%)	2(5%)	0.004 (1,145), 0.95
Fasting during Ramadan[2]	14(8.4%)	48(28.7%)	8(16.7%)	6.01 (1, 167), 0.01
HeLP-Diabetes Newsletter 11-Holiday preparations	16(8.8%)	65(35.7%)	12(18.5%)	11.79 (1, 182), 0.001
How to handle the summer heat?	23(10.8%)	78(36.6%)	18(23.1%)	19.26 (1, 213), <0.001
HeLP-Diabetes Newsletter 12-Your diabetes is in your hands	29(12.4%)	92(39.5%)	25(27.2%)	30.26 (1, 233), <0.001
HeLP-Diabetes Newsletter 13-Get rid of your medication worries![2]	13(5.4%)	87(36%)	9(10.3%)	6.60 (1, 242), 0.01
Smile - You're on Camera!	17(6.8%)	89(35.7%)	13(14.6%)	13.17 (1, 249), <0.001
Autumn health reminder[2]	12(4.5%)	95(35.4%)	5(5.3%)	0.21 (1, 268), 0.64
HeLP-Diabetes Newsletter 14- What's happening this October?	33(11.5%)	111(38.8%)	24(21.6%)	18.06 (1, 286), <0.001
World Diabetes day	45(14.6%)	133(43.2%)	38(28.6%)	36.57 (1, 308), <0.001
HeLP-Diabetes Newsletter 15-Shopping done the right way	35(10.5%)	127(38.1%)	29(22.8%)	33.15 (1, 333), <0.001
HeLP-Diabetes Newsletter 16-Eye care	30(8.9%)	142(42%)	25(17.6%)	23.07 (1, 338), <0.001
Happy Holidays	24(6.9%)	138(39.9%)	22(15.9%)	28.84 (1, 346), <0.001
New Year Tips	31(8.9%)	150(43.1%)	28(18.7%)	30.94 (1, 348), <0.001
HeLP-Diabetes Newsletter 17-Change for 2015	32(8.9%)	125(34.9%)	28(22.4%)	42.75 (1, 358), <0.001
How to manage your diabetes using the HeLP-Diabetes care plan?	40(10.6%)	158(42%)	32(20.3%)	26.50 (1, 376), <0.001
HeLP-Diabetes Newsletter 18-Alcohol, love and activity in February	37(9.5%)	163(41.8%)	33(20.2%)	37.74 (1, 390), <0.001
Get to know HeLP-Diabetes	27(6.7%)	178(44.1%)	23(12.9%)	19.85 (1, 404), <0.001

HeLP-Diabetes Newsletter 19- Spring, delicious recipes and dark chocolate	42(10.3%)	150(36.9%)	34(22.7%)	39.13 (1, 407), <0.001
What HeLP-Diabetes can do for you….	31(7.5%)	160(38.5%)	29(18.1%)	42.94 (1, 416), <0.001
HeLP-Diabetes Newsletter 20- What can you eat?	26(6.3%)	162(38.9%)	20(12.3%)	16.82 (1, 416) <0.001
Making HeLP-Diabetes easier	15(3.5%)	172(40.2%)	14(8.1%)	18.26 (1, 428), <0.001
HeLP-Diabetes Newsletter 21- Mindfulness, HeLP-Diabetes and fruit sugar	29(6.7%)	170(39.4%)	26(15.3%)	32.96 (1, 432), <0.001

Note: df=degree of freedom
[1]2 cells (50.0%) have expected count less than 5.
[2]1 cell (25.0%) has expected count less than 5.

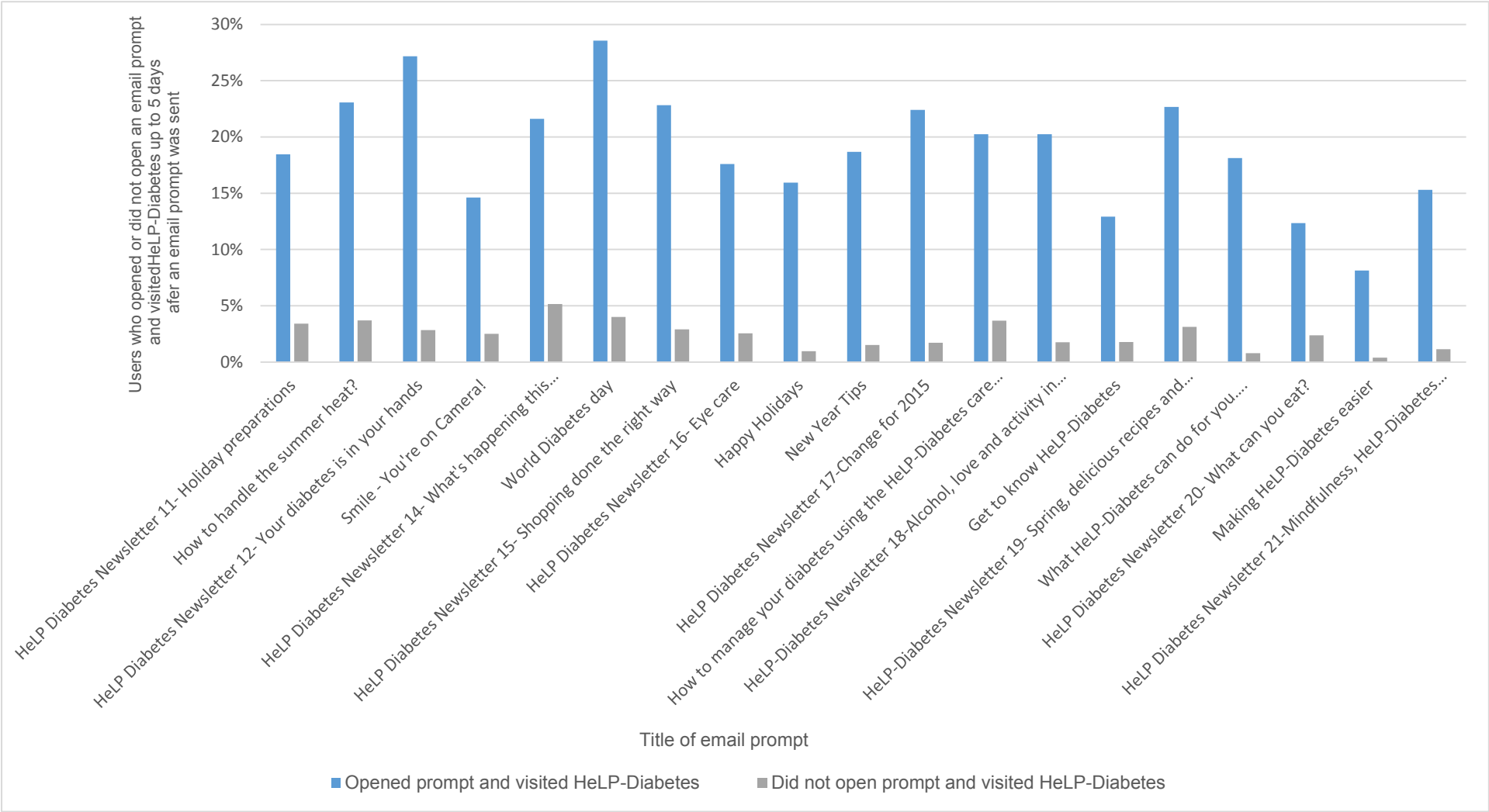


Figure 17: Percentage of users who opened or did not open an email prompt and visited HeLP-Diabetes up to 5 days after an email prompt was sent (for email prompts with a significant association)

Text message prompts

Examining text message prompts and association between subscribing to text message prompts and visiting HeLP-Diabetes

There were seven text message prompts sent between October 2014 and May 2015. None of these seven text message prompts showed a statistically significant association between subscribing to receive text message prompts and visiting HeLP-Diabetes (see Figure 18 and Table 10).

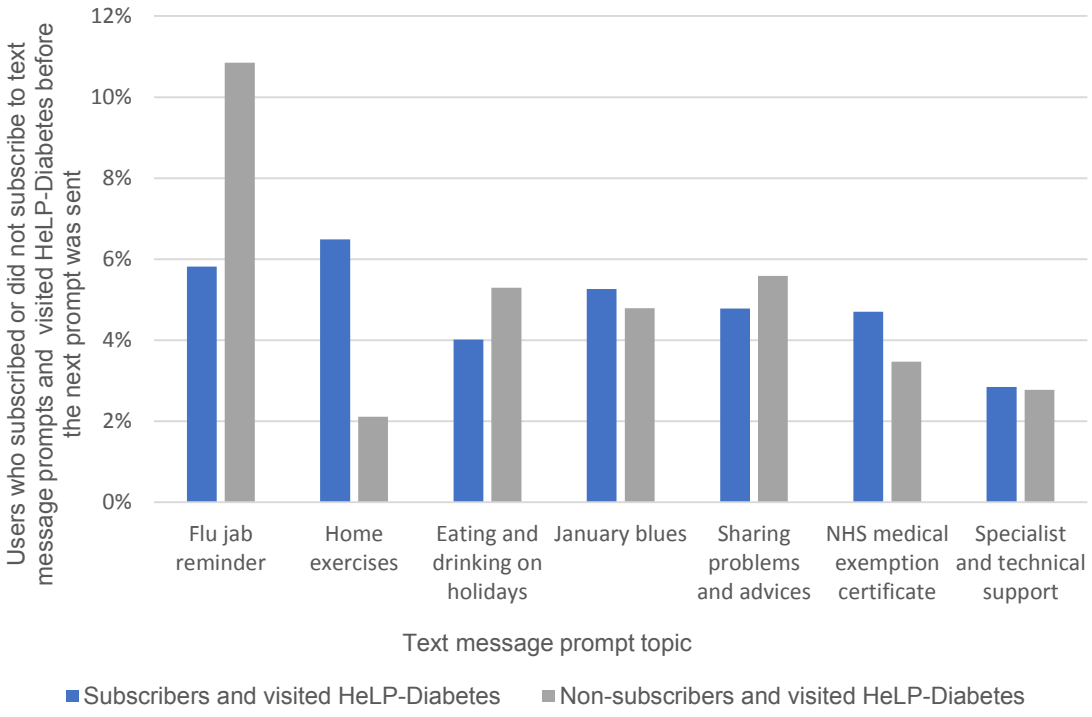


Figure 18: Percentage of users who visited HeLP-Diabetes when a text message prompt was sent for subscribers and non-subscribers and before the next prompt was sent

Table 10: Chi-square test results for users who subscribed or unsubscribed to text message prompts and visited HeLP-Diabetes before the next prompt was sent

Text message prompt topics	Subscribers who visited HeLP-Diabetes N(%)	Non-subscribers who visited HeLP-Diabetes N(%)	Chi-square result X^2 (df, *N*), *P-value*
Flu jab Reminder	10(5.8%)	14(10.9%)	2.55 (1, 301), 0.11
Home exercises	12(6.5%)	3(2.1%)	3.51 (1, 327), 0.06
Eating and drinking on holidays	8(4%)	8(5.3%)	0.32 (1, 350), 0.57
January blues	10(5.3%)	8(4.8%)	0.04 (1, 357), 0.83
Sharing problems and advices	10(4.8%)	9(5.6%)	0.12 (1, 370), 0.72
NHS medical exemption certificate	11(4.7%)	6(3.5%)	0.37 (1, 407),0.53
Specialist and technical support	7(2.8%)	5(2.8%)	0.002 (1, 426), 0.96

Notes: df = degree of freedom

Overall interpretation and summary

For certain email prompts (see Table 9), there was a significant association between opening an email prompt and visiting HeLP-Diabetes; 19 out of the 39 email prompts (48.7%) showed a significant association with visits to HeLP-Diabetes up to five days after an email prompt was sent, 75% of HeLP-Diabetes visits occurred within a period of five days after an email prompt was sent. A mixture of seven email prompts with a significant association between opens and visits that had a low or high percentage of user visits were selected for testing in think aloud interviews. For text message prompts, there was no significant association between subscribing to a text message and visiting HeLP-Diabetes.

5.5 Study 2 Qualitative component

5.5.1 Methods

Participants and procedure

Participants were six patient representatives who had been involved in the development of HeLP-Diabetes and the prompts. Although the sample is a convenience one and might not be considered an ideal sample to interview as their input for prompts was incorporated for each prompt, it was the only available sample as I could not recruit others (see Chapter 4, Section 4.7.1). Conversely, the advantage of using this sample include my familiarity with the group. Building rapport with participants is important for think aloud interviews, as the interviewee in such studies should feel comfortable enough with the researcher and be familiar enough with the procedures for the interviewees to vocalise their opinions and thoughts. Being unfamiliar with the researchers can be a major problem in think aloud interviews, as participants might not be able to give their real thoughts in fear of offending the researcher (Lalmas et al., 2014, Sharp et al., 2007). Also, familiarity with the researcher can involve a more in-depth feedback and comments.

I did practice interviews with some colleagues and through these I was able to identify a limit to the number of emails to discuss during an interview that does not exceed 60 minutes. Sixty minutes is the total duration for interviews allowed before participants start feeling fatigued and exhausted (Gill et al., 2008). Hence, I chose seven email prompts with a high and a low number of visits for the interviews: “How to handle the summer heat? “, HeLP-Diabetes Newsletter 12- Your diabetes in your hands“, “HeLP-Diabetes Newsletter 14- What's happening this October?“, “World Diabetes Day“, “Get to know HeLP-Diabetes“, “HeLP-Diabetes Newsletter 20- What can you eat? “, and “Making HeLP-Diabetes easier“. I also chose two email prompts that did not show a significant association to explore what could have made them not promote engagement, these emails were: “Autumn health reminders” and “HeLP-Diabetes newsletter

13-Get rid of your medication worries", as these emails were sent when there was a large sample size but did not have a significant association with number of visits, nor did they meet the Chi-square test assumptions. All of the email prompts are shown in Appendix 11.

I invited potential participants via emails to participate in the think aloud interviews. When a time and location was determined, I sent patient information sheets and a consent forms to participants (see Appendix 12). The interviews took place at a time and location convenient to the participants, mostly in an office at the University College London (UCL) eHealth unit. I did the necessary security checks, which involved notifying the unit administrator or a colleague of the time and location of the interview and informing them when I finished the interview. During the interview, I re-introduced participants to think aloud interviews, as some of them have participated in such interviews previously. I encouraged participants to say all their thoughts and opinions about each prompt, even if it was negative or they thought it insignificant. I performed a short practice at the beginning of the interview to familiarise participants with the think aloud techniques (e.g. speaking their first thoughts loudly); I asked participants to choose one of the email prompts that did not show a significant association between opening it and visiting HeLP-Diabetes (Autumn health reminders" and "HeLP-Diabetes newsletter 13-Get rid of your medication worries) to practice on. I asked participants to sit in front of a computer where email prompts were shown in a random order for each participant, vocalise their thoughts and opinions while opening each email and describe what they liked or disliked about the content of each prompt. After going through all the email prompts, I asked them some questions based on what they expressed while viewing the emails. In certain cases I tried to explore the participants' thoughts about issues shared across some of the other interviews. I then concluded the interview by getting basic demographic information from the participant, namely their age, sex, education level, duration since their diabetes diagnosis, and perceived level of computer knowledge, as these characteristics may influence participants' perceptions and needs of email prompts.

Age, sex and education were important as some studies showed that these characteristics can influence engagement (Van 't Riet et al., 2010, Schulz et al., 2012, Brouwer et al., 2010), duration since their diabetes diagnosis may influence participants' experience with HeLP-Diabetes, as those who have not had diabetes for a long time might be more motivated to engage with HeLP-Diabetes (Engström et al., 2016), and perceived level of computer knowledge as this may influence how participants use HeLP-Diabetes and respond to email prompts.

Once participants finished their session, I thanked them and provided them with a £20 voucher in appreciation for their help and if appropriate reimbursed them for travel expenses. The first interview transcript was read and commented on by my primary supervisor to check for quality before I proceeded with the rest of the interviews.

This stage of the study took place between July and September 2015. Ethical approval was granted from the UCL Ethics Committee (Project Identification number: 7263/001). This ethics approval was different to that gained for the research described in Chapter 4. That approval was gained from a National Health Services (NHS) ethics committee, since the targeted population were NHS patients, while the participants in this think aloud study were patient representatives recruited originally from INVOLVE and other public and patient involvement in research organisations.

Interview analysis

I recorded all interviews and anonymised them. They were transcribed verbatim by a professional and discreet transcriber who signed a confidentiality agreement. Once I had the transcripts back from the transcriber, I uploaded them into Nvivo 10 for data management and analysis. I saved them according to UCL's guidelines that specifies no one handles the data except the direct research team and all identifiable data are to be archived and stored securely in password protected UCL computers. I went through each transcript while

listening to the recording to check for any errors and to familiarise myself with the content of interviews and used all the field notes I had taken. I analysed the interviews using an inductive thematic analysis approach by identifying themes that are strongly linked to the data rather than my preconceptions or a pre-existing coding frame (Patton, 1990). I applied an open coding process where I coded line-by-line and paragraph-by-paragraph regardless of whether the codes I used were related to the main objectives of the study. I chose this method because it is a flexible one to identify recurrent codes and themes (Braun and Clarke, 2006). I have also used some techniques of qualitative research analysis (Eaves, 2001) such as “in vivo” coding (i.e. coding using participants’ words), using a bottom-up approach where I extracted my codes from the data rather than any preconceived hypothesis and constant comparative method (i.e. constantly comparing the data across all the interviews by moving back and forth between them) (Eaves, 2001). To ensure rigour and thoroughness and to include expert and multidisciplinary input and perspectives, I discussed all the emerging themes and codes with my supervisors and other researchers involved in HeLP-Diabetes throughout the coding and analysis process. I arranged a meeting to present to HeLP-Diabetes researchers some of the coding extracts and themes and discussed my findings with them. I also shared all the transcripts with my supervisors to ensure I had not missed any possible themes and that my codes reflected accurately the raw data I collected during the think aloud interviews.

5.5.2 Results

Participant demographics

Participant demographics are summarised in Table 11. There were six patient representatives who agreed to participate. Five out of the six representatives I had worked with previously, and they provided regular feedback about prompt frequency, content and timing from early 2014. The sixth participant started working with me in mid-2015 and only provided feedback on one prompts. All of the participants were over 50 years old. There were two males, and four

participants had degree-level qualifications. Most of the participants rated their computer experience as medium to high. The length of diabetes diagnosis ranged between 5 and 40 years.

Table 11: Think aloud interviews participants' demographics

ID	Sex	Age, years	Education level	Duration since diabetes diagnosis, years	Computer experience	Length of experience with team, No. of prompts provided feedback on[1]
P1	Female	55	Degree	15	High	From mid-2014, 8 prompts
P2	Male	50	Postgraduate	5	High	From mid-2015, 1 prompt
P3	Female	60	Degree	20	Medium-high	From early 2014, 10 prompts
P4	Male	58	Grammar school	12	Medium	From early 2014, 9 prompts
P5	Female	68	Postgraduate	40	Medium-high	From early 2014, 12 prompts
P6	Female	69	A level	10	Medium	From early 2014, 12 prompts

[1]The prompts the patient representatives provided feedback on are counted until July 2015, although analysis of prompt was until May 2015. I included the number of prompts they provided feedback on until July because that is when the interviews were done.

Themes

The main theme identified was participants' preference for prompt content (see Table 12). There were other abstract themes that I did not explore in-depth as they do not reflect the aim of this study, such as patient need for information and support, the difficulties of living with diabetes and the difference in advice for Type 2 Diabetes newly diagnosed patients and those with existing diagnosis.

Table 12: Three levels of themes identified through think aloud interviews

Level 1	Level 2	Level 3
Participants' preference for prompt content	Dislikes	Vagueness and cluttering
		Directive advice
		Irrelevance
		Visual aspects (e.g. pale colours)
	Likes	Clarity and brevity
		Strong hit (e.g. empowering, strong personal statements)
		Appropriate advice
		Personalisation
		News and updates
		Credibility-professional/health authority reference
		Visual appeal (e.g. bold colours, pictures)

Participants' preference for prompt content

The majority of participants agreed on what they liked and disliked when it came to the email prompts they viewed.

Dislikes

Vague and cluttering: The majority of participants did not like it when the email prompts had a lot of words and information to read through. Participants felt that any prompt they open should have information written succinctly and concisely. These preferences are illustrated in the quotations below with the participant ID and the prompt to which they are referring noted after the quotation.

"I don't like a big sheet where it's all mangled up together" P1

"Too much info. Too much info. I wouldn't really be reading that." P2, HeLP-Diabetes Newsletter 20-What can you eat?.

One of the participants also drew attention to some long sentences and asked to shorten them so they can be easier to read:

> *"I think it's just this second sentence is a little bit wordy, a little bit long, perhaps. You might be able to reduce it, to make it a little bit more succinct?"* P6, HeLP-Diabetes Newsletter 12-Your diabetes is in your hands.

Some of the participants disliked the use of vague words or sentences that were not understandable if they read it once; an example of this would be in the email "How to handle the summer heat?", in which one of the tips for handling the summer heat was to *exercise in the cool*; most of the participant stopped at this tip and felt it was not clear or incomplete.

> *"So, exercise in the cool would be more like, if you exercise, try to be in a cool area or ensure that the area is well – what do you call it – ventilated, etc., or something in that kind, of form. Maybe another word or two to go with that one"* P1, How to handle the summer heat?

