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Evaluating the implementation of *HeLP-Diabetes* within NHS services: study protocol

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Abstract

Background: Self-management by people with type 2 diabetes is central to good health outcomes and the prevention of associated complications. Structured education to teach self-management is recommended by the National Institute for Heath and Clinical Excellence; however, only a small proportion of patients report being offered this education and even fewer attend. This study aims to evaluate the implementation of a new internet-based self-management intervention: *HeLP-Diabetes* (Healthy Living for People with type 2 Diabetes) within the National Health Service. Specific objectives are to *a)* determine the uptake and use of *HeLP-Diabetes* by services and patients; *b)* identify the factors which inhibit or facilitate use; *c)* identify the resources needed for effective implementation; *d)* explore possible effects of *HeLP-Diabetes* use on self-reported patient outcome measures.

Methods/Design: This study will use an iterative design to implement *HeLP-Diabetes* into existing health services within the National Health Service. A two stage implementation process will be taken, whereby batches of General Practice surgeries and diabetes clinics will be offered *HeLP-Diabetes* and will subsequently be asked to participate in evaluating the implementation. We will collect data to describe the number of services and patients who sign up to *HeLP-Diabetes*, the types of services and patients who sign up and the implementation costs. Semi-structured interviews will be conducted with patients and health professionals and cohorts of patient participants will be asked to complete self-report measures at baseline, 3 months, and 12 months.

Discussion: This study will evaluate the implementation of a new online self-management intervention and describe what happens when it is made available to existing National Health Services and patients with type 2 diabetes. We will collect data to describe the uptake and use of the intervention and the resources needed for widespread implementation. We will report on patient benefits from using *HeLP-Diabetes* and the resources needed to achieve these in routine practice. Interviews with key stake holders will identify, define and explain factors that promote or inhibit the normalization of new patterns of patient and professional activity arising from *HeLP-Diabetes*.

Keywords: Implementation, Diabetes, Health services research, Internet, Self-management

Background

Diabetes is one of the most common long-term conditions in the UK affecting around 4.5 per cent of the population. It is a leading factor in the development of chronic illnesses and complications including coronary heart disease, renal failure and blindness, as well as reducing life expectancy [1]. Diabetes and related

complications put considerable strain on health budgets with the estimated cost to the National Health Service (NHS) of £14 billion a year [2].

Self-management by the patient is central to good diabetes care [3-5], and structured education in which the knowledge and skills necessary for self-management are taught, has been found to provide a fourfold decrease in the risk of complications developing [6]. Structured education at diagnosis with annual reinforcement is recommended by the UK's National Institute for Health and Clinical Excellence (NICE) for all people with type 2 diabetes (T2DM). However, only 8.7 per cent of people

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with T2DM who were newly diagnosed in 2008–2009 reported being offered structured education during 2009–2011 while only 3.6 per cent reported actually attending structured education [7].

Structured education, currently delivered as a group based activity, may be particularly unsuitable for people with caring responsibilities, some ethnic minority populations, those with physical disabilities and those who find group interactions challenging. With NHS resources unlikely to increase for such education and the poor referral and uptake of existing programmes there is an urgent need for new cost effective ways of delivering self-management education which are acceptable to patients and clinicians. The use of new information and communication technologies to improve health and health care is now a central part of NHS policy, and NHS Choices is already delivering a number of websites although many of these have yet to be evaluated.

The internet offers huge potential for delivering public health interventions [8]. Internet- based interventions have a number of potential benefits including convenience, accessibility, anonymity and may be cost-effective in delivering education to large numbers of people. Although the current evidence on the use of new technology in diabetes is still evolving, positive effects of such interventions have been demonstrated in several studies. A Cochrane systematic review of interactive healthcare applications looked at 24 randomised control trials (RCTs) in a range of chronic diseases including diabetes. It found mostly positive effects, with users tending to become more knowledgeable, feel better supported, with possible improved behavioural and clinical outcomes compared with non-users [9]. Another systematic review produced a narrative report of interactive computer-assisted technology in diabetes care [10]. It identified 14 studies that looked at HbA1c levels (a measure of glucose metabolism which reflects average blood glucose levels over six to eight weeks) and found that 6 of 14 studies demonstrated significant improvements in HbA1c. The interventions also appeared to improve healthcare utilisation with more foot examinations and HbA1c monitoring. Evidence from a recent systematic review of 16 RCTs suggests internet-based self-management programmes for people with T2DM can improve HbA1c [11]. This review suggested that these positive effects on HbA1c may decrease over time, which is similar to the effects of more traditional group-based self-management education on HbA1c which also show a similar decline in benefits over time [4,12,13]. The American Diabetes Association standards for self-management education recognise the need for both initial training and subsequent on-going support to try and maintain the benefits of educational interventions [14]. Internet-based interventions are ideally suited to providing ongoing self-management support that could allow sustained improvements and long-term improvements in outcomes.

We have developed an internet based self-management intervention for people with T2DM: '*HeLP-Diabetes: Healthy Living for People with Type 2 Diabetes*'. The design of this complex intervention has been informed by theory and the needs and preferences of patients and health professionals. It has been developed using a process of participatory design with users (people with T2DM and health professionals) heavily involved in the conception and creation. *HeLP-Diabetes* takes a holistic view of self-management and addresses a wide range of patient needs including education, lifestyle changes, medicine management, emotional management, social support with forums and personal stories and also addresses how patients interact and work with health professionals. A facility to interface with patients electronic medical records has been designed to provide patients access to self-management metrics recorded by General Practice (GP) surgeries. The information provided on *HeLP-Diabetes* is based on NICE guidelines and has been developed to complement existing structured group education.

This study will explore the implementation of *HeLP-Diabetes* within the NHS, addressing the facilitators and barriers associated with initial and continued engagement by staff and patients and the resources required to make *HeLP-Diabetes* a viable part of routine diabetes care. This implementation study is being conducted in parallel to a randomised control trial of the *HeLP-Diabetes* intervention. The Medical Research Council (MRC) framework for complex interventions [15] stresses the importance of considering the implementation of complex interventions throughout the development and evaluation phases in a