The participants also did not like the use of 'HeLP-Diabetes' in the title as they interpreted the title as help with Type 2 Diabetes rather than the name of the digital intervention itself.

> *"That's the one I didn't like. The title's a bit misleading,"*P4, Making HeLP-Diabetes easier

Furthermore, regarding the prompts' titles, participants did not like their expectations of email content to not match with the titles. One example is a participant who did not like the use of 'Autumn health reminder' as a title for an email reminder about flu jabs:

> "*It's a little vague. I think it wouldn't hurt to perhaps have flu in there"*P4, Autumn health reminder

One participant asked to replace complicated words or titles with simplified terms; for example, such words or titles as aerobic, sulfonylureas and hyperglycaemia.

Directive advice: Most of the participants disapproved of advice written in a directive way and asked for it to be changed; their reason being that they are bombarded by actions they should do on a daily basis and would prefer advice to give them the encouragement to act without them feeling forced or obligated to do it:

> *"Just to soften it a bit, because I think as diabetic, you're always been told what to do and what you shouldn't do*" P6, HeLP-Diabetes Newsletter 14-What's happening this October?

Participants specifically preferred the use of the word *try* instead of the word *do or should do* when advice is given:

> *"This is very directive stay optimistic, stay happy. Rather than, try to stay optimistic is more of an empowering sort of thing."* P2, HeLP-Diabetes Newsletter 12-Your diabetes is in your hands

Irrelevance: Some participants stated they found some of the prompt content irrelevant, and this discouraged them from clicking the links in the email prompt. They were able to indicate content that was extraneous and how to make them pertinent to the rest of the users. For example, when the content is specific for a certain group of participants as one participant pointed out that if the content mentioned patients on oral medication that excludes those on diet or insulin. Thus, this might indicate a preference for generalising the content to include the needs of different patients.

> *"The next part of the news is can Metformin help people live longer? …I'd be looking at to say more what about me who uses diet control, what effect does that have?"* P2, HeLP-Diabetes Newsletter 12-Your diabetes is in your hands

Indeed, participants felt that the content has to be more inclusive, for example, one participant suggested to change the topic of 'How to handle the summer heat?' to 'How to handle the heat?' making it more general.

Another participant disliked the fact that the titles of subheadings in a newsletter is unrelated to its content. She emphasised her dislike when she read the email 'HeLP-Diabetes Newsletter 14- What's happening this October?'. In the tools section there was links to news about events in October as well as tools, but she felt that news should only be included in the news section.

> *"I think 'tools' doesn't reflect what this is about. So, it's either news item or it's an information or updated information on what's going on in that, because you said it was launched in October, so it's a news item, it's new."* P1, HeLP-Diabetes Newsletter 14-What's happening this October?

An interesting finding was that some participants disliked the mention of Type 1 Diabetes in 'HeLP-Diabetes Newsletter 14-What's happening this October?', as a teaser about the next issue was included, and it contained the exciting news about a possible cure for Type 1 Diabetes. The participants felt it was irrelevant and should not be cited in an email directed to patients with Type 2 Diabetes. Only one participant did not mind the mention of Type 1 Diabetes, but she attributed it to her general interest in any type of research; she still felt though that the word 'cure' was a strong word to use.

Finally, most of the participants mentioned that some of the advice and links provided might be more relevant to those who were recently diagnosed with Type 2 Diabetes rather than those with an existing diagnosis. The participants

felt that a patient recently diagnosed might be interested in general diabetes-related information such as the ‘eat well plate ‘or ‘how diabetes affects different body organs’, while in their case (since all of them had been diagnosed for five or more years) they felt that new research articles and HeLP-Diabetes updated topics or sections are more attention-grabbing.

Visual aspects: In general, participants disliked light grey colours for text and light blue for links. They preferred darker and bolder colours to easily distinguish between general text and links, as discussed further below in the liked visual aspects.

Likes

Participants shared what they liked or would have liked the email prompt to have in terms of content and visual aspects.

Clarity and brevity: Most of the participants, as evidenced in the sub-theme *Vague and cluttering,* preferred short and clear email content. Participants suggested adding more links to clarify any short statement, while they did not specify the number of links they wanted an email to have, the more links there were without overwhelming the recipients, the better. One participant liked it when the included links specified clearly what they would link to:

> *“So, someone might say, I haven’t got time to watch a video, and they look at their watch, and next the computer says, watch the three minute video, so that would be good, because three minutes is nothing, isn’t it? I like that.”* P4, HeLP-Diabetes Newsletter 12-Your diabetes is in your hands.

Some participants liked having an overview at the beginning of emails that summarises what the content of the email is about:

> *"I like the fact that it just gives a quick kind of an overview of what autumn does. So, it doesn't go straight into what you need to do."* P1, Autumn Health Reminder.

Strong hit (i.e., empowering, strong personal or attractive statements): The content and empowering statement in the beginning of the email "HeLP-Diabetes Newsletter 12-Your diabetes is in your hands" was well received amongst most of the participants. In fact, it was one of the emails with the highest percentage of visits (27.2%). That email's content gave the participants a feeling of empowerment, as they felt that they are capable of change and are in control of their condition. Participants also liked other statements describing the importance of research and understanding their health condition, as they felt this is integral to being able to control their condition. One participant liked that some statements would point towards patients not feeling guilty about their condition:

> "*So it can also help with someone's guilt. I've got diabetes, got to keep it quiet. No, cry it aloud, why."* P3, World Diabetes day

There were some participants who liked titles of emails that were written as a question (e.g. How to handle the summer heat? and HeLP-Diabetes Newsletter 20-What can you eat?), which they thought of as catchy and thought provoking.

Appropriate advice: The type of advice participants preferred was soft, non-directive, took into consideration the burden of living with Type 2 Diabetes and balanced the emphasis on the patients' ability to control the condition with getting advice from health professionals, while listing or linking to points that can help with better managing the condition.

Personalisation: It was not clear whether participants preferred having their usernames on all the email prompts or not as they had different opinions on this. Some participants preferred having short emails tailored to their

usernames but not personalised newsletters (longer emails), as they felt short emails were more personal. Others felt having an email directed to them made no difference, although one of those participants who shared this view noticed when an email was directed to him.

Another participant thought that it would be nice to personalise any email prompt whether it was a short or long email.

News and updates: Most participants liked having news or updates in some of the email prompts; this was attributed to their interest in research in medical science or the fact that any new updates regarding diabetes was more attention-grabbing than the usual information they have been getting since they were first diagnosed with diabetes.

> *"Well, obviously new developments and things like that, and research and obviously this October stuff. Things like that, topical things. Topical things to keep people engaged. Just anything new that's coming out, and keeping people up to date with research and stuff like."* P6

Credibility/Health professional reference: Some of the participants, specifically those with a higher educational degree, pointed towards the importance of referencing health professionals and how other patients should seek their advice; and that clicking the links to HeLP-Diabetes pages on the role of health professionals and the type of advice to seek from them can help them with that. One participant also preferred highlighting recommendations from the Department of Health and similar authorities:

> *"So, it's recommended by the Department of Health that everyone with diabetes should have the flu vac and then it tells you where to contact. So, I would maybe look at the fact that the recommendation goes first"* P1, Autumn health reminder.

Visual aspects (e.g., bold colours, pictures, bullet points): Participants liked having short emails with newsletters not exceeding an A4 page. They liked bold colours for the text and thought that the links should have different and bolder colours than the rest of the text. They preferred the use of bullet points and pictures that can break the text.

Overall interpretation and summary

The analysis of the usage data identified email prompts significantly associated with the lowest and highest percentage of user visits to HeLP-Diabetes. The identified prompts explored in think aloud interviews with patient representatives led to the categorisation of features a prompt content should and should not contain. An email prompt should be short, written using clear words and short sentences with lots of links, use non-directive advice, contain empowering statements, include health professional references, be personalised, and most importantly contain news and updates. Participants also specified the visual aspects they liked such as using bullet points, pictures and bold colours. Most of the email prompts contained a mixture of the things patient representatives liked and disliked; the email prompts with the higher percentage of visits “HeLP-Diabetes Newsletter 12-Your diabetes is in your hands” and “World Diabetes day” had more features patient representatives liked than disliked while “HeLP-Diabetes Newsletter 13- Get rid of your medication worries!” and “Autumn health reminder”, which were not associated with visits to HeLP-Diabetes, had more disliked features. Surprisingly, “How to handle the summer heat?”, which had a relatively high percentage of visits compared to the rest of the email prompts (23.1%) had more disliked features than liked ones.

5.6 Discussion

This mixed methods study provides an insight into the potential components or characteristics (specifically delivery modes and content) that can potentially promote engagement within a defined context and what could have possibly influenced their effectiveness. However, the results have to be interpreted with

caution due to the small sample sizes, non-randomised groups, and prompts being context-specific interventions so results might not be generalisable.

5.6.1 Principal findings

The results of this study show a statistically significant association between opening an email and visiting HeLP-Diabetes in certain email prompts. No association was found between being subscribed to text messages and visiting HeLP-Diabetes.

The first result is consistent with the result of the systematic review detailed in Chapter 2. Prompts can potentially promote engagement. However, the second result concerning text messages was surprising, as the literature shows that text messages were more effective than emails at promoting use of a digital intervention and behaviour change (Webb et al., 2010). There are many possible explanations to why there is no association between use of text message prompts and visits to a digital intervention, including a sample that might not own smart phones to click the links contained within the text messages, or the text messages not being tailored nor detailed to grab attention of users.

With regards to email, some emails (i.e. especially early emails) did not show a statistically significant association between opening the emails and visiting HeLP-Diabetes; and for some emails such as “How do I lose weight and feel better?” none of the recipients of that email visited HeLP-Diabetes before the next email prompt was sent. This lack of engagement might be due to reasons such as the title being discouraging to users or the number of registered users during that period being very low and therefore very few users for whom this topic was interesting. Other interesting observations include a relatively high percentage (16%) of users (compared to other email prompts) visited HeLP-Diabetes after receiving the email “Fasting during Ramadan”, although the topic of the email might be related to a specific group of users (i.e. Muslims) (as shown in Figure 14). However, in Figure 15 the email “Fasting during Ramadan” had the highest percentage of users (13%) who did not open the email, so the visits might not be due to the prompt only.

The significant association between opening email prompts and visits to HeLP-Diabetes helped in identifying email prompts to use in think aloud interviews; these interviews, were focused completely on the content of the prompts, and these interview results were then used to decide on the groups to randomise in a pilot randomised controlled study outlined in Chapter 6. The difference in the percentage of email prompts associated positively with visits to HeLP-Diabetes (48.7%) compared to none of the text message showing a significant association led to my decision to compare email to text message prompts in Chapter 6.

Another important result is that 75% of HeLP-Diabetes visits occurred within a period of five days after an email prompt was sent, and that half of the user visits were within one day of receiving the prompts.

As for the results of the think aloud interview, many features of the prompts they found engaging were highlighted by the users. Of the email content features identified in the interviews, five had evidence related to their effectiveness on behaviour change in general. The first feature was non-directive advice. The literature suggests that use of autonomy-supportive language in support provided in face-to-face settings does have an influence on behaviour change (Stewart et al., 2012). Developers and researchers of digital interventions have recommended the use of non-directive language in digital intervention content (Yardley et al., 2015). To the best of my knowledge, one study has explored the effect of such language in engagement prompts. It was a questionnaire study with 41 participants that explored the effect of using prompts with directive or non-directive language to engage users of behaviour change digital intervention. There was no difference in users' preference to directive or non-directive content of prompts. The author of that study concluded that this might be due to non-directive language having an effect only in face-to-face settings as opposed to in written materials (Rachman, 2015); that might be due to most communication relaying on nonverbal cues which is missing in written material (Burgoon et al., 2011).

The second feature liked by some of the interview participants and supported by research evidence is personalisation. Personalisation or tailoring has been shown in some studies to have a positive effect on behaviour change, as the more a person perceives a message to be relevant to them, the more likely change will occur (Noar et al., 2009). However, within the context of this study, tailoring can only apply to usernames level as HeLP-Diabetes prompts' cannot be tailored to a more complicated level such as tailoring content to users' interest whether it is diet or physical activity, thus, the effect of username level of tailoring is not clear as the current evidence show higher level of tailoring (e.g. tailoring the content or tools of the digital intervention) (Yardley et al., 2015, Noar et al., 2009).

The third feature is visual appeal, which is an important feature often emphasised in the human-computer interaction field (Sharp et al., 2007, Lalmas et al., 2014). However, the field of eHealth change at a very quick pace, and what can be appealing now can change in a very short time.

The fourth feature is the inclusion of health professional references, as patients prefer to use a service if it was recommended by a health authority (Jariwala, 2005). As I mentioned previously in Chapter 3, Section 3.4.4, the content of the prompts was seasonal and some of them would include non-health related information or incentives, thus including a health professional reference in each prompt would not have been applicable.

The final feature, news and updates, was the only feature explored in a study identified by the systematic review (see Chapter 2, Section 2.5.11). That study concluded that the inclusion of updates and news items in a prompt might promote engagement (Schneider et al., 2013b).

5.6.2 Research implications

Riley et al. (2013) reported that it can take around seven years from applying for a grant until disseminating results of a randomised controlled study. In the

eHealth field there has been a call to accelerate the pace of health research to correlate with the speed of technology development. A rising and clearly favoured suggestion to accelerate eHealth research is the use of studies with smaller samples that answer discrete, specific questions, rather than conducting one major randomised controlled study (Riley et al., 2013, Baker et al., 2014). This study provided an example of a study to develop and explore technological prompts before testing them in a randomised controlled study.

There were abstract themes (see Section 5.5.2) that were not explored further, because they would have needed more participants and time and they did not meet my PhD objectives; they could, however, be explored further in future studies.

5.6.3 Strengths and limitations of the study's methodology

There are many methodological strengths and limitations to this study. The main strength of this study is the combination of two types of data, quantitative and qualitative, to reach a specific aim. The length of time for sending prompts and number of prompts enabled me to collect enough rich data to help with the interview study. Cleaning and validating the quantitative data was conducted independently and reviewed by an experienced data manager, and having two other authors review the transcripts and codes ensured rigour of the qualitative study. The rapport I had developed with the patient representatives' over time made for a relaxing and open environment where patients felt comfortable to voice their thoughts and opinions aloud. This study methodology takes into consideration the shift in technology by using the latest possible method of sending prompts; it uses an outcome measure (i.e. HeLP-Diabetes visits) that is objective, meaningful, highly sensitive and quickly responsive to change; and it incorporates patient representatives' input. This research was conducted in a real-life setting rather than a controlled setting where variables that might influence causation are removed. This naturalistic setting showed how the prompts would work with the actual population that registers to HeLP-Diabetes

rather than a selective population that might not be representative of HeLP-Diabetes' targeted population.

However, the latter point can also be a limitation, as a non-randomised study in a non-controlled setting cannot determine what made a prompt effective. Another possible limitation is that the participants in the think aloud interviews might not have been a representative sample. Hence, this sample may not have been enough to identify all possible HeLP-Diabetes users' preferences for prompt content. However, they were the only sample available for interviews.
These two limitations show that this study was good for hypothesis generation rather than in-depth exploration and effectiveness determination.

Other limitations of the think aloud interviews include that participants were not very diverse in terms of their length of diabetes, experience with computers, age, and length of involvement with the HeLP-Diabetes team and development of prompts. As for usage data, the advantages are listed above for using this data but there are also limitations, such as email opens not being reported accurately (i.e. an email open is only counted if the email client of a user downloads the HTML content and not only the text) or a HeLP-Diabetes visit not being counted if the user did not enter his/her username and log in. In addition, some earlier email prompts did not show any association with visits, that might have been due to small sample sizes rather than the email prompt itself.

5.6.4 Final thoughts and lessons learned

Quantitative data

There were some issues to do with deciding on which usage data to use for measuring engagement and how to analyse it. The decisions regarding these two issues were based on the available resources and time constraints.
However, there were other options that I would have explored if it were feasible: besides visits to HeLP-Diabetes and email opens, there were two other types of usage data I could have used to measure engagement. The first one is number

of links clicked, but I chose email opens as users might be triggered to visit HeLP-Diabetes without clicking the links in the email, thus email open was a better measure. The other outcome measure is web page visited; that measure would have showed me users' interests as well as whether they visited the pages in the prompts or not. However, as with the earlier measure (i.e. links clicked and email opens), visits to HeLP-Diabetes are more general and better to catch users' activity than a specific measure.

Analysis of the email prompts was done using Chi-square tests instead of regression. Regression would have enabled me to adjust for possible covariates (e.g. user characteristics) and explore the interactions between these covariates and the effect of the prompt; however, I used Chi-square test because the characteristics proportions were different for each email prompt (i.e. users were continuously registering as shown in Table 8) and analysing a number of prompts can show a trend or pattern that can indicate an association between the two analysed factors. The Chi-square test analysis helped in exploring and identifying prompts that might potentially promote engagement and explore them further in a think aloud interview followed by the pilot randomised study in Chapter 6 to test the accuracy of the findings of this chapter. As mentioned earlier, this study was mostly for hypothesis generation. However, to ensure that the statistically significant association between opening a prompt and visiting HeLP-Diabetes for the 19 email prompt (see Figure 17 for these emails) were not due to possible confounders (e.g. age, sex), an adjusted logistic regression was conducted for these 19 email prompts. The significant association between email opens and HeLP-Diabetes visits persisted even after adjustment for possible confounders (see Appendix 13).

Qualitative data

To the best of my knowledge, this was the first think aloud interview study exploring content of prompts. Although the number of participants was low compared to other think aloud interview studies or semi-structured interview studies (Maxwell, 2009), the results demonstrate what the content of prompts

that users can potentially like or dislike, thus either prompting engagement or not. The results of this study also reinforce the type of content that participants expressed that they wanted to see in the qualitative interviews and focus groups done while developing HeLP-Diabetes (Pal et al., 2013a). Interestingly, although the users contributed much to developing the prompts, there were still some content they disliked. The feedback they provided through the interviews was longer and had more detail compared with the feedback they sent through emails during the development period, as mentioned in in Chapter 3, Section 3.4.4.

If time allowed and the number of participants was larger, I would have made two modifications in the think aloud interviews. The first being the emails I chose for the interviews. The emails were the same for all the participants to ensure the consistency of some results, but it meant that some of the issues that can be found in other emails were not explored or identified. The other issue is that the more abstract themes that were raised from some of the interviews could not be explored further (see Section 5.5.2); one of those themes was that diabetic patients who have existing diagnosis have different content needs or preferences than those who were recently diagnosed. Raising of this issue, though, indicated the importance of adjusting for the variable "length of diabetes" in the pilot randomised study in Chapter 6.

If it were possible to repeat this study, I would have arranged for think aloud interviews at intervals throughout the period of usage data analysis instead of getting user feedback on one prompt through emails (Chapter 3, Section 3.4.4). However, as I was trying to recruit participants to the semi-structured interviews rather than interviewing patient representatives, this was not a possible option at the time.

5.7 Conclusion

This mixed methods study showed that email prompts can potentially promote engagement with a digital intervention, but the effect seems to be small, while text messages do not show any effect on engagement for their subscribers. HeLP-Diabetes users tended to visit the website within a period of five days from receiving an email prompt. The identified prompts explored in think aloud interviews with patient representatives led to the categorisation of the content features a prompt should and should not contain.

This study combined both empirical evidence in terms of analysing the usage data and think aloud interviews, and anecdotal evidence when prompts were selected based on data visualisation to be used in think aloud interviews. However, I acknowledge that this study is a suggestive and explorative study rather than a definitive and investigative one. It did assist in narrowing the scope of what prompt content and delivery mode to test for potential effectiveness in the pilot randomised controlled study in Chapter 6.

Chapter 6 Content and delivery modes of HeLP-Diabetes prompts: two pilot randomised controlled trials

6.1 Abstract

Background: Characteristics of prompts to promote engagement in digital interventions have not previously been thoroughly investigated. Content and delivery modes in particular have been suggested as having an effect on engagement. This chapter describes the final study included in this thesis. The results from the previous chapters (Chapters 2 and 5) and the work described in Chapter 3 have led to the design of two consecutive pilot randomised controlled trials. A pilot randomised controlled trial design was used because it was expected that the trials will be underpowered to evaluate the effectiveness of different content and delivery modes of prompts on visits to HeLP-Diabetes, as the sample was limited to users registered on HeLP-Diabetes. Hence, the results of the first trial that tested the effects of different content for email prompts (Trial 1) and the second trial that tested the effects of different modes of delivery (Trial 2) can be used to inform future definitive trials.

Aims: To test the potential effects of different content and delivery modes of prompts on promoting engagement with HeLP-Diabetes. To test the procedures of the pilot trial (randomisation, delivery of intervention, data collection and analysis, sample size calculation) to identify any potential challenges for future trials.

Method: I conducted two-arm consecutive pilot randomised controlled trials online. The first trial looked at adding news and research articles into an email prompt compared to not adding them; the second trial looked at email prompts compared to text message prompts. The primary outcome was the proportion of participants who visited HeLP-Diabetes within a five-day period after the prompt was sent. The secondary outcome for Trial 1 was email opens.

Results: Both trials were underpowered. In the first trial (Trial 1), 279 participants were randomised. The trial showed no association between receiving an email with news and a research article and visiting HeLP-Diabetes.

It did show, however, that there was a significant association between opening an email prompt and visiting HeLP-Diabetes for both arms. In the second trial (Trial 2), 180 participants were randomised. Results of this trial showed there was no association between different delivery modes (email or text messages) and visiting HeLP-Diabetes.

Conclusion: There is no evidence to support the inclusion or exclusion of news and research articles in email prompts, nor is there evidence to prioritise the use of email over text messages or vice versa. However, prompts have the potential to promote engagement with a digital intervention, as shown with the positive association between opening an email prompt and visiting HeLP-Diabetes in Trial 1 for both arms. Further research in large sample sizes is needed to identify whether different content or other prompt characteristics can influence engagement. Additionally, the design of both trials provide a feasible way of testing engagement prompts' characteristics.

6.2 Introduction

6.2.1 Chapter rationale and link with previous chapters

Results from the systematic review in Chapter 2 suggested that the use of prompts can potentially enhance engagement with a digital intervention. However, there was some uncertainty about which of the eight characteristic identified in the review (timing, duration, frequency, content, sender, mode of delivery, theory, tailoring) might have had a significant impact on engagement. The Medical Research Council guidance followed in this thesis (see Chapter 3) emphasised the importance of testing complex interventions in a way that enables assessment of the effectiveness of active ingredients. However, due to time and context constraints, content and mode of delivery were the only characteristics examined in Chapter 5 and tested using a randomised study design in this chapter.

6.2.2 Rationale for investigation of content and delivery mode of prompts

Content and mode of delivery were chosen to test due to their importance in the literature, time constraints that did not allow me to test other characteristics, and the convenience of testing these two characteristics throughout this PhD (see Chapter 5). Testing other characteristics, such as timing, duration and frequency of prompts was not possible as users continued to register while the prompts were being tested, instead of having a fixed sample. I sent the prompts myself, as the prompts could not have been automated and there was no available researcher or peer to send them, hence testing different senders was not possible. Tailoring could not be tested as it could only be done to usernames and nothing more complex, since the technological resources for that were not available. Use of theory to develop the prompts was not possible, as the systematic review did not find any study that used theory for the prompts' development or evaluation. Furthermore, the semi-structured interviews that could have identified targeted source of behaviour from the COM-B model (i.e. Capability, Opportunity and/or Motivation) and behaviour change techniques

(BCTs) (see Chapter 3, Section 3.4.2) did not succeed in recruiting participants (see Chapter 4).

Content of prompts

Examining the effects of the content of prompts on engagement with a digital intervention was prioritised for investigation in this thesis because there has been a push towards investigating content of digital interventions (Michie, 2008, Webb et al., 2010) to understand which BCTs, known (Michie et al., 2013) or yet unknown, are effective in specific contexts (Michie et al., 2011). By knowing this, it will help in developing a theory about engagement with digital interventions and in refining our use of prompts.

In Chapter 2, content was categorised into five main categories (advertising and describing digital intervention features, providing technical assistance, linking to specific pages or sections, reminding to users to complete usage, and providing therapeutic support) and coded as BCTs when possible. In one study, content of the digital intervention was advertised via emails and the participants were randomised into groups that received emails with news and updates and those that received emails without news and updates. Results of this study showed that the use of emails with new content appeared to engage users more than those without, but the difference was not significant (OR= 2.286, 95% CI 0.892 to 5.856, *P* = .09) (Schneider et al., 2013b). The different content categories and BCTs identified in the systematic reviews were tested in the prompts sent from February 2014 until May 2015, when feasible; however, the email content would be edited after being reviewed by the HeLP-Diabetes team and patient representatives, as detailed in Chapter 3, Section 3.4.4. The prompts were then examined and used in think aloud interviews (see Chapter 5), where the results showed that inclusion of news and updates can potentially promote engagement. Hence, the decision to test whether the inclusion of news and updates in a prompt can promote engagement is due to two reasons. The first is the results of the study identified through the systematic review and mentioned above (Schneider et al., 2013b). The other reason was that most of HeLP-

Diabetes users – over 70% – had had diabetes for more than one year, thus they would have been introduced to basic Type 2 Diabetes information and would, based on the think aloud interview insight (Chapter 5) and focus groups during HeLP-Diabetes development (Pal et al., 2013a), be more interested in news or updates.

Delivery mode of prompts

Mode of delivery was chosen as the second characteristic to investigate for two reasons. The first being that different modes of deliveries were associated with different levels of effectiveness on changing behaviour, with a published meta-regression showing that text messages were more effective than emails at prompting engagement in digital interventions and behaviour change (d_+= 0.81, k = 4, 95% CI 0.14 to 1.49; d_+= 0.18, k = 19, 95% CI 0.07 to 0.29, respectively) (Webb et al., 2010). The mixed methods study in Chapter 5 showed that none of the different text messages sent were significantly associated with visits to HeLP-Diabetes, while 48.7% of emails showed a significant association. Thus, a study comparing these two modes of delivery was needed to confirm, within HeLP-Diabetes, which delivery mode better promotes engagement. The second reason for choosing mode of delivery is the practicality and necessity of investigating this characteristic, as all the resources were available, unlike other characteristics as mentioned above, and the HeLP-Diabetes team would need to prioritise allocated resources to either delivery mode.

6.2.3 Randomised controlled trials for testing prompt characteristics within HeLP-Diabetes

Decisions about the effectiveness of interventions are usually made based on the results of appropriately designed and executed Randomised Controlled Trials (RCTs). RCTs randomise participants to groups with the only differences between these groups are attributed to the intervention and chance (Kennedy-Martin et al., 2015, Schulz et al., 2010). Sufficiently powered and well-designed RCTs can allow inference of causality, as opposed to observational studies, which can only show associations. However, both are important to decide on

whether an intervention is effective for its designated population. A recent literature review showed that for RCTs, the gold-standard primary study design for producing evidence of intervention efficacy, their external validity needs improvement, as the populations in RCTs are mostly not representative of the target population (Kennedy-Martin et al., 2015). That literature review suggested two ways of tackling this issue. The first way is to design the trial to include participants who are truly representative of the actual population who will receive the intervention, while being aware that this might lower the internal validity of the trial (i.e. internal validity is acquired by having a homogenous sample to lower variances and remove potential confounders in order to find a true association between the intervention and outcome). The second way to increase external validity is to supplement the RCT evidence with data generated from observational studies, as the latter studies intervene under normal conditions (e.g. clinical practices) rather than rigid ones. Thus, if the evidence from both types of studies are combined, it potentially optimises the internal and external validity of the study's intervention (Kennedy-Martin et al., 2015). In this chapter, a pilot RCT was used because of the expected small sample size, and the issue of external validity was addressed by testing the prompts on the same participants using HeLP-Diabetes and who would register to use HeLP-Diabetes when it is implemented in a real-life setting (i.e. the sample included in the chapter excluded participants recruited in the trial evaluating HeLP-Diabetes). A pilot RCT cannot determine whether the intervention is effective but it can assess the outcome and inform future definitive trials.

6.3 Aim

The main aim for both pilot trials was to examine the effects of the prompts on promoting engagement with HeLP-Diabetes by achieving the following objectives:

1. Test the potential effect of email prompts with news and a research article against emails without news and a research article under similar conditions of frequency and timing.

Hypothesis Trial 1: Email prompts with news and a research article will be associated with better engagement than those without.

2. Test the potential effect of email prompts against text messages prompts under similar conditions of frequency, timing and content.

Hypothesis Trial 2: Email prompts will be associated with better engagement than text message prompts.

3. Test the procedures of the pilot trial in terms of randomisation, delivery of intervention, data collection and analysis, sample size calculation, to inform and to identify any potential challenges for future trials.

6.4 Methods

6.4.1 Design

This study consisted of two consecutive online pilot trials. Both were two-arm individually randomised trials. HeLP-Diabetes participants, excluding HeLP-Diabetes trial participants, were first randomised to receive email prompts with different contents and followed-up for five days, then a subset were randomised again to receive either email or text message prompts and again followed-up for five days. The study was registered at the International Standard Randomised Controlled Trial Number registry (ISRCTN15997240) on 25/05/2016.

6.4.2 Setting and Participants

The interventions in both trials were tested online, and the participants were available online through HeLP-Diabetes. However, the participants were recruited from different locations depending on their group.

- **Implementation study participants:** this group of users was recruited from the Northwest London boroughs of Camden and Islington. They had the following inclusion criteria: patients who are 18 years old or above; registered at participating general practitioners' surgeries, community diabetes clinics or hospital-based diabetes clinics; and have a diagnosis of Type 2 Diabetes
- **Diabetes Modernisation initiative participants**: A rollout of HeLP-Diabetes as a service provided for people with Type 2 Diabetes in South London borough of Lambeth. The inclusion criteria are detailed in Chapter 4, Section 4.3.1, but in summary were as follows: adult patients of Type 2 Diabetes who declined to attend a National Health Services group-based education programme and those completing the group-based education programme

Inclusion and exclusion criteria

Trial 1

Inclusion criteria:

1. Registered users of HeLP-Diabetes.
2. Subscribers to email prompts.

Exclusion criteria:

1. Users registered after 30 September 2015, as anyone who registered after this date would not have received an email or a text message prompt until the intervention period.
2. Users registered on HeLP-Diabetes RCT plan, as this group of users could not be randomised to receive different prompts until the end of the trial in early 2016.

Trial 2

Inclusion criteria:

1. Registered users of HeLP-Diabetes who provided mobile phone numbers and agreed to receive text message prompts.[1]
2. Subscribers to email prompts.
3. Included in Trial 1.

Exclusion criteria:

1. Users registered after 30 September 2015 for the reason mentioned above.
2. Users registered on HeLP-Diabetes RCT plan for the reason mentioned above.

6.4.3 Recruitment

Users were recruited to use HeLP-Diabetes based on their registration group, whether they were included in the implementation or Diabetes Modernisation Initiative group (see Chapter 3, Section 3.4.3 for details on their recruitment). For this study, no recruitment effort was made as users meeting the inclusion criteria were enrolled in the study automatically.

6.4.4 Consent

Consent to receive prompts was sought with consent for participation, as detailed in Chapter 3, Section 3.4.3, as when a user registers, they agree to the terms and condition of HeLP-Diabetes, which includes receiving email and text message prompts. Participants also can agree to receive text messages by including their mobile phone number, and they can unsubscribe from both emails and text messages whenever they want.

[1] Users registering on HeLP-Diabetes are required to provide an email to be signed up, while providing a mobile phone number is optional.

6.4.5 Randomisation

Randomisation was done by extracting only user identification numbers from the HeLP-Diabetes database then using the website random.org (https://www.random.org/), to generate two lists of randomised identification numbers. The website was used in one of the papers I had identified through my systematic review (Titov et al., 2009). Each list was then halved, resulting in four groups: two for Trial 1 and two for Trial 2. After getting the randomised list of user identification numbers for all the groups, SoftForge (i.e. the developers of HeLP-Diabetes) built the four groups into the HeLP-Diabetes system, enabling me to send all the email and text message prompts by user identification numbers while maintaining participants' anonymity. The limitation of this approach was that the number of users who 'unsubscribed' was not clear until after randomisation; thus, the absolute number of participants in each group was not equal (see Figure 19: CONSORT diagram).

6.4.6 Intervention

The prompts for both Trials 1 and 2 were developed based on the results of the mixed methods study in Chapter 5. After developing the prompts, I showed them to the HeLP-Diabetes team (during a HeLP-Diabetes team meeting) and patient representatives (via emails) for feedback to improve them. Any suggested changes were then discussed with supervisors before I sent the prompts per the schedule below (see Figure 19: CONSORT diagram). It should be noted that the last prompt that was sent before the start of Trial 1 was on the 30th of September 2015, and no washout period was used (i.e. no extended period where the users did not receive prompts to eliminate the effect of the previous prompts was used), as I considered this might have introduced a possible confounder, where users who expect to receive two to three prompts per month do not receive it for a longer period of time, and so might be more likely to open it. Table 13 shows the main difference in textual content between the arms of both trial. Figures 20 and 21 are screenshots of the prompts.

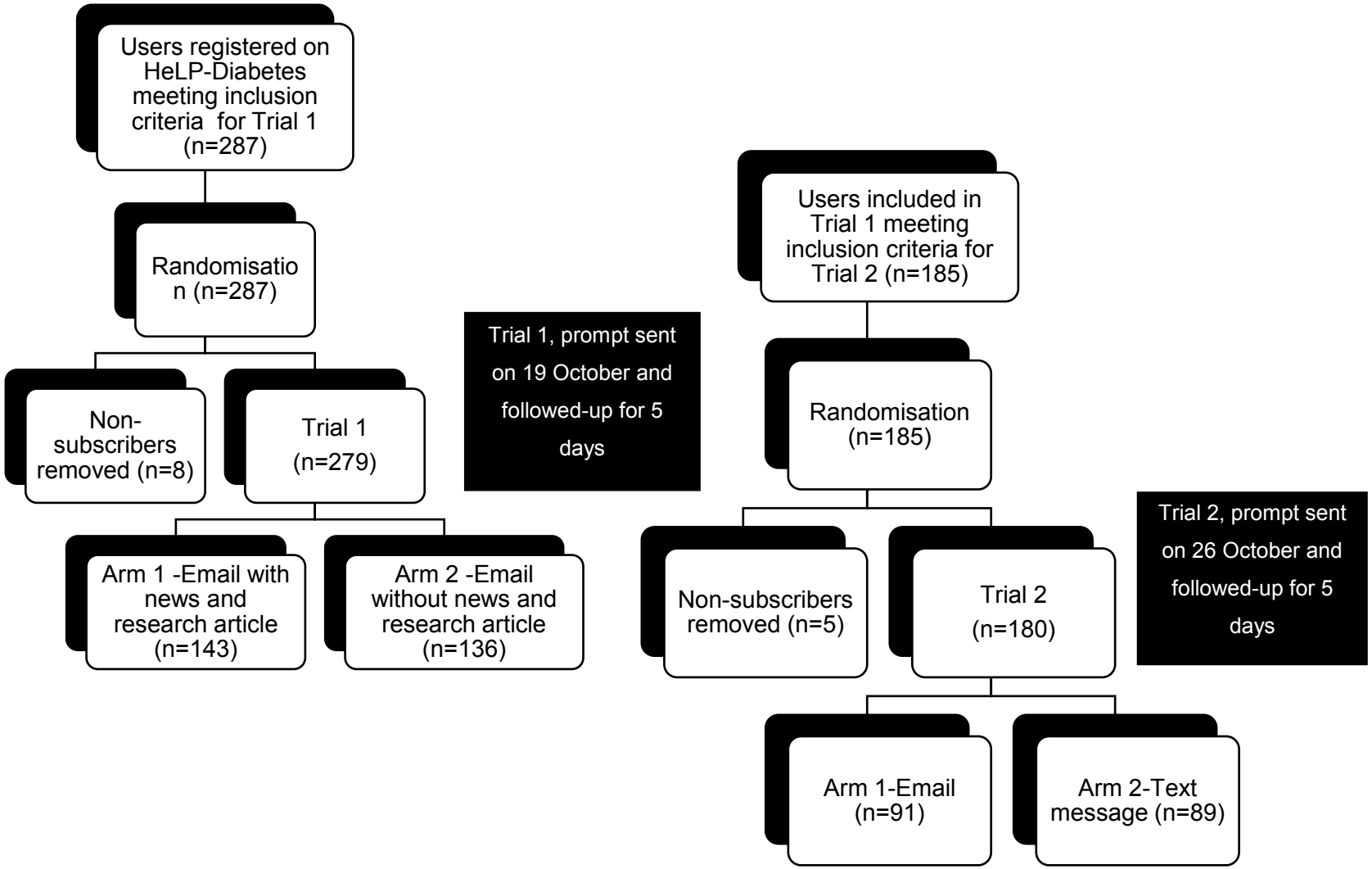
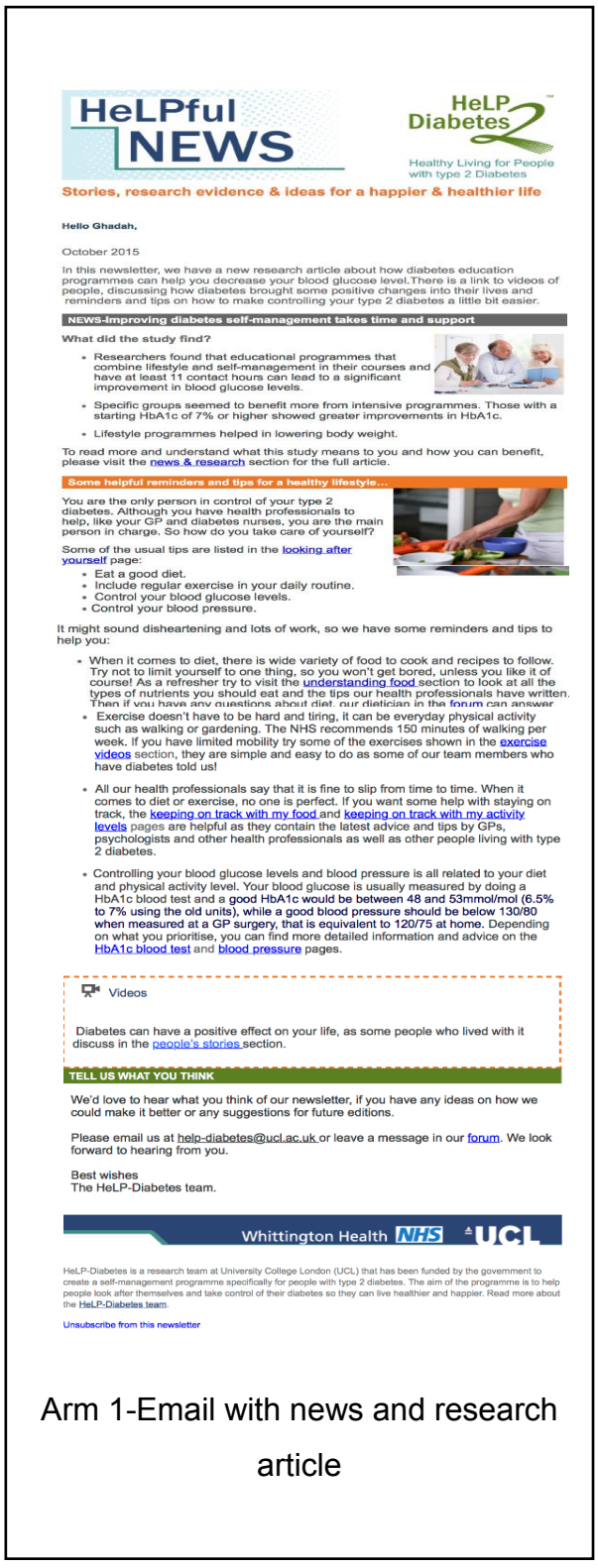


Figure 19: CONSORT diagram for participants' flow through the study for both trials

Table 13: Difference in intervention textual content for Trials 1 and 2

Trial 1, Arm 1: Email with news and research article	Trial 1, Arm 2: Email without news and research article
Introduction paragraph: In this newsletter, we have a new research article about how diabetes education programmes can help you decrease your blood glucose level. There is a link to videos of people discussing how diabetes brought some positive changes into their lives and reminders and tips on how to make controlling your Type 2 Diabetes a little bit easier. News section: NEWS-Improving diabetes self-management takes time and support What did the study find? • Researchers found that educational programmes that combine lifestyle and self-management in their courses and have at least 11 contact hours can lead to a significant improvement in blood glucose levels. • Specific groups seemed to benefit more from intensive programmes. Those with a starting HbA1c of 7% or higher showed greater improvements in HbA1c. • Lifestyle programmes helped in lowering body weight. To read more and understand what this study means to you and how you can benefit, please visit the news & research section for the full article.	Introduction paragraph: In this newsletter, we have reminders and tips on how to make controlling your Type 2 Diabetes a little bit easier. There is a link to videos of people, discussing how diabetes brought some positive changes into their lives. No news section.
Trial 2, Arm 1: Email	**Trial 2, Arm 2: Text message**
Title: Banana Muffins/bread recipe Dear [name], We were inspired by the Great British Bake Off, and wanted to share a delicious banana muffins recipe with you in the forum. Best wishes, HeLP-Diabetes team	[name] we were inspired by the Great British Bake Off and wanted to share a delicious banana muffins recipe with you at https://www.help-diabetes.org.uk/forum-help/forum/diet dilemmas



HeLPful NEWS

HeLP Diabetes2

Healthy Living for People with type 2 Diabetes

Stories, research evidence & ideas for a happier & healthier life

Hello Ghadah,

October 2015

In this newsletter, we have a new research article about how diabetes education programmes can help you decrease your blood glucose level.There is a link to videos of people, discussing how diabetes brought some positive changes into their lives and reminders and tips on how to make controlling your type 2 diabetes a little bit easier.

NEWS-Improving diabetes self-management takes time and support

What did the study find?

- Researchers found that educational programmes that combine lifestyle and self-management in their courses and have at least 11 contact hours can lead to a significant improvement in blood glucose levels.
- Specific groups seemed to benefit more from intensive programmes. Those with a starting HbA1c of 7% or higher showed greater improvements in HbA1c.
- Lifestyle programmes helped in lowering body weight.

To read more and understand what this study means to you and how you can benefit, please visit the news & research section for the full article.

Some helpful reminders and tips for a healthy lifestyle...

You are the only person in control of your type 2 diabetes. Although you have health professionals to help, like your GP and diabetes nurses, you are the main person in charge. So how do you take care of yourself?

Some of the usual tips are listed in the looking after yourself page:

- Eat a good diet.
- Include regular exercise in your daily routine.
- Control your blood glucose levels.
- Control your blood pressure.

It might sound disheartening and lots of work, so we have some reminders and tips to help you:

- When it comes to diet, there is wide variety of food to cook and recipes to follow. Try not to limit yourself to one thing, so you won't get bored, unless you like it of course! As a refresher try to visit the understanding food section to look at all the types of nutrients you should eat and the tips our health professionals have written. Then if you have any questions about diet, our dietician in the forum can answer
- Exercise doesn't have to be hard and tiring, it can be everyday physical activity such as walking or gardening. The NHS recommends 150 minutes of walking per week. If you have limited mobility try some of the exercises shown in the exercise videos section, they are simple and easy to do as some of our team members who have diabetes told us!
- All our health professionals say that it is fine to slip from time to time. When it comes to diet or exercise, no one is perfect. If you want some help with staying on track, the keeping on track with my food and keeping on track with my activity levels pages are helpful as they contain the latest advice and tips by GPs, psychologists and other health professionals as well as other people living with type 2 diabetes.
- Controlling your blood glucose levels and blood pressure is all related to your diet and physical activity level. Your blood glucose is usually measured by doing a HbA1c blood test and a good HbA1c would be between 48 and 53mmol/mol (6.5% to 7% using the old units), while a good blood pressure should be below 130/80 when measured at a GP surgery, that is equivalent to 120/75 at home. Depending on what you prioritise, you can find more detailed information and advice on the HbA1c blood test and blood pressure pages.

Videos

Diabetes can have a positive effect on your life, as some people who lived with it discuss in the people's stories section.

TELL US WHAT YOU THINK

We'd love to hear what you think of our newsletter, if you have any ideas on how we could make it better or any suggestions for future editions.

Please email us at help-diabetes@ucl.ac.uk or leave a message in our forum. We look forward to hearing from you.

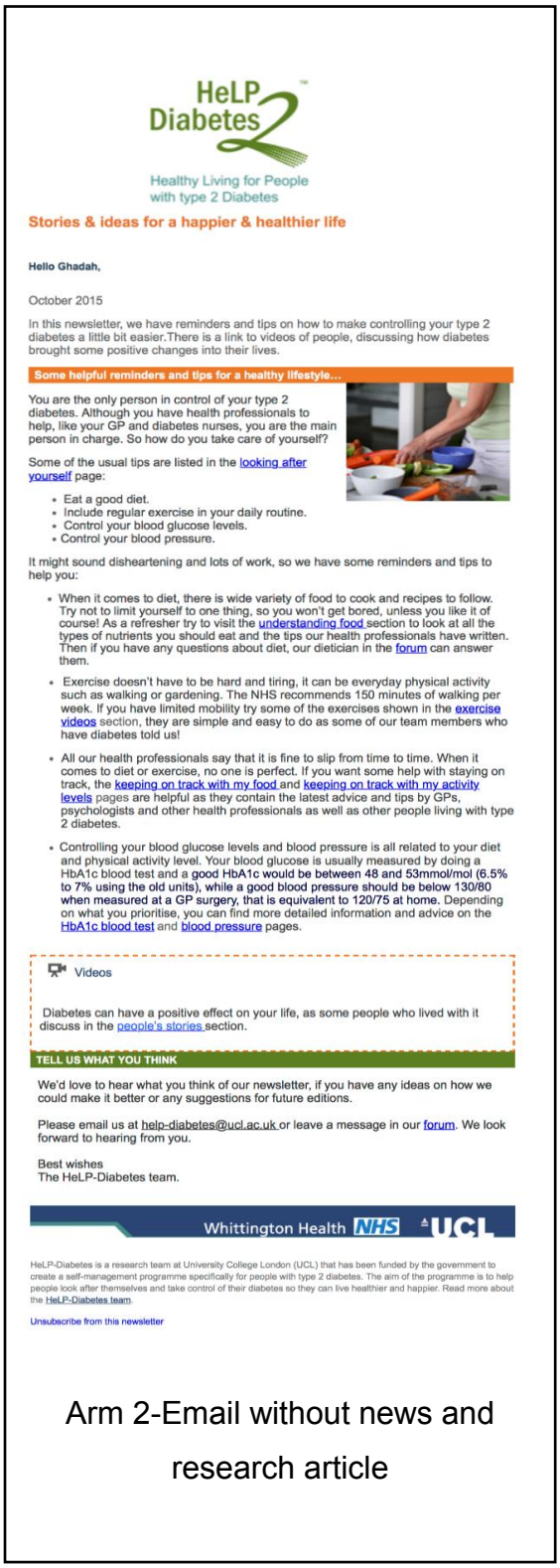
Best wishes
The HeLP-Diabetes team.

Whittington Health NHS UCL

HeLP-Diabetes is a research team at University College London (UCL) that has been funded by the government to create a self-management programme specifically for people with type 2 diabetes. The aim of the programme is to help people look after themselves and take control of their diabetes so they can live healthier and happier. Read more about the HeLP-Diabetes team.

Unsubscribe from this newsletter

Arm 1-Email with news and research article



HeLP Diabetes2

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Stories & ideas for a happier & healthier life

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Unsubscribe from this newsletter

Arm 2-Email without news and research article

Figure 20: Screenshot of prompts used in Trial 1

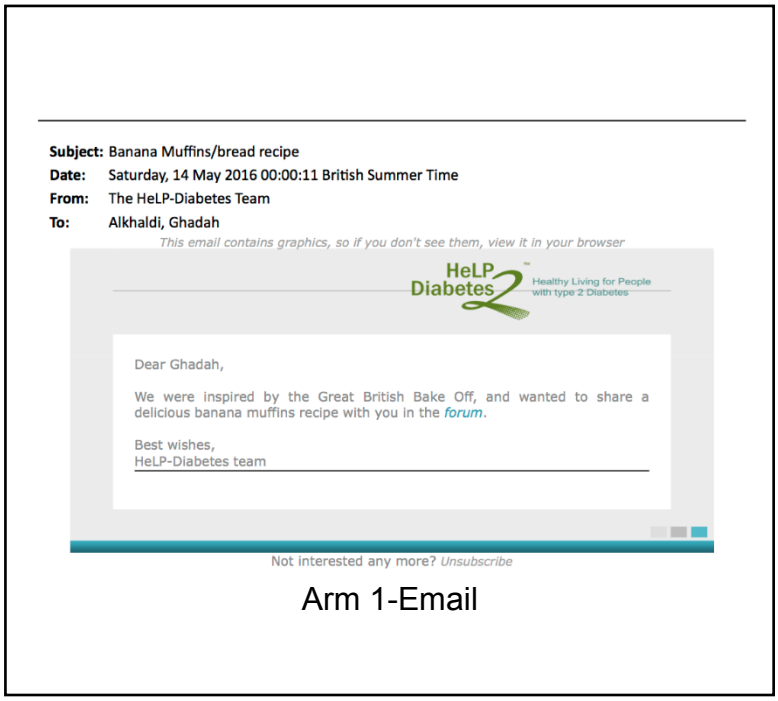


Figure 21: Screenshots of prompts used in Trial 2

Delivery of intervention

Trial 1: participants in both groups received their respective email prompts on the same day, 19th of October 2015. They were followed-up for five days, including the day the emails were sent.

Trial 2: participants in both groups received their text message or email prompts on the 26th of October 2015. They were followed-up for five days, including the day the prompts were sent.

Follow-up period

The follow-up period for both trials was five days. This number was based on the analysis of the length of time it took for 75% of users to visit HeLP-Diabetes after receiving email prompts (see Chapter 5, Section 5.4.2). Figure 22 shows the timeline from users' recruitment to conclusion of the trial.

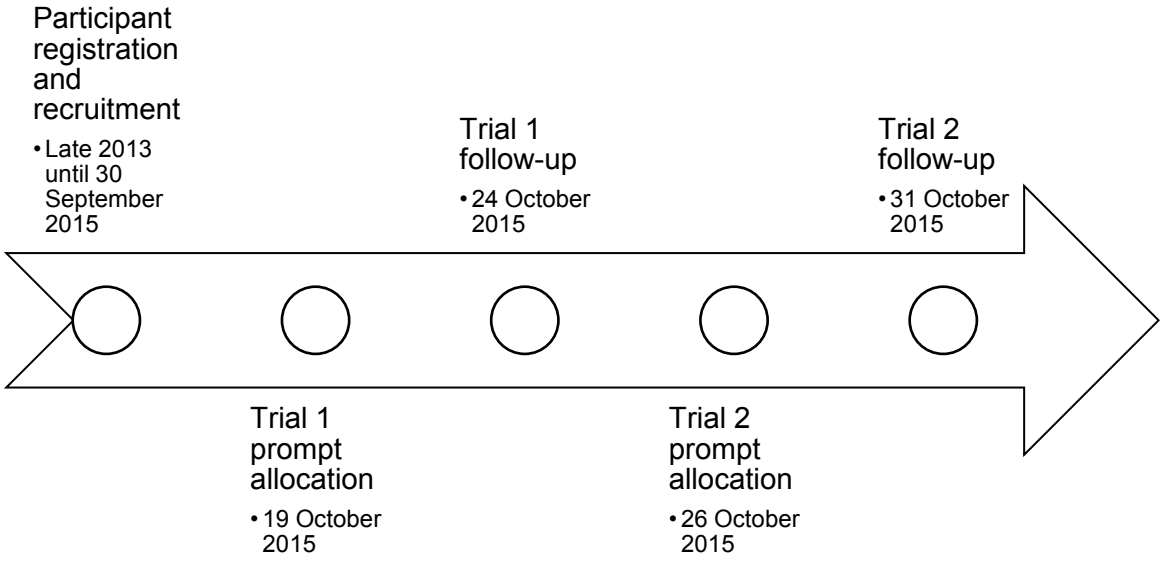


Figure 22: Study timeline

6.4.7 Analysis

Sample size and power calculation

An adequate sample size provides the least number of users needed to produce a significant and meaningful result (Kirkwood and Sterne, 2003). To determine the sample size three numbers are needed: clinically important difference between the intervention and control group (which is usually acquired from the literature and experts), power of the hypothesis test; and significance level (*P*-value) indicating the degree to which a difference between the intervention and control group is due only to chance (Kirkwood and Sterne, 2003, Altman, 1991).

In the case of this study, the sample size was restricted to the available registered users on HeLP-Diabetes. However, I needed to know the power. Power is required to calculate the number of participants required to avoid type II error; type II error would occur if I incorrectly fail to reject the null hypothesis. (i.e. stating that there is no difference between the groups when in fact there is). Power is defined as the probability to reject the hypothesis that there is no difference in effect between the arms in both trial 1 and 2 when that hypothesis is false, it is usually set to either 80% or 90% (Kirkwood and Sterne, 2003, Altman, 1991).

There were two options for calculating power: the first was to use the effect size in Schneider et al (2013b), which evaluated the effect of different prompt contents (OR= 2.286, 95% CI 0.892 to 5.856, *P* = 0.09) (Schneider et al., 2013b), and the second one was to use the effect size from the systematic review in Chapter 2 calculated in the meta-analysis (see Appendix 4) that excluded one study that introduced substantial heterogeneity (Relative Risk = 1.25 , 95% CI 1.06 to 1.48). The latter was the option I used for this study, as it provides a collection of studies rather than one study, as in Schneider et al. (2013b).

Analysis plan for outcomes

Descriptive analysis of baseline information

The following baseline variables were compared between arms for each trial:

1. Age, gender: the literature in Chapter 1 showed that in some studies users who are middle-aged women completed digital intervention sessions; therefore, age and gender had to be considered when conducting the analysis (Brouwer et al., 2010, Schulz et al., 2012, Van 't Riet et al., 2010). These two variables were categorical, and the users chose from the following categories when they register: Age = 18 to 40 years, 41 to 60 years, 61 years and older; Gender = female, male. [1]
2. Computer knowledge: How users rate their computer use, skills and knowledge was compared between arms, as this might have an influence on how they use HeLP-Diabetes and respond to email or text message prompts. This variable was categorical: basic, intermediate, advanced and not answered.
3. Length of diabetes: the length of having Type 2 Diabetes may influence users' experience with HeLP-Diabetes, as those who have not had diabetes for a long time might be more motivated to engage with HeLP-Diabetes, as newly diagnosed patients usually need more contact with diabetes care for guidance (Engström et al., 2016). The length of time since diabetes diagnosis was a categorical variable that users chose when they register: < 1 year, 1-5 years, 5-10 years, 10-20 years, > 20 years.

All of the information regarding the previous three variables was provided when users register at HeLP-Diabetes.

[1] Although the literature shows that higher education is associated with more use of digital interventions, education data was not available for most of the users because it was not asked on registration.

4. Length of registration: engagement reduces over time; the longer users are registered on a digital intervention, the less likely they are to engage (Christensen et al., 2004, Christensen and Mackinnon, 2006, Farvolden et al., 2005, Verheijden et al., 2007). This variable was continuous and calculated from the date the user registered until the day I downloaded the registration data on 30 September 2015. It was expected that the data would be skewed because registration on HeLP-Diabetes increased in mid-to-late-2014; therefore the median was calculated rather than the mean.
5. The HeLP-Diabetes participant group: users from the implementation study group and the Diabetes Modernisation Initiative group were included in the current study. The Diabetes Modernisation Initiative participants were a harder-to-reach group as they were recruited using post mail in Lambeth borough of London. The implementation group participants were recruited using numerous other methods from the Camden and Islington Boroughs of London. The recruitment methods and different locations in London may have some influence on users' motivation or opportunities to use HeLP-Diabetes, thus this variable was also considered (see Chapter 3, Section 3.4.3 for HeLP-Diabetes prompt recipient groups and Chapter 4, Section 4.3 for more information about the two groups).

Primary outcome

The HeLP-Diabetes user visits measure was used for both trials.

A HeLP-Diabetes visit was defined as an individual user accessing HeLP-Diabetes by entering his/her username and password within a defined time period. 'Visits' were defined when the data was downloaded as one visit per day per user. It should be noted that in the results, only one user visit per user identification number during a specific time period is calculated.

Secondary outcome

For Trial 1, since both arms received an email, and Chapter 5 showed that those who opened an email were more likely to visit HeLP-Diabetes, the dichotomous variable of opening an email was included. An email open is

counted if the user's email client (e.g. gmail, yahoomail, outlook) downloaded the images embedded in the email; only one user open per user identification number during a specific time period was calculated.

6.4.8 Data collection

Data was downloaded through the HeLP-Diabetes website. Baseline information such as age and gender were entered by users when they registered, while the outcome data (user visits) was an objective measure tracked by the website and stored for downloading. For Trial 1, user visits between 19 October 2015 and 24 October 2015 were downloaded, while for Trial 2, user visits between 26 October 2015 and 31 October 2015 were downloaded

6.4.9 Statistical analysis

Sample size

Power of the current sample for both trials: if the power was less than 80% with $P = .05$, I planned to calculate the sample size with 80% power. Power calculations were conducted using STATA version 14.

Baseline variables

Age group, gender, computer knowledge, length of diabetes (in year bands) and participant group were recorded at baseline as categorical variables. Length of registration at the time of randomisation was recorded as a continuous variable. To examine whether the participants in the two experimental groups differed significantly at baseline, the Chi-square test was used for categorical variables, (with Fisher's exact test used for small samples), and Mann–Whitney *U* test was used for continuous variables with a non-normal distribution (mainly length of registration).

Primary outcome

Chi-square tests and Fisher's exact test for small samples were used to detect any significant difference between the two arms in each trial in terms of number

of visits to HeLP-Diabetes. If there was a significant difference, logistic regression would have been conducted to derive the odds ratio (OR) of participants visiting HeLP-Diabetes after receiving email with news and a research article or without in Trial 1 and after receiving text messages or emails in Trial 2. 95% confidence intervals and *P*-values would have been calculated for all models.

The binary dependent variable for logistic regression was participants visiting or not visiting HeLP-Diabetes up to five days after the prompt was sent.

The independent variable for logistic regression was prompt content (email with news and a research article and email without) for Trial 1, and mode of delivery (emails and text messages) for Trial 2.

Secondary outcome

Email opens were categorical variables and were analysed within and across arms for Trial 1 using Chi-square tests or Fisher's exact test when sample sizes were small.

Analysis for baseline and primary outcome was done using SPSS version 22.

6.4.10 Confidentiality and data handling

No identifiable data was used in this study. All demographic and usage information about each participant were anonymised when collected and downloaded. A secure online database was created to enter and store participants' demographic information, and access to this database was only provided to authorised research staff. Usage data were collected and downloaded based on identification numbers given to participants when they register, so that no identifiable information was used.

6.4.11 Data checks

Usage was recorded automatically on the website server; the validity and accuracy of the usage data was checked and ensured throughout the development process by me and an experienced data manager as detailed in Chapter 5 Section 5.4.1.

6.4.12 Measures to avoid bias

According to Cochrane, there are five types of bias that need to be evaluated for any trial; they are selection, performance, detection, attrition and reporting bias (see Appendix 14: for detailed definition of types of bias). An adequate random sequence generation and allocation concealment can minimise selection bias; performance bias can be reduced through blinding of participants and research personnel; detection bias through blinding of outcome assessors; attrition bias by providing complete outcome data; and reporting bias can be reduced by avoiding selective reporting of positive outcome data (Higgins and Green, 2011). By judging the sources of bias for the studies identified in the systematic review in Chapter 2, sources of bias were minimised for this study as follows:

1. Randomisation and sequence generation: this was done by using a randomisation website (http://www.random.org) with user identification numbers so that any systematic differences between the arms in both trials was minimised
2. Blinding: Demographic information were collected when the users registered (i.e. before randomisation), and their allocation was not revealed as they were only informed when they registered that they would receive prompts via email and text message and they have been receiving prompts before the start of this study. Usage data were collected automatically and with no indefinable information. Since users had been receiving prompts since they first registered on HeLP-Diabetes, they were not aware of any differences in the prompts they received unless they discussed that with other participants in HeLP-Diabetes. As for

investigator's blinding, I was not able to identify participants in the randomised groups when sending the prompts, as the HeLP-Diabetes developer (SoftForge) labelled the randomised groups in HeLP-Diabetes to enable me to send the prompts without viewing any identifiable information

3. Incomplete outcome data was not anticipated to be a serious issue as the server that stores the usage data has been extensively checked and rechecked from 2014. The outcomes are as specified above and these were the only outcomes reported and analysed

6.4.13 Data Monitoring and Ethics Committee

As this is a low risk trial and HeLP-Diabetes was approved for sending email and text message prompts, no Data Monitoring and Ethics Committee approvals were needed[1].

6.5 Results

6.5.1 Sample Size and power calculation

For a power of 80% with *P*-value = 0.05, the total sample size needed to be 372, with 186 for each arm. Thus, for Trial 1 the power was 68% and for Trial 2 it was 49%.

6.5.2 Trial 1

Participants' demographics

A total of 279 participants were randomised for Trial 1 to receive email prompts with news and a research article (Arm 1, n = 143) or without (Arm 2, n = 136) (see Figure 19: CONSORT diagram). The characteristics of participants in each arm were similar (Table 14). The majority of participants in Arm 1 and 2 were within the age group 41 to 60 years (54.3% and 50.7%, respectively). Around

[1] I have consulted with the HeLP-Diabetes project manager and a University College London ethics employee who have extensive ethics experience.

55.9% were male in Arm 1 and 52.2% in Arm 2. The highest percentage of participants had diabetes for less than a year in Arm 1 (32.1%) and 1 to 5 years in Arms 2 (38.2%). Computer knowledge was basic for Arm 1 and 2 (29.4% and 30.9%, respectively). Half of the participants in Arm 1 were registered for a period 62 weeks and 63 weeks for Arm 2. Most of the participants were from the implementation group for both Arms 1 and 2 (84.6% and 80.1%, respectively).

Proportion of user opens and visits per arm

About one-third (n = 48, 34%) of users in Arm 1 opened their emails, while 29.4% (n = 40) in Arm 2 opened theirs (X^2 (1, N = 279) = .55, P =0.45). Only 3% (n = 4) of those who received an email with news and a research article (Arm 1) visited HeLP-Diabetes, and out of those in Arm 2, 4% (n = 5) visited HeLP-Diabetes (P = 0.74). Although, there was no significant difference between the arms in terms of opens and visits, across the arms there was a significant association between opening an email (regardless of whether it has news and research article or do not) and visiting HeLP-Diabetes; 10% (n = 9) of those who opened an email visited HeLP-Diabetes (P < 0.001). Within Arm 1, there was a significant positive association between opening an email and visiting HeLP-Diabetes (P = 0.01), with 8% (n = 4) of those who opened an email visiting HeLP-Diabetes and none of the users who did not open an email visited HeLP-Diabetes. As for Arm 2, 13% (n = 5) who opened an email visited HeLP-Diabetes (P =0.002) (Table 16).

Table 14: Characteristics of Trial 1 Participants

Characteristic	Arm 1-Email with news and research article (n = 143) N(%)	Arm 2-Email without news and research article (n = 136) N(%)	*P*-value
Gender			
Female	63 (44.1%)	65 (47.8%)	.53
Male	80 (55.9%)	71 (52.2%)	
Age, years[1]			
18 to 40	14 (10%)	14 (10.4%)	.83
41 to 60	76 (54.3%)	68 (50.7%)	
61+	50 (35.7%)	52 (38.8%)	
Length of diabetes, years[2]			
< 1	44 (32.1%)	34 (26%)	.54
1-5	39 (28.5%)	50 (38.2%)	
5-10	24 (17.5%)	22 (16.8%)	
10-20	22 (16.1%)	18 (13.7%)	
> 20	8 (5.8%)	7 (5.3%)	
Computer knowledge			
Basic	42 (29.4%)	42 (30.9%)	.61
Intermediate	37 (25.9%)	37 (27.2%)	
Advanced	32 (22.4%)	22 (16.2%)	
Not answered	32 (22.4%)	35 (25.7%)	
Participants group			
Implementation group	121 (84.6%)	109 (80.1%)	.32

Diabetes Modernisation Initiative group	22 (15.4%)	27 (19.9%)	
	Median (25, 75 interquartile range)	**Median (25, 75 interquartile range)**	
Number of weeks since registration	62 (31,80)	63 (32,85)	.32

[1] 5 missing values
[2] 11 missing values

Comparing emails with news and a research article to emails without on promoting engagement with HeLP-Diabetes

The Fisher's exact test shows that there is no difference between the two arms (P = 0.74). Logistic regression was not conducted as there was no significant difference between the arms in terms of HeLP-Diabetes visits and baseline variables were balanced between them.

6.5.3 Trial 2

Participants' demographics

A total of 180 participants were randomised for Trial 2 to receive email prompts (Arm 1, n = 91) or text message prompts (Arm 2, n = 89) (Figure 19: CONSORT diagram). The characteristics of participants in each arm were similar (Table 15). The majority of participants in Arm 1 and 2 were within the age group 41 to 60 years (56% and 56.3%, respectively). Around 57.1% were male in Arm 1 and 55.1% in Arm 2. The highest percentage of participants had diabetes for 1 to 5 years in Arm 1 and 2 (37.9% and 29.9%, respectively). Computer knowledge was basic for Arm 1 and 2 (29.7% and 29.2%, respectively). Half of the participants in Arm 1 were registered for a period of 68 weeks and 63 weeks for Arm 2. Most of the participants were from the implementation group for both

Arms 1 and 2 (83.5% and 85.4%, respectively). There was no significant difference between being randomised in Trial 1 then Trial 2 (*P* =0.76).

Proportion of user visits per arm

Only 3% (n = 3) of those who received an email prompt (Arm 1) visited HeLP-Diabetes. Of those who received a text message prompt, 6% (n = 5) visited HeLP-Diabetes. There was no significant difference between the two arms (*P* =0.49) (Table 16).

Table 15: Characteristics of Trial 2 participants

Characteristic	Arm 1-Email (n = 91) N(%)	Arm 2-Text message (n=89) N(%)	*P*-value
Gender			
Female	39 (42.9%)	40 (44.9%)	.77
Male	52 (57.1%)	49 (55.1%)	
Age, years[1]			
18 to 40	8 (8.8%)	12 (13.8%)	.50
41 to 60	51 (56%)	49 (56.3%)	
61+	32 (35.2%)	26 (29.9%)	
Length of diabetes, years[2]			
< 1	25 (28.7%)	25 (28.7%)	.47
1-5	33 (37.9%)	26 (29.9%)	
5-10	12 (13.8%)	18 (20.7%)	
10-20	10 (11.5%)	14 (16.1%)	
> 20	7 (8%)	4 (4.6%)	
Computer knowledge			
Basic	27 (29.7%)	26 (29.2%)	.96

Intermediate	24 (26.4%)	25 (28.1%)	
Advanced	18 (19.8%)	19 (21.3%)	
Not answered	22 (24.2%)	19 (21.3%)	
Participants group			
Implementation group	76 (83.5%)	76 (85.4%)	.72
Diabetes Modernisation Initiative group	15 (16.5%)	13 (14.6%)	
	Median (25, 75 interquartile range)	**Median (25, 75 interquartile range)**	
Number of weeks since registration	68 (34, 84)	63 (31, 80)	.33

[1] 2 missing values
[2] 6 missing values

Comparing email prompts with text message prompts on promoting engagement with HeLP-Diabetes

Results of the Fisher's exact test showed that there was no difference between the two arms on promoting visits to HeLP-Diabetes (P =0.49). Logistic regression was not conducted as there was no significant difference between the arms in terms of HeLP-Diabetes visits and baseline variables were balanced between them.

Table 16: List of results of Trial 1 and Trial 2

Trial 1	Arm 1-Email with news and research article (n = 143) N(%)	Arm 2-Email without news and research article (n = 136) N(%)	*P*-value
Visits to HeLP-Diabetes	4 (3%)	5 (4%)	0.74
Email opens	48 (34%)	40 (29.4%)	(X^2 (1, N = 279) = 0.55, P =0.45)
Email opens and visiting HeLP-Diabetes within each arm	4 (8%), (P = 0.01)	5 (13%), (P =0.002).	
Trial 2	**Arm 1-Email (n = 91) N(%)**	**Arm 2-Text message (n=89) N(%)**	***P*-value**
Visits to HeLP-Diabetes	3 (3%)	5 (6%)	0. 49

6.6 Discussion

6.6.1 Principal findings

The results of both Trials 1 and 2 showed that prompts in general were not associated with visits to HeLP-Diabetes. Trial 1 showed that there was no association between sending a prompt with new content and visiting HeLP-Diabetes. However, there was a significant positive association between opening prompts and visiting HeLP-Diabetes within the different arms and across them, with no difference between them in terms of opening or visiting. In addition, Trial 2 did not find any difference on number of visits to HeLP-Diabetes between sending an email or text message prompt.

The results of Trials 1 and 2 might be due to many reasons related to the intervention, the design of the trial and its sample size. Although, the latter could be a primary reason as the samples for both trials were underpowered. Also, there might have been no true effect of content or mode of delivery of prompts on engagement and the results in Chapter 5 might have been due to other reasons.

6.6.2 Fit with literature and previous research

Adding new content or updates seemed to promote engagement in one study (Schneider et al., 2013b), and this was one type of preferred content for patient representatives in the think aloud interviews outlined in Chapter 5, Section 5.5.2. However, one of the main differences between Schneider., et al (2013b) and this study was that in this study, the email prompt was not the first prompt users had ever received, hence, the results of Schneider., et al (2013b) might have been due to novelty of the prompt rather than the inclusion of the news and updates (Schneider et al., 2013b).

As for results of Trial 2, the hypothesis was that email prompts would result in more visits than text messages. This hypothesis was based on the results of the analysis of usage data described in Chapter 5, which showed that 48.7% of email prompts were associated with visits to HeLP-Diabetes while none of text messages were associated with visits. The difference in results in Chapter 5 between emails and text messages might have been due to reasons other than modality such as topic of prompt.

6.6.3 The intervention

In Trial 1, choosing news and a research article as the content to test in a randomised trial was justified as it was the most feasible, evidence-based and long-term applicable option for email prompt content. It is feasible, unlike other content such as health authority references, as this content can originate from sources such as peers or can be more than just health advice (i.e. events or

recipes). Choice of content for this trial was based on evidence derived from the systematic review and think aloud interviews within this thesis context. Finally, adding news and updates is applicable in the long-term, as eHealth researchers need to develop eHealth strategies that will work in the future, not only in the present (Baker et al., 2014). News, research and HeLP-Diabetes updates are an ongoing process. Prompts can direct users to these new content, especially when it comes to patients who have had Type 2 Diabetes for some time as they are more interested in new information whether it is research or updates to the intervention they are using (see chapter 5)

There is a chance that the title of the prompt is more important than the content, with the title being what makes users more likely to open an email prompt. For both prompts in this study, the title was the same.

As for Trial 2, comparing emails with text messages was expected to show a difference on the number of visits to HeLP-Diabetes. Accessing HeLP-Diabetes would have been easier for users checking emails rather than text messages (i.e. accessing HeLP-Diabetes would be easier using the link included in the email, especially if users do not own a smartphone) but no significant difference was shown.

6.6.4 The trial

The five days follow-up period for both trials was based on the analysis of the time period when 75% of HeLP-Diabetes visits occurred after an email prompt was sent (see Chapter 5, Section 5.4.2); thus, the rest who did not visit HeLP-Diabetes within a period of five days would have been excluded. However, if the period was longer then the chance of counting visits not related to the effect of the prompts might have been higher.

The trials were underpowered as the sample size was small, and the effect size of the prompt showed a borderline small effect in the systematic review (Chapter 2); thus, a bigger sample size might have shown a significant effect.

Participants in Trial 2 were also included in Trial 1, and receiving two prompts within a two-week period might have had an effect on their engagement.

I decided against including a washout period before conducting the trials after discussion with the team and a statistician. Each prompt sent whether within the trials or before them was treated as a separate intervention and its effect was examined while the registration period of the users was adjusted for (i.e. the length of registration was an indicator of how many prompts a user received, the longer a user is registered the more prompts he/she has received).
The follow-up period of the trials can be labelled as short-term follow-up periods that do not detect change over time. However, the aim of this study was to test the effect of prompts' specific characteristics rather than the effect of prompts on engagement over time.

6.6.5 Implications for future research

The study, although not conclusive, does provide questions that can be answered in future research. Future studies can look at the effect of other types of content as identified in Chapters 2, Section 2.5.6 and Chapter 5, Section 5.5.2, other types of delivery modes such as telephone calls, or could replicate the prompts in this study but in a larger sample and for a longer period. This study can be replicated using a bigger sample size of HeLP-Diabetes users (e.g. when the HeLP-Diabetes trial concludes), thereby providing a sample size sufficiently powered to detect an effect. Although, as the current study did not show an effect, it could be argued that this might be unethical and a waste of resources; however, the time needed to conduct the trial was relatively short compared to other trials and there was not any cost involved, such as payment for nurses to follow-up patients or recruitment of patients using incentives.
Another important element that needs to be considered for future research is to interview a sample of the participants' post-trial to explore their views on the prompts they received.

The design of this trial is a feasible option for testing future engagement promoting prompts; the follow-up period has to be relatively short in order to exclude non-prompt related visits to HeLP-Diabetes, outcome measures are objective and the expenses for conducting the trial are relatively low in terms of time and resources.

Although the results of this study were not conclusive, the association between opening email prompts and visiting HeLP-Diabetes, regardless of the difference in content of both email prompts, suggests that the title of email prompts might be one of the reasons behind this association as the title of an email can influence the recipient's decision to read the content or not (Wainer et al., 2011).

6.6.6 Strengths and limitations of the study's methodology

The main strength of this study is that the intervention and methods are based on previous studies conducted within the context of this PhD. Bias was taken into consideration by avoiding as much as possible the bias pitfalls that were evident in the studies identified by the systematic review (Chapter 2, Section 2.5.9). I used a software-based randomisation that resulted in trials with no significant difference between baseline variables; I included objective outcome measures that are highly unlikely to be influenced by human error; and ensured completeness of data collection, unlike outcomes generated through questionnaires.

The major limitation is the low sample size, as this might have been the biggest cause of no observed difference in effect in both trials. Another possible limitation related to participants is the non-generalisability of the study to HeLP-Diabetes users living outside of London, as the participants included were those recruited through London Boroughs only. However, time constraints did not allow the inclusion of HeLP-Diabetes trial participants who were recruited from different parts of England.

An ethical concern is the randomisation of participants to different prompts without their explicit consent; this, however, could be justified by the fact that the participant had agreed to receive emails and text messages, and could unsubscribe to the prompts whenever they wanted, which is also the cause of slightly different numbers in the different arms of the trials. Also, the prompts were unlikely to cause any harm.

6.6.7 Final thoughts and lessons learned

If time and recruits allowed, a factorial RCT design might have been suitable to test the different content identified in the think aloud study (see Chapter 5, Section 5.5.2) and the systematic review (see Chapter 2, Section 2.5.6) or to have a single factorial RCT with the factors content (levels: news, no news) and delivery mode (levels: email, text). These type of trials allow for the testing of multiple interventions without losing power as each participant would have been independently randomly assigned to each evaluated content (factor). Moreover, a factorial randomised trial would have allowed testing any possible interaction effect between the different factors, which can show which content to match when sending the prompts (Baker et al., 2014).

I believe that email prompts to engage users of HeLP-Diabetes should continue while using other content features than just the inclusion of news, as the results from Chapter 5 shows that emails may have the potential to promote engagement. With regards to sending text message prompts, it remains unclear if they can promote engagement or not as both chapters did not show any potential.

6.7 Conclusion

There was no evidence to support inclusion or exclusion of news and a research article in email prompts, nor for prioritising the use of email or text

message prompts. Future trials could replicate Trials 1 and 2 with a bigger sample size, as well as test other prompt content and characteristics, including the effect of email titles on opening an email then visiting the digital intervention, as Trial 1 showed that email opens were significantly associated with visits to HeLP-Diabetes regardless of prompt content. The study also demonstrated the feasibility of conducting a randomised trial to test the effect of different prompt characteristics.

Chapter 7 Overall discussion of thesis

7.1 Abstract

This chapter presents the overall thesis discussion. The chapter starts with an examination of the aim and objectives of the PhD and whether they were achieved. Next, I summarise the main findings of the empirical studies that made up the thesis and highlight the overall thesis strengths and limitations. I conclude the chapter with a reflection of what I could have done differently and my personal journey through this PhD.

7.2 Aim, objectives of PhD and how they were achieved

Digital interventions are increasingly needed in health care (Murray, 2012). Their level of effectiveness is associated positively with their users' level of engagement (Hutton et al., 2011, McClure et al., 2013, Strecher et al., 2008). Engagement can potentially be optimised through the use of context-specific prompts such as emails and text messages (Eysenbach, 2005, Murray et al., 2013). The main aim of this PhD was to inform, develop and test the potential of using email and text message as prompts to optimise HeLP-Diabetes users' engagement. This aim was addressed through a series of empirical studies guided by the following four main objectives.

7.2.1 Determine the effectiveness and range of technology based engagement prompts

This objective was achieved by conducting the systematic review of randomised controlled trials (RCT) that evaluated technology-based prompts. The review included a meta-analysis of the effectiveness of using prompts compared with not using them and described the different characteristics of the included prompts (Chapter 2).

7.2.2 Identify the methodological and practical challenges of developing engagement prompts and integrating them with a digital intervention

This objective was achieved by describing the thesis methodology in Chapter 3, including choosing HeLP-Diabetes as the context of the prompt and following the Medical Research Council (MRC) framework for complex interventions to develop and test the impact of the prompts.

7.2.3 Identify the characteristics of prompts, specifically the content and delivery mode, that have the potential to promote engagement with HeLP-Diabetes

My original objective was to explore the acceptability of, and preference for, engagement prompts among HeLP-Diabetes users through semi-structured interviews. However, this was not possible due to difficulties recruiting participants, as described in Chapter 4. Hence, the objective was changed to identifying and exploring the delivery mode and content of prompts that have the potential to promote engagement with HeLP-Diabetes. This objective was achieved through the analysis of both quantitative and qualitative data for content of prompts and quantitative data for prompts' delivery modes.

7.2.4 Test the potential impact of prompts on engagement with HeLP-Diabetes

This objective was addressed by undertaking two pilot RCTs that tested the effects of different content and delivery modes of prompts on engagement with HeLP-Diabetes. I was not able to test other characteristics of prompts due to time constraints, and the context of HeLP-Diabetes facilitated the study of two characteristics only. I was also limited in my sample size, which was pre-determined by the number of registered HeLP-Diabetes users. Therefore, the sample size for both prompt trials was not fully powered to reach a definitive conclusion about the effects of the tested prompt on engagement with HeLP-Diabetes (see Chapter 6).

7.3 Summary of PhD findings

7.3.1 Study 1: Systematic review of technological-based strategies to promote engagement with digital interventions

To my knowledge, this was the first systematic review and meta-analyses to evaluate the effectiveness of technology-based prompts to engage users with a digital intervention. It tentatively concluded that prompts can potentially promote engagement, with an effect size of RR = 1.34; 95% CI: 1.07 to1.67. However, it

was not possible to determine the optimal characteristics of prompts for engaging with a digital intervention such as frequency, duration, timing, content, delivery mode, sender, use of behavioural theory and tailoring. These characteristics need to be investigated in further studies to determine whether they have differential effectiveness on promoting engagement. In addition, the results of the meta-analyses have to be interpreted with caution due to the high statistical heterogeneity, small sample sizes and the lack of statistical significance in the analysis of continuous outcomes.

7.3.2 Study 2: A mixed methods study of email and text message prompts used to promote engagement with HeLP-Diabetes

This study was developed when it proved difficult to recruit participants to the semi-structured interview study to assess HeLP-Diabetes users' preferences for prompts (see Chapter 4). Thus, in order to develop prompts that were potentially acceptable to HeLP-Diabetes users and evaluate them in RCTs, usage data analysis and think aloud interviews were conducted (see Chapter 5). The usage data showed that email prompts appear to be associated with visits to HeLP-Diabetes, with 48.7% of email prompts showing a significant association between opening them and visiting HeLP-Diabetes, while text messages do not appear to show an association with visiting HeLP-Diabetes. The usage data analysis facilitated the selection of prompts to be used in think aloud interviews. The results of the think aloud interview showed that patient representatives liked emails that were clear and brief, personalised by username, included news about Type 2 Diabetes or anything related, included recommendations from health authorities, non-directive advice and were visually appealing in terms of having bold colours, pictures and bullet points.

7.3.3 Study 3: Pilot randomised controlled trials testing different prompt content and delivery modes to promote engagement with HeLP-Diabetes

This study consisted of two pilot RCTs with each trial testing a different hypothesis: the first one compared different prompt content on visits to HeLP-

Diabetes, while the second one compared an email prompt versus a text message prompt on visits. The second trial also contained a subset of users who received the prompts in the first trial. Neither trial was powered to detect an effect, as the sample sizes were small. However, the study demonstrated the process and feasibility of conducting trials to evaluate two characteristics of prompts: content and delivery modes. It was feasible to randomise participants, determine an appropriate follow-up period, and analyse usage data. Also, the first trial did suggest that opening email prompts might be associated positively with visits to HeLP-Diabetes, regardless of prompt content, but what specific content and/or delivery mode promote user engagement remains unclear.

7.3.4 Summary of overall finding of this thesis, areas for further research and issues to consider

Technology-based prompts provide one method of potentially promoting engagement (Chapter 2). These prompts are context-specific interventions; they need to be developed within a specific context to understand whether or not they can potentially promote engagement in that context. The MRC guidance is one possible method of developing and testing them (Chapter 3). The use of both qualitative and quantitative data to explore whether email and text message prompts can promote engagement within the context of a specific digital intervention showed that some emails are statistically significantly associated with engaging users of HeLP-Diabetes, while text messages showed no evidence for promoting engagement. The mixed methods study also showed that 75% of HeLP-Diabetes visits occurred within five days of receiving an email prompt, and the content of email prompts users like or dislike (Chapter 5). That mixed methods study provided the information needed to construct the arms of the pilot randomised controlled trials testing emails versus text messages, and emails with news versus those without news (Chapter 6).

The thesis highlighted the need for more studies to understand users' engagement with HeLP-Diabetes (and other digital interventions) and what they prefer when it comes to prompt characteristics (Chapter 4); to undertake a fully

powered RCT to compare different prompt content and delivery modes; to understand why none of the text messages were significantly associated with visits to help-Diabetes compared to 48.7% of emails (Chapter 5); and to explore the differential effectiveness of the other characteristics of prompts within the context of HeLP-Diabetes and other digital interventions (Chapter 2).

My experience with the research methods, developing prompts and analysing usage data provided me with first-hand experience of what issues to expect or consider when planning to research engagement prompts.

Recruitment online within a specific context needs to be considered carefully and thoroughly in terms of the methods used. One method of recruitment is not enough e.g. sending email invitations only. A longer recruitment period needs to be slotted in the research timeline, and recruitment should not commence until a solid guarantee of a large number of possible participants is provided (Chapter 4).

To understand engagement, more than one type of data and research methods should be used within a defined context. The type of data or research method to use would depend on the objective of the researcher. In the case of engagement prompts in this thesis, I needed a systematic review to evaluate the evidence base about engagement prompts and their characteristics (Chapter 2); a mixed method study done within HeLP-Diabetes (my context) combining quantitative usage data and qualitative think aloud study data to decide on what characteristics to test in RCTs (Chapter 5); and finally a pilot study to test the feasibility of a RCTs for prompts and their characteristics (Chapter 6). Each study was connected to the other studies, however I used different data and methods depending on my objectives. Hence, when a researcher is planning to study engagement, the objectives have to clarify the data, methods to be used and the context of the study. This has to be done with the understanding that one type of data or research method would not be enough to reach a full understanding of the phenomena of engagement (or

engagement prompts). A defined and clearly described context is essential for the study of engagement. A recently published paper written by researchers in the field of engagement described engagement as having two levels, a micro level which focuses on the moment to moment engagement and a macro level which includes all aspects of the wider context e.g. characteristics of digital intervention, users and targeted health condition (Yardley et al., 2016). Indeed, context according to Yardley et al (2016) is a deciding factor in what they labeled “effective engagement” as opposed to “engagement” only. Effective engagement is determined using empirical studies conducted within the context of a particular digital intervention, with the digital intervention’s aim and expected outcomes clearly defined. When this is done, engagement can be measured to determine whether it was effective (i.e. did it lead to better digital intervention-related outcomes?) or not. I have defined engagement in my PhD (see Chapter 1,Section 1.2.3), I also acknowledged that to study engagement, a specific context is essential (see Chapter 3, Section 3.4.3). The results of this thesis showed that prompts were positively associated with engagement, but not whether engagement led to positive health outcomes for users of HeLP-Diabetes. Hence, the label of “effective engagement” would need to be determined through future studies looking at whether engagement due to prompts led to users’ health improvement.

Developing prompts and analysing usage data was not a simple and straightforward process as evidenced by the list of technical difficulties in Table 6. The main lesson I learned throughout the process was that the language between developers (SoftForge in my thesis) and researchers is very different. The way the developers perceive, think and approach a problem is not the same as we would do it, thus, researchers have to be very clear about what they need and how they need it (e.g. do not write in text what type of usage data you need and in what format, rather try to illustrate it with an example). Other lessons, specific to usage data, are to ensure it is downloaded in an understandable and usable format in the testing period before the digital intervention is used on the targeted population; usage data is downloaded and

saved regularly to ensure no data is lost due to technical error. Finally, to understand that usage data alone is not enough to determine engagement or lack of it, it is a complex, messy and huge set of data that needs qualitative insight into what it shows and whether assumptions derived from it are accurate (i.e. low usage does not necessarily lead to low digital intervention effectiveness, rather users might have benefited from the digital intervention and did not need to use it again).

7.3.5 Strengths and limitations of this thesis

The individual studies' strengths and limitations are detailed in each study's chapter. This section will detail the strengths and limitations of this thesis as whole.

This thesis followed a systematic and reproducible step-by-step guide for developing prompts (MRC guidance). To achieve the aim of this thesis, I used a mixed methods approach and triangulated three types of evidence (see Chapter 3 for more details): context-free scientific evidence through published studies identified in the systematic review; context-specific scientific evidence through the mixed methods study and pilot RCTs; and colloquial evidence from experts and patient representatives' feedback on the prompts. The studies undertaken here also tested the prompts on the actual targeted population, which may make the results generalisable to populations of people with Type 2 Diabetes in similar health care systems to the National Health Service (NHS) in the United Kingdom who use digital interventions similar to HeLP-Diabetes. During the development of the prompts, I used a user-centred approach by incorporating patient representatives' feedback and comments, thus eliminating an important bias associated with eHealth research, innovation bias, which occurs when developers are focused on the innovation rather than user needs or preferences (Baker et al., 2014).

The main limitation of this thesis is not having a theoretical basis for the prompts, as this did not allow for an in-depth exploration and understanding of

engagement and the mechanism of action for prompts that might have potentially promoted engagement or did not (Chapter 5 and 6). The Behaviour Change Wheel and the COM-B Model would have provided the optimal way of selecting the most suitable Behaviour Change Techniques based on the behaviour source (i.e. Capability, Opportunity and/or Motivation) that underlined HeLP-Diabetes users' engagement. If a behavioural theory was chosen without this understanding-which could have been available from interviewing the users-it would have led to the use of an inaccurate or inappropriate theory (Kinmonth et al., 2008, Michie et al., 2014).

Another major limitation is not measuring engagement prior to sending the prompts. If visits were measured prior to sending the prompts, then their usage data compared with after sending them, it would have allowed for measuring their effect accurately. However, within the context of this PhD, in terms of time and the available sample, it was not possible to do that.

Finally, I was not able to randomise users to receiving prompts or not receiving prompts, as the HeLP-Diabetes ethics approval states that all users can receive prompts, but they cannot be excluded from receiving them.

7.3.6 Ethics

Getting ethical approval for a study that involves human participants is a pre-requisite for any type of human research study. The level of ethical approval depends on the sensitivity and intrusiveness of the research focus. The focus of this thesis was a 'safe' topic; it was not considered a sensitive topic, thus application for interviewing patients whether for the semi–structured interviews (Chapter 4) or the think aloud interviews (Chapter 5) was classified as research requiring proportionate review instead of full community review. I obtained ethical approval for conducting the studies from the relevant authorities, either the NHS or University College London depending on the location of participants' recruitment. Ethical approval was not sought for the pilot RCTs, as sending prompts was part of the overall HeLP-Diabetes ethics approval.

7.3.7 Fit with other literature and implications for research

Engagement, and specifically engaging users of digital interventions using prompts, is an emerging field of research that is rapidly gaining the interest of researchers. However, the research published about prompts show that they are associated with small to moderate levels of engagement (see Chapter 2), which fits with the results of the thesis. Most of the research focused on engagement combined prompts with other strategies for engagement or studied the effect of prompts as a whole without exploring their characteristics separately (Berger et al., 2011a, Berger et al., 2011b, Brouwer et al., 2011, Couper et al., 2010, Farrer et al., 2011, Greaney et al., 2012, McClure et al., 2013, Mohr et al., 2013, Muñoz et al., 2009, Proudfoot et al., 2012, Santucci et al., 2014, Schneider et al., 2012, Simon et al., 2011, Titov et al., 2009, Titov et al., 2013). Prompts are complex interventions consisting of several components, and they need to be studied separately. In order to do that and in conjunction with the current recommendations in the eHealth field, developers and researchers might benefit from the use of studies with small numbers of participants that target discrete and clear questions. These small studies can be used instead of large studies, as larger studies are expensive and time consuming, and their results might be out of date by the time they are published (Baker et al., 2014). By using studies with small numbers of participants, researchers might be able to answer questions such as what do users like in terms of the different prompts characteristics, and do prompts work differently across different contexts and users. For researchers using more than one prompt throughout the study period, they may benefit from treating each prompt as a separate intervention and analysing them accordingly, in order to learn more about their prompts' characteristics (see Chapter 5).

As research on engagement is in its infancy, a clear and simple definition of engagement needs to be standardised to help digital intervention developers and researchers understand the engagement behaviour of their intervention users; how to measure engagement properly; and what the usage data

demonstrates, as research have shown that the analysis of usage data may show a high level engagement but it can be misleading (Lalmas et al., 2014).

In addition, studies have shown that user engagement decreases over time (Christensen et al., 2004, Christensen and Mackinnon, 2006, Farvolden et al., 2005, Lalmas et al., 2014, Verheijden et al., 2007). However, the use of prompts and analysing them separately, as described in Chapter 5, showed that different email prompts were associated with different percentages of visits (Figure 16, Section 5.4.2), even later emails. This result could be explained in different ways: either the studies that used prompts did not use different prompt content, delivery mode or frequencies, as used in this thesis; or this difference could be attributed to HeLP-Diabetes users registering throughout the study time, so a declining trend could not have been developed, as the users increased over time.

Other questions that need to be researched include what are the factors in the context of a digital intervention that can produce effective engagement (i.e. lead to beneficial behavioural or health outcomes). Two key strategies to promote effective engagement are to tailor the intervention to users' need, motivation and personal characteristics by using a patient centred development and design process, as well as facilitating engagement using human support in any form (e.g. telephone or email contact). These two strategies were incorporated in HeLP-Diabetes (to a degree), a patient-centred design was used when developing HeLP-Diabetes to ensure the digital intervention covering the needs and preferences of Type 2 diabetes patients; and human support was facilitated in the use of prompts sent from the HeLP-Diabetes team. The HeLP-Diabetes RCT showed that users' with higher engagement were associated positively with better health outcomes, but not whether higher engagement definitely caused the improvement in health outcomes. Hence, the questions of what in HeLP-Diabetes can results in effective engagement and what is the definition of effective engagement in HeLP-Diabetes can be explored in future studies.

7.3.8 What I could have done differently?

In hindsight, I could have made some changes to the PhD protocol to facilitate the attainment of definitive results regarding the effect of prompts on engagement and users' engagement behaviour. For the latter, if there had been time to conduct qualitative interviews with participants following the pilot RCTs, instead of before them, this might have helped explain the results of these studies. In addition, if users were randomised to different email prompts when they registered, the results in Chapter 5 would have provided a clearer picture of the effect of different content on engagement.

7.3.9 Reflection on PhD and personal journey

Research is a challenging process of iteratively trying to obtain answers to research questions but facing many blocks in terms of resources and uncertainties. As a PhD student with no research experience and conducting research in a field of research still in its infancy, I have been through many challenges that made me revise my protocol and change it to what the evidence and the experts deem as the best method.

I have come to the realisation that primary research is not a simple or an easy process. It is about utilising resources and attempting to answer research questions in a different way when the original plan does not work as intended. It is about sharing and learning from other researchers' experience (even the unsuccessful ones), knowledge and wisdom, and not only published work. It is about innovation within set boundaries that ensures the production of good quality research. It is not about positive results but rigorous, transparent and reproducible methodology with strong, clear justification as to why it is essential to conduct this research; although positive results are a bonus!

With my background in community health promotion, specialised in designing health awareness campaigns, this PhD provided me with the knowledge and the honed skills to take this one step further and design behaviour change interventions that target more than people's knowledge. I was able to learn

different research methodologies and develop my skills in working with a research team on a major grant. This PhD also made me more aware of what the patients need and how to accommodate that without losing the scientific value of a research study. Most importantly, this PhD equipped me with an understanding of the major issue facing many digital interventions: that is, lack of engagement, and the different possible ways of researching this topic and developing methods to intervene and optimise it.

7.4 Conclusion

In this thesis, I used different methodologies and study designs to develop and test email and text message prompts to promote user engagement. Findings from this thesis contribute towards the literature on engagement prompts. The findings demonstrate that technology-based prompts may potentially improve engagement; prompts are context-specific interventions that need to be developed and described clearly to enable their replication and improvement in future studies. Some email prompts, within the context of HeLP-Diabetes, were associated positively with better engagement, and patient representatives identified certain content that they thought was engaging. Finally, the outcomes of the research reported in this thesis demonstrated no evidence to support the inclusion or exclusion of news in email prompts, and no evidence to support prioritising the use of email prompt over a text message or vice versa. Thus, there still remains the need to test the different effects of prompts' characteristics on engagement using larger sample sizes.

Appendices:

Appendix 1: MEDLINE Search strategy

1 Computer Communication Networks/
2 Medical Informatics/
3 Medical Informatics Applications/
4 Decision Support Techniques/
5 Educational Technology/
6 Audiovisual Aids/
7 Telecommunications/
8 Public Health Informatics/
9 Computer-Assisted Instruction/
10 Hypermedia/
11 Internet/
12 reminder system/
13 exp Telemedicine/
14 computer literacy/
15 exp Telephone/
16 exp Computers, Handheld/
17 exp Hotlines/
18 (Internet or local area network$).ti,ab.
19 (Decision tree$ or decision aid$).ti,ab.
20 (Software or software design).ti,ab.
21 (CD-ROM or Compact disk$ or cd-rom or CDROM).ti,ab.
22 (Electronic mail$ or e-mail$ or email$).ti,ab.
23 (World wide web or world-wide-web or www or world-wide web or worldwide web or website$).ti,ab.
24 (Video recording or video record$ or DVD).ti,ab.
25 (Online or on-line).ti,ab.
26 (Chat room$ or chatroom$).ti,ab.
27 (blog$ or web-log$ or weblog$).ti,ab.
28 (bulletin board$ or bulletinboard$ or messageboard$ or message board$).ti,ab.
29 Interactive health communicat$.ti,ab.
30 interactive televis$.ti,ab.
31 interactive video$.ti,ab.
32 Interactive technology.ti,ab.
33 Interactive multimedia.ti,ab.
34 (E-health or ehealth or electronic health).ti,ab.
35 Consumer health informatic$.ti,ab.
36 Virtual reality.ti,ab.
37 (surf$ adj4 web$).ti,ab.
38 (surf$ adj3 internet).ti,ab.
39 (text message$ or short message$ service$ or SMS).ti,ab.
40 (multimedia message$ or multimedia message$ service$ or MMS).ti,ab.
41 (voicemail$ or voice mail$ or interactive voice response system$).ti,ab.
42 social network$.ti,ab.
43 (m-health or mobile health or mobilehealth or mhealth).ti,ab.

44 (tele-care or telecommunication care or telecare).ti,ab.
45 (tele-health or telecommunication health or telehealth).ti,ab.
46 (phone$ or telephone$ or tele-phone$ or smartphone$ or smart-phone$).ti,ab.
47 (cyberpsychology or cybertherap$ or etherap$ or ecounsel$).ti,ab.
48 (Electronic message$ or e-message$ or emessage$).ti,ab.
49 (voice adj (response or recognition or messag$ or mail$ or service$ or system$)).ti,ab.
50 ((prerecorded or pre-recorded) and (voice$ or hotline$ or hot line$ or call$ or messag$)).ti,ab.
51 (computer$ adj3 (pocket$ or palm$ or hand-held or handheld)).ti,ab.
52 mobile device$.ti,ab.
53 digital intervention$.ti,ab.
54 (Computer$ or microcomputer$).ti,ab.
55 or/1-54
56 randomized controlled trial.pt.
57 controlled clinical trial.pt.
58 randomized.ab.
59 placebo.ab.
60 clinical trials as topic.sh.
61 randomly.ab.
62 trial$.ti,ab.
63 or/56-62
64 exp animals/ not humans.sh.
65 63 not 64
66 Patient Compliance/
67 Patient Dropouts/
68 exp consumer participation/
69 Guideline Adherence/ 70 ((patient$ or user$ or consumer$ or client$ or participant$ or people) adj5 (attrition or participat$ or adher$ or engage$ or feedback or remind$ or prompt$ or invit$ or educat$ or interact$ or retention or retain)).ti,ab.
71 or/66-70
72 55 and 65 and 71

Appendix 2: List of ongoing studies

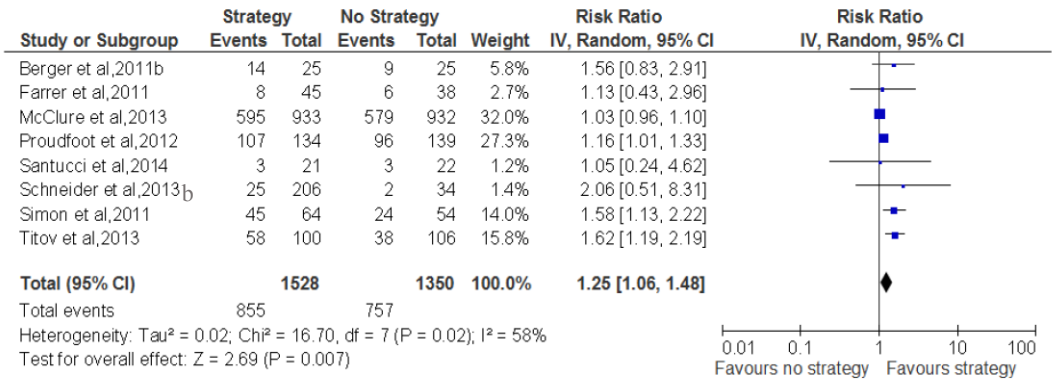
Authors	Title
Ongoing studies	
(Christensen et al., 2010)	Protocol for a randomised controlled trial investigating the effectiveness of an online e-health application for the prevention of Generalised Anxiety Disorder
(Gega et al., 2012)	Computerised therapy for depression with clinician vs. assistant and brief vs. extended phone support: study protocol for a randomised controlled trial
(Hebden et al., 2013)	TXT2BFiT' a mobile phone-based healthy lifestyle program for preventing unhealthy weight gain in young adults: study protocol for a randomized controlled trial
(Houston et al., 2010b)	The QUIT-PRIMO provider-patient Internet-delivered smoking cessation referral intervention: a cluster-randomized comparative effectiveness trial: study protocol
Conference abstract-author did not provide full text-paper	
(Kavanagh et al., 2012)	Online treatment for depressed drinkers: Is a therapist needed?

Appendix 3: Behaviour Change Techniques definitions used by study

Study	BCT	Definition of BCT by Michie et al.,(2013)
Berger et al., 2011a	• Social support (unspecified) • Feedback on the behaviour • Social reward • Feedback on outcome(s) of behaviour	**Social support (unspecified):** Advise on, arrange or provide social support (e.g. from friends, relatives, colleagues, 'buddies' or staff) or non-contingent praise or reward for performance of the behaviour. It includes encouragement and counselling, but only when it is directed at the behaviour. **Feedback on the behaviour:** Monitor and provide informative or evaluative feedback on performance of the behaviour (e.g. form, frequency, duration, intensity). **Social reward:** Arrange verbal or non-verbal reward if and only if there has been effort and/or progress in performing the behaviour **Feedback on outcome(s) of behaviour:** Monitor and provide feedback on the outcome of performance of the behaviour.
Berger et al., 2011b	• Social support (unspecified) • Feedback on the behaviour • Social reward • Feedback on outcome(s) of behaviour	See definitions above
Clarke et al., 2005	Instruction on how to perform a behaviour	**Instruction on how to perform a behaviour:** Advise or agree on how to perform the behaviour.
Couper et al., 2010	No code applicable	
Farrer et al., 2011	No code applicable	

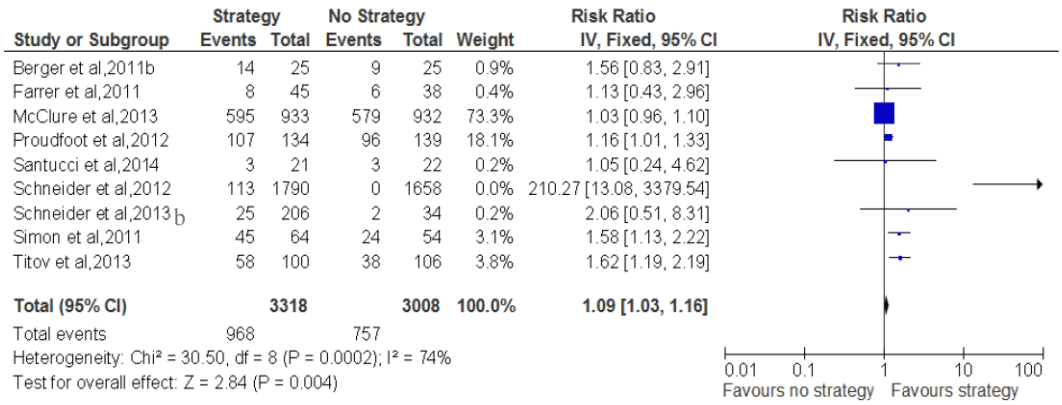
Greaney et al., 2012	Feedback on the behaviour	See definition above
McClure et al., 2013	• Social support (unspecified) • Prompts/cue	see definition above **Prompts/cue:** Introduce or define environmental or social stimulus with the purpose of prompting or cueing the behaviour. The prompt or cue would normally occur at the time or place of performance.
Mohr et al.,2013	Goal setting (behaviour)	**Goal setting (behaviour):** Set or agree a goal defined in terms of the behaviour to be achieved
Muñoz et al., 2009	Prompts/cue	See definition above
Proudfoot et al., 2012	Social support (unspecified)	See definition above
Santucci et al., 2013	Prompts/cue	See definition above
Schneider et al., 2012	Prompts/cue	See definition above
Schneider et al., 2013b	No code applicable	
Simon et al., 2011	No code applicable	See definition above
Titov et al., 2009	• Social support (unspecified) • Social reward	See definitions above
Titov et al.,2013	Prompts/cue	See definition above

Appendix 4. Analysis 1.3. Comparison engagement strategy vs.no engagement strategy, dichotomous outcomes-sensitivity analysis-removing Schneider et al. 2012

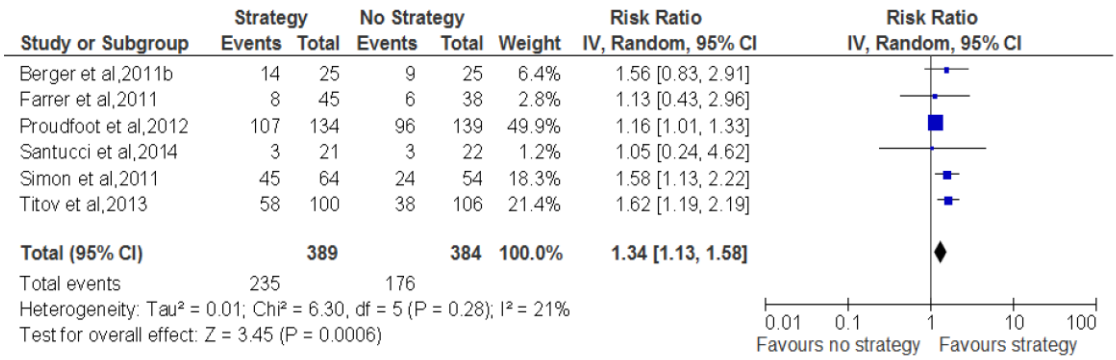


Appendix 5: Data and Analysis- additional data analysis figures:

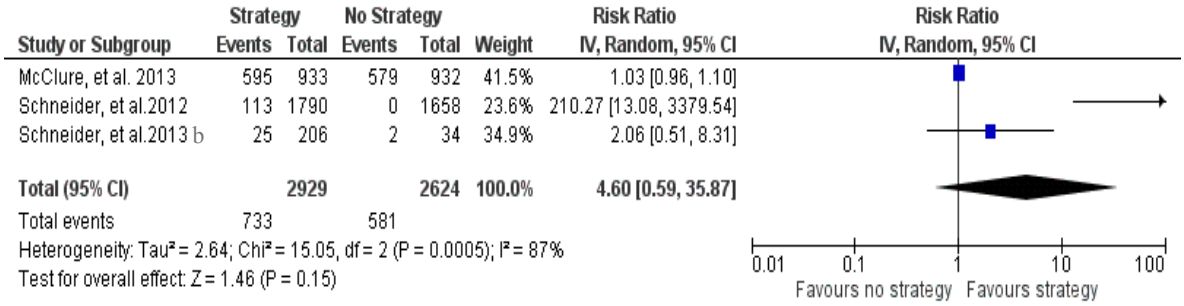
Analysis 1.4. Comparison engagement strategy vs. no engagement strategy, Outcome-dichotomous engagement measures (fixed effect model)



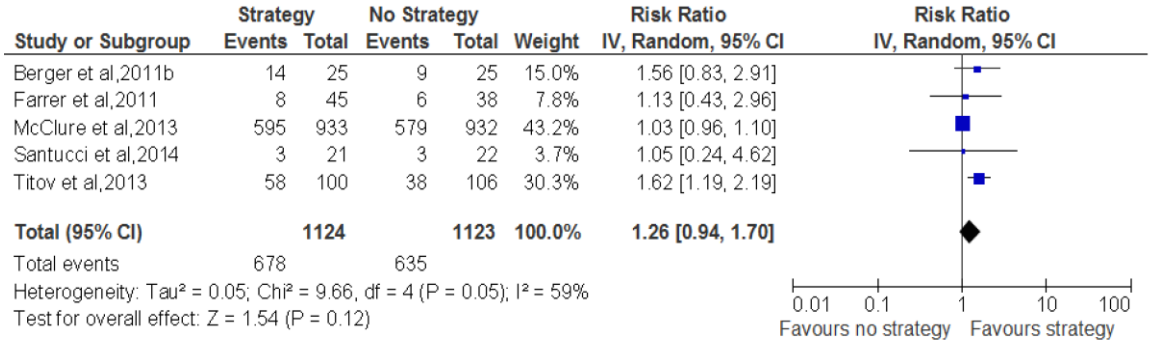
Analysis 1.5. Comparison engagement strategy vs. no engagement strategy - Outcome dichotomous engagement measures - Sensitivity analysis, removing non-mental health-targeted DIs



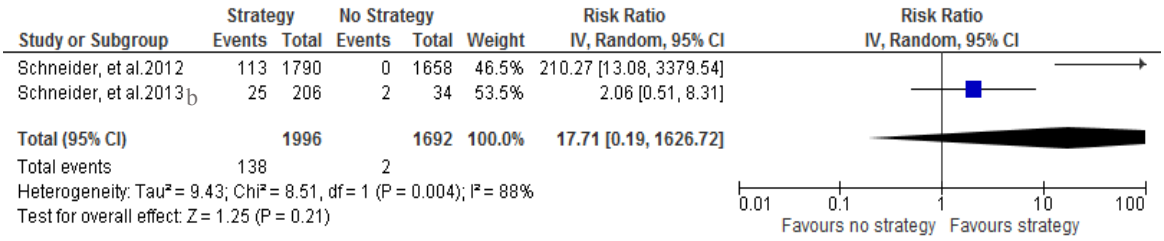
Analysis 1.6. Comparison engagement strategy vs. no engagement strategy - Outcome dichotomous engagement measures - Sensitivity analysis, removing non-health behaviour-targeted digital interventions



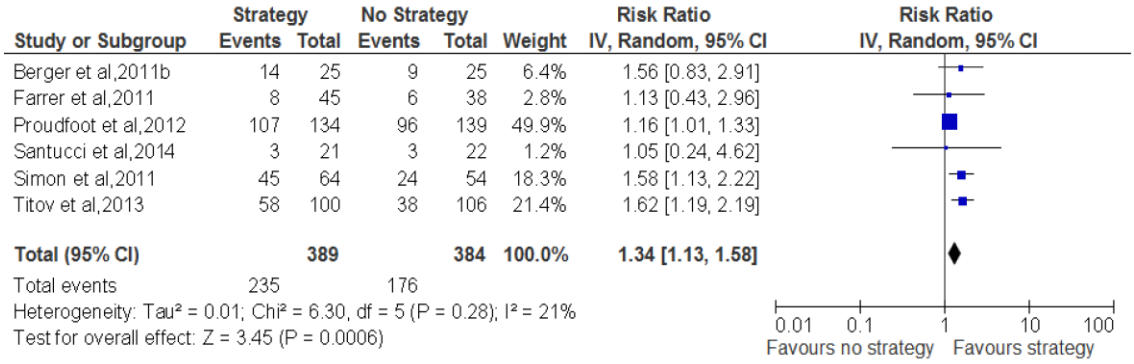
Analysis 1.7. Comparison engagement strategy vs. no engagement strategy - Outcome dichotomous engagement measures -Sensitivity analysis, removing strategies not used at least once a week



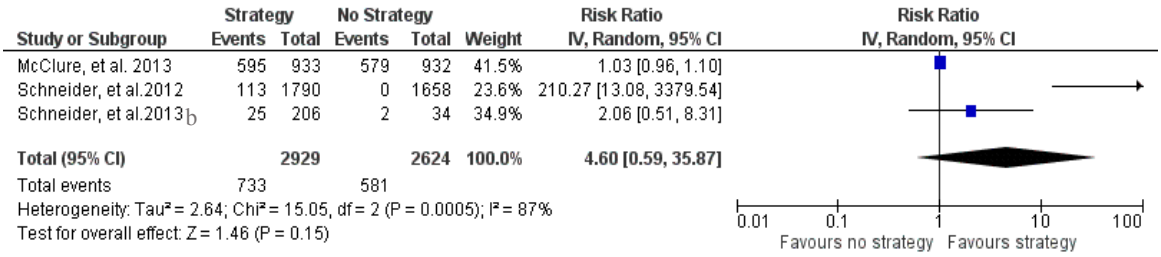
Analysis 1.8. Comparison engagement strategy vs. no engagement strategy - Outcome dichotomous engagement measures - Sensitivity analysis, removing strategies not used once



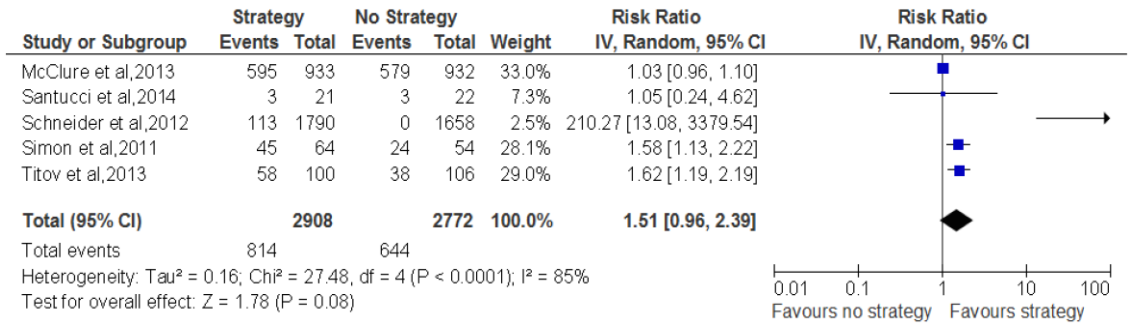
Analysis 1.9. Comparison engagement strategy vs. no engagement strategy - Outcome dichotomous engagement measures - Sensitivity analysis, removing strategies not used for the duration of the DI



Analysis 1.10. Comparison engagement strategy vs. no engagement strategy - Outcome dichotomous engagement measures - Sensitivity analysis, removing strategies not used for specific intervals



Analysis 1.11. Comparison engagement strategy vs.no engagement strategy - Outcome dichotomous engagement measures - Sensitivity analysis, removing strategies that were not coded as prompt/cue



Appendix 6: Screenshot of HeLP-Diabetes home page

Appendix 7: Invitation email

e-Health Unit
UCL Research Department of Primary Care & Population Health
Upper 3rd Floor, Royal Free Campus
Rowland Hill Street
London NW3 2PF

Evaluating the patient-led rollout of HeLP-Diabetes
PhD Research Project-Researcher: Ghadah Alkhaldi

Dear [Username]
Thank you for registering to use HeLP-Diabetes. We hope you find it useful and helps you lead a happy, healthy life. We are always trying to improve the website and the experience people have when using it. Would you be interested in helping us do this?

If so, please email us at ghadah.alkhaldi.12@ucl.ac.uk, if you prefer to contact us by phone, please call 020 7794 0500 on extension 31399.

Helping us will not take much of your time. You have been given access to HeLP-Diabetes through a pilot scheme in Lambeth and Southwark. We want to know what you think about HeLP-Diabetes use and how it can be improved. We'll also ask you some questions about engaging with the website. If you do offer to help us, a researcher from UCL (Ghadah Alkhaldi) will send you more details about what would be involved. Once you've had a chance to read this information, you will be asked to decide whether to help us or not, and you can

change your mind at any point and this won't affect your care or your ability to use the website.

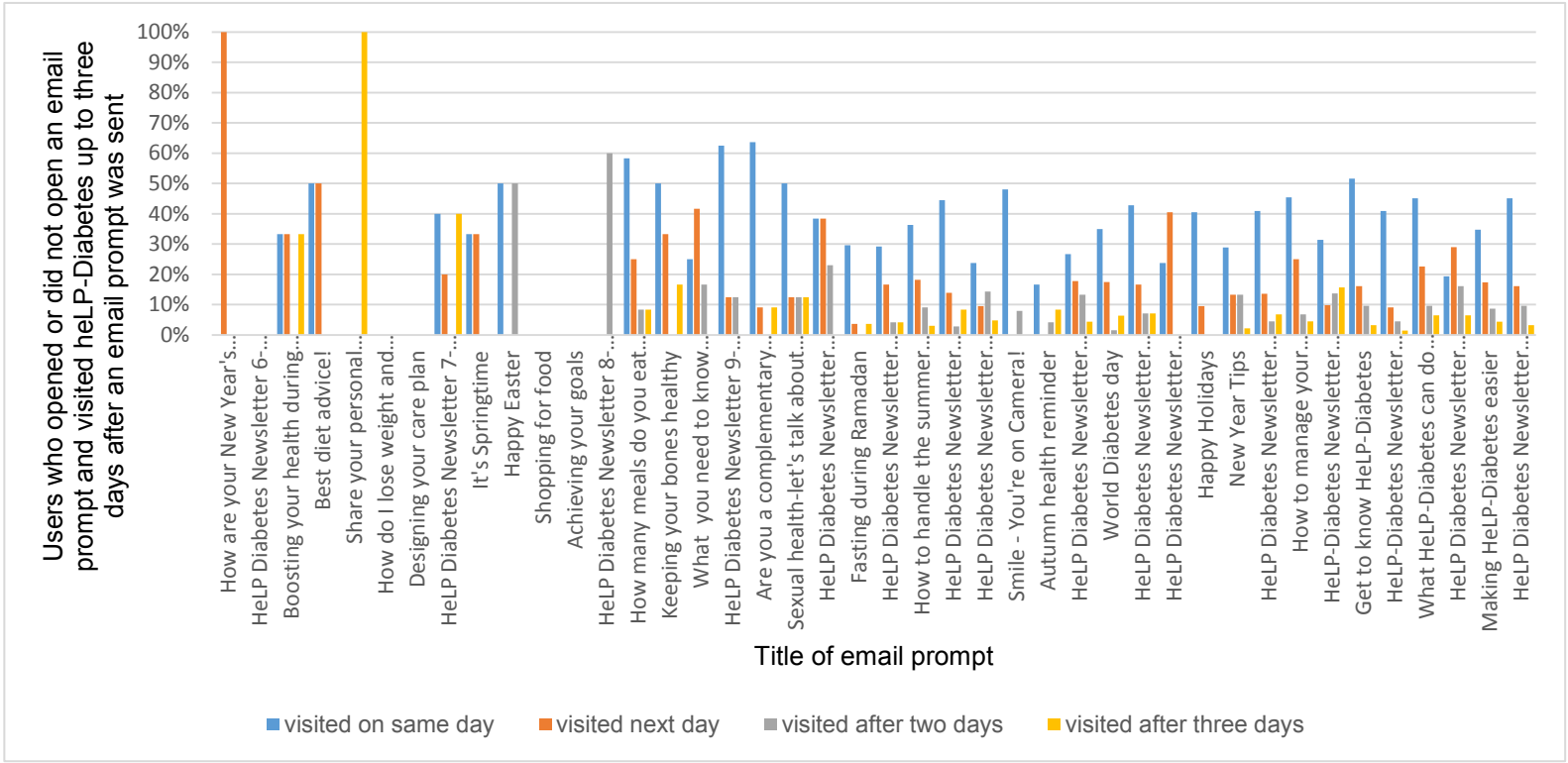
We hope you will want to help us. HeLP-Diabetes is as good as it is because of the input from lots of people like you who have diabetes. Help us make it even better!

With best wishes
HeLP-Diabetes Team

Appendix 8: Email prompt analysis steps:

1. I opened data set number 2 and sorted the data according to the earliest sent date.
2. I selected the specific email prompt and sorted information about who opened the email prompt and when by user identification number.
3. I opened data set number 1 and sorted the data by user identification number to allow for matching the data sets by identification numbers in step 5.
4. I selected the time period for when the specific email in step 1 was sent until the date of the next email prompt, which provided data about all users who visited HeLP-Diabetes from the day the email prompt in step 2 was sent till the day before the next email prompt was sent.
5. I merged the files produced from step 2 and 4 and users who have not received the email prompt in the period specified in step 2 were deleted (e.g. users who registered on the day after the email prompt was sent and visited HeLP-Diabetes before the next email prompt was sent).
6. I produced graphs and tables.

Appendix 9: Percentage of users who opened or did not open an email prompt and visited HeLP-Diabetes up to three days after an email prompt is sent



Appendix 10: Text message prompt analysis steps:

1. I selected the time period from when the text message was sent until the day another prompt was sent either email or text message (done manually for each text message prompt).
2. I downloaded data set number 4 and identified unsubscribed user identification numbers, then sorted the users' registration date and identification numbers to be matched in the following steps. The reason for using this data set although I did not use it in the email prompt analysis was to have the correct user identification numbers for both groups, those who subscribed and unsubscribed to text message prompt.
3. I matched the registered identification numbers with data set number 3 then sorted by identification number and divided to subscribers or non-subscribers.
4. I downloaded data set number 1 and restricted to the period between the text message prompt being sent and the date until the next prompt whether email or text message is sent.
5. Then I merged the files produced from step 3 and 4 and produced graphs and tables.

Appendix 11: Email prompts used in think aloud interviews

How to handle the summer heat?

This email contains graphics, so if you don't see them, view it in your browser

HeLP Diabetes™ Healthy Living for People with type 2 Diabetes

Dear Ghadah,

Summer brings with it sunshine and warmth but sometimes the weather becomes very hot ...

So we wanted to remind you of some tips to help you protect yourself from any complications due to the heat wave…

- Keep hydrated. Maintain your blood glucose levels under control especially in summer as high blood glucose levels (otherwise called hyperglycaemia) lead to urinating more frequently. Make sure you check your blood glucose levels constantly if it is very hot or if you're feeling unwell. To learn how to keep hydrated, visit the *hyperglycaemia* section.
- Exercise in the cool. For exercise examples, visit the *exercise videos* section.
- Look out for signs of heat exhaustion. Signs or symptoms include, sweating a lot, skin feeling clammy, fainting or feeling dizzy, feeling nauseous, rapid heartbeat or headaches. If you experience any of these symptoms, go and rest in a cool place, drink lots of fluids and seek medical care if necessary.
- If you take insulin, make sure you store it in a cool and dry place.

If you have any tips for keeping cool during summer you could share them with the rest of the website members in the *forum*.

Best wishes,
The HeLP-Diabetes Team

HeLP-Diabetes Newsletter 12- Your diabetes is in your hands

Problems reading the newsletter? View it online .

HeLPful NEWS

HeLP Diabetes

Healthy Living for Peop
with type 2 Diabetes

Stories, research evidence & ideas for a happier & healthier l

Hi Ghadah

August 2014
Studies have shown that people who know more about diabetes and how to manage it have better control of their blood glucose levels and develop fewer complications.

TIP OF THE MONTH

You are the most important person of your diabetes team in managing you diabetes.The things you choose to do will have a much bigger effect on you diabetes than those anyone else can do for you

There are certain skills that can help you improve your diabetes management.

- understand exactly what diabetes is and how it can affect you. To read more abc this, visit the section on understanding diabetes.
- stay optimistic and have confidence in your ability to manage your diabetes. Lea more by visiting our happiness and well-being and confidence pages.
- try to work through negative emotions such as guilt or denial. The pages on guilt and denial provide you with tools and tips that can help you manage these emotions.
- don't be afraid to ask for support when you need it from others; whether that be family member, friend, health professional or someone else with diabetes. To rea more about this, take a look at our support newsletter.

Tool

Have you used the diabetes care plan ?

The care plan provide you with lots of tools to manage your diabetes including, a tool help you keep track of your appointments, set goals and plans to manage your diabet and a list of your yearly medical reviews.

Give it a go and tell us what you think in the forum or by replying to the newsletter.

Video

You may find it useful to watch the three minutes video on learning to self-manage you diabetes in the what is self-management section.

Here you will find discussions between people living with diabetes and doctors on the most important aspects of self-management.

NEWS

Combining aerobic and strength training is best for your blood glucose levels

- A study found that aerobic and resistance training were both useful in reducing HbA1c in a population of people with type 2 diabetes.
- Looked at individually, aerobic training appeared to be the more effective of the t types of training.
- However, the study found that, compared with aerobic or resistance training, combining the two types of training resulted in improvements in their control of th blood glucose levels.

To read more about this study, visit the news and research section

NEWS

Can Metformin help people live longer?

- Researchers looked at a very large sample of UK patient data and compared rat of survival between two groups of people living with diabetes type 2 (those on metformin or sulphonylureas) and carefully-matched patients who did not have ty 2 diabetes.
- Surprisingly, the type 2 diabetes group who were given metformin appear to hav rate of survival which is "at least as good" as the matched patients who did not have type 2 diabetes.

To learn more about what this study means for you if you are taking metformin or sulphonylureas, visit the news and research section

Member spotlight

One of our users has been very pro-active in looking after his diabetes, and has recorded his food intake and weight loss every day in the forum. He has lost an impress 19lb and his blood glucose levels are mostly within the normal range. Well done!

Take a look at his journal and share your thoughts and experiences in the forum.

TELL US WHAT YOU THINK

We'd love to hear your views on our newsletter. If you have any suggestions on how w could improve it, or any ideas for future editions.

Please email us at help-diabetes@ucl.ac.uk or leave us a message in our forum. We l forward to hearing from you.

Best wishes
The HeLP-Diabetes team.

Whittington Health NHS UCL

HeLP-Diabetes is a research team at University College London (UCL) that has been funded by the government to create a self-management programme specifically for peo with type 2 diabetes. The aim of the programme is to help people look after themselves take control of their diabetes so they can live healthier and happier. Read more about th HeLP-Diabetes team.

Unsubscribe from this newsletter

HeLP-Diabetes Newsletter 13- Get rid of your medication worries!

Problems reading the newsletter? View it online .

HeLPful NEWS

HeLP Diabetes2

Healthy Living for Peop
with type 2 Diabetes

Stories, research evidence & ideas for a happier & healthier l

Hi Ghadah

September 2014

We often hear about or get offered new medications. This can make us feel anxious for several reasons.
This newsletter will explore such concerns and introduce some tools that you might find useful for dealing with any worries you might have about taking your medicines.

TIP OF THE MONTH

Recognising your concerns is the first step to controlling your anxiety.

Some of the common questions about medications include the following:

Will I ever be able to stop treatment?

Sometimes it is possible to stop or reduce your dose of diabetes-related medicines; fo example, if you lose a substantial amount of weight or get much fitter. We also know th living healthily can delay the need for medication.

However, diabetes is a long-term condition, which means that most people eventually take several medicines to help manage their diabetes and their overall risk most effectively.

I have heard worrying or conflicting reports about my medication in the news an don't know what to do?

Before deciding to make any changes to your medication dose or stop taking it, seek medical advice and discuss your concerns with your doctor or your diabetes care tean as some news articles will not be applicable to you.

For example, some news articles report studies that might not have come to a conclus yet or those with results that apply to very specific groups of people.

To look at examples of news and research done on diabetes and medication, visit the news and research section.

If you can relate to any of these concerns, visit our page on concerns about taking medication where you'll find questions about taking medications and advice on what y can do to reduce your worry about taking them.

Also, If you have questions about specific medications such as how to take them; wha the side effects are; can you drive while taking them; take a look at the list of medicatic categories on the right-hand side of the medicines section and choose the category you're interested in.

For example if your questions are about metformin (a type of medication used for bloo glucose control), visit the glucose control page and click metformin .

Tool

Do you have trouble remembering to take your medication? If so it might help to desig 'medicine plan' to keep track of your medicine doses and when to take them.

Visit the medicine planner and start recording your medication to help you keep track those which help control blood glucose, blood pressure and cholesterol.

Video

Many people living with diabetes type 2 are prescribed oral medication to control their blood glucose, blood pressure and cholesterol levels.

In the people's stories section, you will find people sharing their stories of how they started taking them and the side effects they experienced and how they managed tho effects.

NEWS

NICE considers expansion of weight loss surgery

- New draft guidelines from the National Institute for Health and Care Excellence (NICE) recommends that people with recently diagnosed type 2 diabetes with a of 35 or more can be offered an assessment for bariatric surgery.
- Those who might be at particular risk of diabetic complications, such as people c Asian origin, might be assessed if they have a lower BMI.

To learn more, visit the news and research section

TELL US WHAT YOU THINK

We'd love to hear what you think of our newsletter, if you have any ideas on how we could make it better or any suggestions for future editions, please email us at help-diabetes@ucl.ac.uk or leave a message in our forum. We look forward to hearing from you.

Best wishes
The HeLP-Diabetes team.

Whittington Health NHS UCL

HeLP-Diabetes is a research team at University College London (UCL) that has been funded by the government to create a self-management programme specifically for peo with type 2 diabetes. The aim of the programme is to help people look after themselves take control of their diabetes so they can live healthier and happier. Read more about th HeLP-Diabetes team.

Unsubscribe from this newsletter

Autumn health reminder

This email contains graphics, so if you don't see them, view it in your browser

HeLP Diabetes™ Healthy Living for People with type 2 Diabetes

Dear Ghadah,

Autumn has arrived. It's time to embrace leafy city strolls and country getaways but don't forget autumn is also the start of the flu season…

You can help prevent getting flu this autumn by contacting your GP practice to check if you can get a free flu jab (otherwise known as a flu vaccine).

It is recommended by the Department of Health that everyone with diabetes should have a flu vaccine annually.

Even if you had a flu vaccine last year, you will need another this year because the virus is constantly changing.

Sometimes people worry that having the vaccine will give them the flu. This is not possible because the vaccine consists of a "killed virus" meaning the flu virus is dead before it's put into the vaccine. The virus doesn't make you ill; instead it teaches your immune system how to recognise the live flu virus and how to fight the live virus if it does find its way into your system.

If you'd like to read more about flu and diabetes, please visit the *flu vaccine* page.

Also if you have any tips for preventing coughs and colds, share them with the rest of us in the *forum*!

Best wishes,
The HeLP-Diabetes Team

Not interested any more? *Unsubscribe*

HeLP-Diabetes Newsletter 14- What's happening this October?

Problems reading the newsletter? View it online .

HeLPful NEWS

HeLP Diabetes

Healthy Living for Peop
with type 2 Diabetes

Stories, research evidence & ideas for a happier & healthier l

Hi Ghadah

October 2014
October is here and lots of things are happening this month: we're saying a fond farewell to summer and looking forward to autumn with celebrations and campaigns to kick start some healthy habits

TIP OF THE MONTH

How to enjoy special occasions without over-indulging

There are many reasons to celebrate this autumn, including Halloween, Harvest Festi
Diwali, Yom Kippur, Eid and many others...

Over-indulgence on special occasions can happen to anyone so here are some tips to
help you enjoy guilt-free fun....

- Plan ahead; you could ask your host what kind of food they plan to serve and make
  your food choice ahead of time.
- Try not to attend events when you're hungry - eat something beforehand. Try not to
  starve yourself in order to over-indulge later because if you arrive hungry, you a
  more likely to overeat.
- Be careful with buffets. Decide on what you are going to have and resist the tempta
  for second helpings.

For more tips, visit the eating at celebrations page.

Tools

Two major public health campaigns are launched in October; one to encourage smoke
to stop smoking-'Stoptober'- and the other one; 'Sober October' is to help people stay
sober throughout October!

To help those of you who would like to join these campaigns, have a look at our page
smoking, and visit the alcohol section to design a personalised plan for cutting down c
alcohol.

A new look for HeLP-Diabetes

We have just updated the website based on your really helpful feedback. We hope thi
makes it easier for you to find your way around the website and discover new things.

What do you think of the changes?

Have a look and tell us what you think in the forum.

NEWS

Low carbohydrate diets may be better for losing weight

What did this study find?

- A recent US study on an ethnically-diverse sample of men and women without h disease or diabetes compared low carbohydrate and low fat diets.
- Weight loss in the low-carbohydrate diet was greater at 3, 6 and 12 months.
- After a year the low carbohydrate diet group lost an average of 3.5kg more than low fat group.
- The risk of heart attack or stroke was lower in the low-carbohydrate group.
- There were no serious side effects reported for either group.
- The authors conclude that the low carbohydrate diet was more effective than the low fat diet and that it should be an option for people seeking to lose weight and reduce heart diseases risk.

Good carb, Bad carb...

- Carbohydrates such as wholegrain foods, fruit, vegetables, beans and lentils are essential fuel for the body and can reduce the risk of hypoglycaemia (hypos).
- Carbohydrates found in sugary and processed foods like cakes and biscuits are n closely linked with weight gain and and therefore are best had in moderation.

For more information on effective ways to lose weight and reduce the risk of heart disea visit the understanding food section. For more details about this study, visit the news research section.

NEXT ISSUE

In November's newsletter we will be discussing the breaking news about a cure type 1 diabetes, so keep an eye out.

TELL US WHAT YOU THINK

We'd love to hear your views on our newsletter. If you have any suggestions on how w could improve it, or any ideas for future editions.

Please email us at help-diabetes@ucl.ac.uk or leave us a message in our forum. We look forward to hearing from you.

Best wishes
The HeLP-Diabetes team.

Whittington Health NHS UCL

HeLP-Diabetes is a research team at University College London (UCL) that has been funded by the government to create a self-management programme specifically for peo with type 2 diabetes. The aim of the programme is to help people look after themselves take control of their diabetes so they can live healthier and happier. Read more about th HeLP-Diabetes team.

Unsubscribe from this newsletter

World Diabetes day

This email contains graphics, so if you don't see them, view it in your browser

HeLP Diabetes™ Healthy Living for People with type 2 Diabetes

Dear Ghadah,

Friday the 14th of November is International World Diabetes Day and this year's theme is about healthy living and diabetes.

The three key messages of the campaign are:

- Make healthy food the easy choice- visit the *practical diet advice* section to find out more.
- Make the right choices - To be able to do this it helps if you understand your food. Visit our *understanding food* section to see how different food and drink influence our bodies.
- Healthy eating begins at breakfast time - do you have any special breakfast recipes? Please share them with us in the *forum*.

Best wishes,
HeLP-Diabetes team

Not interested any more? *Unsubscribe*

Get to know HeLP-Diabetes

This email contains graphics, so if you don't see them, view it in your browser

HeLP Diabetes™ Healthy Living for People with type 2 Diabetes

Dear Ghadah,

We talked to one of our users about what new things they learned through HeLP-Diabetes and this is what one of our users found out:

"There was one thing that was important, that I just noticed, on driving, one thing I didn't know, and really ought to have known. If one was diagnosed with Type 2 Diabetes, you tell your motor insurance. And now I've done that."

To find out more about this issue, visit the *driving* page. You can also find more information about other aspects of life and work in the *living and working with diabetes* section that is updated by health professionals regularly.

Did you find out something new through HeLP-Diabetes, tell us what it is so we can share it with the rest of the users.

Please email us on *help-diabetes@ucl.ac.uk* or post about it in the *forum*.

Best wishes,
HeLP-Diabetes team

Not interested any more? *Unsubscribe*

HeLP-Diabetes Newsletter 20- What can you eat?

HeLPful NEWS

HeLP Diabetes™

Healthy Living for People with type 2 Diabetes

Stories, research evidence & ideas for a happier & healthier life

April 2015

Hello Ghadah Alkhaldi,

Do you constantly ask yourself what can you eat?
Well, let us help you find food that you enjoy *and* keeps you healthy.

A Balanced Diet

The eatwell plate is a good place to start. To make sure you get the right balance of the 5 different food groups try to eat:

1. A variety of fruit and vegetables each day, including pulses. They are rich in vitamins and minerals, high in fibre and low in fat.
2. Some milk and dairy products. If you are trying to cut down on fat, consider choosing lower-fat milk and dairy products.
3. Some meat, fish, eggs, beans and other non-dairy sources of protein. Meat can be high in saturated fat that raises cholesterol levels so choose leaner cuts of meat and remove visible fat from meat and skin from poultry before cooking.
4. Wholegrain starchy carbohydrates, as they are high in fibre - for example try granary, seeded or rye bread instead of white bread, or brown rice instead of white rice. Beans and pulses are also a high fibre source of carbohydrate and offer a healthy alternative to potatoes, rice and pasta.

5. Try and avoid foods or drinks that are high in fat and / or sugar, such as fizzy drinks, cakes and sweets. These foods can be enjoyed occasionally as part of a healthy balanced diet, but try not to have them too often.

The eatwell plate can help you to decide on the proportions of different types of food to give you the vitamins and minerals you need.

But depending on your individual requirements, you may want to adjust the proportions - for example if you are trying to lose weight or lower your blood glucose levels, reduce the amount of carbohydrate and increase the amount of vegetables on your plate.

There are other types of diet that you might like to try - like a Mediterranean diet, low carbohydrate diet or low calorie diets.

We have added a new page on the website looking at the evidence for these different diets.

We also have very exciting news!

An experienced dietician just joined the HeLP-Diabetes team and she will be very happy to answer any questions you have about food and eating. Or give you suggestions for healthy and tasty recipes.

All you have to do is visit the questions I would like to ask a dietician thread in the forum and post your questions there.

NEWS- Exercise of any kind can reduce waistlines

What did the study find?

- Regular low-intensity exercise might be as good as high intensity in helping obese people lose weight.
- All of the exercise groups reduced their weight compared with the no exercise control group.
- On average, all groups showed the same changes in waist circumference:– 4.6 cm at 24 weeks.

Visit the news & research for more information about what this study means to you.

TELL US WHAT YOU THINK

We'd love to hear what you think of our newsletter, if you have any ideas

on how we could make it better or any suggestions for future editions.

Please email us at help-diabetes@ucl.ac.uk or leave a message in our forum. We look forward to hearing from you.

Best wishes
The HeLP-Diabetes team.

HeLP-Diabetes is a research team at University College London (UCL) that has been funded by the government to create a self-management programme specifically for people with type 2 diabetes. The aim of the programme is to help people look after themselves and take control of their diabetes so they can live healthier and happier. Read more about the HeLP-Diabetes team.

Unsubscribe from this newsletter

Making HeLP-Diabetes easier

This email contains graphics, so if you don't see them, view it in your browser

HeLP Diabetes™ Healthy Living for People with type 2 Diabetes

Dear Ghadah,

HeLP-Diabetes is a website with the latest research about type 2 diabetes. You can also find answers to any questions you have about type 2 diabetes and it can help you manage your condition.

We want you to benefit as much as possible from using HeLP-Diabetes so here are some tips to get you going.

1.to protect your personal information *HeLP-Diabetes* needs a username and password to login. You can also login by using your email address as your username. If you have forgotten your password, go to the *lost password* page.

2.once you enter your username and password, you can visit any page, watch any video and use any tool on HeLP-Diabetes. For example, you can start with general information from the *Quick Guides* in the *Understanding diabetes* section. Or for specific information on treatment options for type 2 diabetes – including newer treatments like SGLT2 inhibitors and gliptins - visit the *Treating diabetes* section.

3.if you have a problem with watching the videos visit the *FAQs: Using HeLP-Diabetes* page which has instructions on how to install Flash player. If you have other question not included on this page, post them in the *forum*.

4.most importantly, choose a time and place where you can browse HeLP-Diabetes at your leisure. We're sure you'll find information you didn't know before - some of our users told us they weren't aware they had to notify their *motor insurance* company of their diabetes. Or you might find tools that really help - one of our users told us they loved sending free text reminders to do some simple exercises to their phone using the *my reminders* tool.

We really hope that you find using HeLP-Diabetes easy and worthwhile, but if you have any suggestions to improve it, don't hesitate to post them in the *forum*.

Best wishes,
HeLP-Diabetes team

Not interested any more? *Unsubscribe*

Appendix 12: Participant information sheet and consent form

PARTICIPANT INFORMATION SHEET
Email prompts to promote engagement with HeLP-Diabetes: patient representatives' perspective
PhD Research Project-Researcher: Ghadah Alkhaldi

You are being invited to take part in our research study. Before you make a decision, it may help to understand why the research is being done and what it would involve for you.

What is the study, and why are we doing it?
We believe that patients should be involved in every aspect of diabetes care and that includes activities like research. You have been an extremely helpful member of the patient representatives group in assisting the HeLP-Diabetes team in the development and improvement of its services. Part of the HeLP-Diabetes programme is the use of email prompts to encourage users of the website to revisit and use it more (i.e. engage more). We would like to show you some of those email prompts and get your opinion about them, we hope that this will help us understand how we can improve them in the future. This study will form part of a PhD thesis.
Why have I been invited?
We are inviting people who have been involved in the development and improvement of HeLP-Diabetes. We want to hear as many views as possible, as this will help us get a more complete picture of what characteristics of these email prompts made users of HeLP-Diabetes engage more or disengage.
Do I have to take part in this UCL study?
No –taking part will make no difference to your involvement and work with the HeLP-Diabetes team. You can use HeLP-Diabetes and work with the team whether or not you take part. If you do decide to, you can let us know by: **emailing us** on this address: Ghadah.alkhaldi.12@ucl.ac.uk or **calling us** on this number: 02077940500 ext: 31399.

What would I have to do if I do take part in this UCL study?
If you do decide to take part, this is what will happen:

- The researcher will contact you to arrange a time and place to meet with you that suit both you and the researcher for a one-to-one interview.
- You will be asked to sign a consent form.
- The researcher will show you some email prompts on a laptop and will ask you to say aloud your thoughts and feeling of the prompts while going through them, what you like about them, what you do not like and what do you think should be changed.
- The interview will take about 30 – 40 minutes, and it will be recorded.
- Before you decide whether to take part, it is important that you understand why the study is being done and what it will involve. Please read this

information carefully. Discuss it with others if you wish. Take time to decide whether or not you want to take part.

- It is up to you to decide whether or not to take part. Saying no will not affect your involvement and work with the HeLP-Diabetes team, your use of HeLP-Diabetes or your legal rights.
- If you agree, you will be asked to sign a consent form to confirm your participation. Even after signing the consent form you can still withdraw whenever you wish without giving any reason.
- All your personal information will be kept confidential and transcripts will be kept anonymous.
- The data will be collected and stored in accordance with the Data Protection Act 1998 and will be disposed of in a secure manner.

What will happen to the recording of my interview?

- The recording will be transcribed (typed up).
- Any information that could identify you will be removed from the transcript (written version of the recording).
- Your views, and the views of all the other people who are interviewed, will be analysed by a team of experienced researchers. This team will not know who you are, and will not be able to work it out from the transcript.

Anything else I should know?

We will give you a £20 voucher as a token of our appreciation if you do decide to take part. Also, we will reimburse you for any travel expenses.

What are the possible benefits of taking part?

Research has shown that people who use websites, particularly those containing good quality information and support, are more likely to improve their health. The views and opinions you express in this study will help us design better email prompts to encourage people to use the website more.

What if there is a problem?

- It is difficult to anticipate disadvantages to taking part in this study in advance. In seeking your opinions on email prompts for HeLP-Diabetes we think it highly unlikely that you will come to any harm. However, we will answer any concerns on this matter.
- If you encounter any problems during the study process, please contact the study manager, Ghadah Alkhaldi (details below). If she cannot help, contact the lead researcher, Prof Elizabeth Murray (details below). If you remained unhappy, you could make a formal complaint through the NHS Patient Advice and Liaison Service (PALS) www.pals.nhs.uk
- In the unlikely event that a study participant became unable to make decisions for themselves, that person would not continue in the study. Any information received before such an event occurred would be used in the study. Please let us know if you would require an alternative arrangement should these circumstances arise.

What will happen to my information in the study?

- The results of the interviews will help to inform how to improve the email prompts which are currently used to encourage users of HeLP-Diabetes to engage more with it.
- The results will also be written up and published in an academic journal. If you are interested, we can send you a summary of the results once the study is over.

- If you would like to be sent this summary, please complete the 2nd page of the consent form.

Is there an independent contact point where I can get general advice about taking part in research?

Yes. INVOLVE is a national advisory group that provides advice on public involvement in research. You can find out more from their website: www.invo.org.uk. You can contact them at: INVOLVE, Wessex House, Upper Market Street, Eastleigh, Hampshire, SO50 9FD or Telephone: 023 8065 1088

Who is organising and funding the research?

The study is run by University College London (UCL). The lead researcher is Prof. Elizabeth Murray, who is a GP and a health researcher. The study is being managed by Ghadah Alkhaldi (PhD student) and you should contact her if you have any questions. The other member of the team is Dr. Fiona Hamilton who is a GP.

Who has reviewed this study?

All research by UCL is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been given favorable opinion by UCL ethics committee (Project Identification number: **7263/001)** .

Further information and contact details

If you have any questions at all about the study or would like further information, please contact the study manager, Ghadah Alkhaldi using the contact details below.

Name	Ghadah Alkhaldi	Professor Elizabeth Murray
Role	PhD student and study manager	Chief Investigator
Tel	02077940500 ext 31399	020 7794 0500 ext 36747
Email	ghadah.alkhaldi.12@ucl.ac.uk	elizabeth.murray@ucl.ac.uk
Address	eHealth Unit, UCL Research Department of Primary Care & Population Health Upper 3rd Floor, Royal Free Hospital, Rowland Hill Street London NW3 2PF	
Fax	020 7794 1224	
Web	https://www.ucl.ac.uk/pcph/research-groups-themes/e-health	

What do I do if I wish to take part?

If you are interested in taking part in the study please fill in the **consent form** enclosed and return it via email to Ghadah.alkhaldi.12@ucl.ac.uk or contact **Ghadah Alkhaldi** using the details above**.**

THANK YOU FOR YOUR TIME IN READING

Study Number: 7263/001
Participant ID:

Email prompts to promote engagement with HeLP-Diabetes: patient representatives' perspective

PhD Research Project-Researcher: Ghadah Alkhaldi

Consent form for HeLP-Diabetes patient representatives

Please initial all boxes in this section	Initials here
I confirm that I have read and understood the participant information sheet version 1.1 dated 12.06.2015 I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
I understand that I am volunteering to be interviewed about my opinions on email prompts to engage users registered on HeLP-Diabetes.	
I understand that all the information I provide will be confidential and that I will remain anonymous.	
I understand that the information I provide will be recorded or saved on computer and used for the purposes of this research study only. I also understand that once the information has been transcribed, names and all other personal data will be destroyed in accordance with the Data Protection Act 1998.	
I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without involvement and work with the HeLP-Diabetes team, use of HeLP-Diabetes or legal rights being affected.	
I agree to take part in this study.	

*This form is to be completed independently by the participant.

Name of participant	Date	Signature
Name of person taking consent	Date	Signature

Thank you very much for taking part in the study

For any enquiries contact:
Ghadah Alkhaldi
e-Health Unit, UCL Research Department of Primary Care & Population Health
Upper 3rd Floor, Royal Free Campus, Rowland Hill Street, London NW3 2PF
Email:Ghadah.alkhaldi.12@ucl.ac.uk
Tel: 020 7794 0500 ext: 31399

If you would like us to send you a summary of the results once the study has been completed, ☐

Please tick here

Please provide your email address below

Email address: ……

This piece of paper will be stored apart from your consent form, and will not be linked to the data you provide in any way.

Appendix 13: Results of adjusted logistic regression

Title of email prompt	N[2]	OR[3]	95% CI
HeLP-Diabetes Newsletter 11-Holiday preparations	182	0.07	0.01-0.45
How to handle the summer heat?	213	0 .16	0.05-0.52
HeLP-Diabetes Newsletter 12-Your diabetes is in your hands	233	0.04	0.009-0.20
Smile - You're on Camera!	249	0.13	0.03-0.47
HeLP-Diabetes Newsletter 14- What's happening this October?	286	0.37	0.14-0.96
World Diabetes day	308	0.11	0.04-0.30
HeLP-Diabetes Newsletter 15-Shopping done the right way	333	0.12	0.04-0.31
HeLP-Diabetes Newsletter 16-Eye care	338	0.12	0.04-0.38
Happy Holidays	346	0.06	0.01-0.30
New Year Tips	348	0.04	0.01-0.20
HeLP-Diabetes Newsletter 17-Change for 2015	358	0.06	0.02-0.21

How to manage your diabetes using the HeLP-Diabetes care plan?	376	0.18	0.07-0.45
HeLP-Diabetes Newsletter 18-Alcohol, love and activity in February	390	0.09	0.03-0.28
Get to know HeLP-Diabetes	404	0.12	0.04-0.40
HeLP-Diabetes Newsletter 19- Spring, delicious recipes and dark chocolate	407	0.13	0.06-0.31
What HeLP-Diabetes can do for you….[3]	411	0.04	0.01-0.18
HeLP-Diabetes Newsletter 20- What can you eat? [3]	411	0.17	0.06-0.48
Making HeLP-Diabetes easier[3]	411	0.05	0.006-0.43
HeLP-Diabetes Newsletter 21- Mindfulness, HeLP-Diabetes and fruit sugar[3]	410	0.06	0.01-0.23

1 OR<1 not opening the email prompt is associated with lower odds of user visits to HeLP-Diabetes
2 These email prompts had lower number of participants because of missing variables.
3 Adjusted variables were gender, age groups, length of diabetes, computer knowledge, participants group and length of registration.

Appendix 14: Cochrane definition of sources of bias

Source of bias	Definition in Higgins and Green (2011)
Selection bias	"systematic differences between baseline characteristics of the groups that are compared"
Performance bias	"systematic differences between groups in the care that is provided, or in exposure to factors other than the interventions of interest."
Detection bias	"systematic differences between groups in how outcomes are determined"
Attrition bias	"systematic differences between groups in withdrawals from a study"
Reporting bias	"systematic differences between reported and unreported findings"

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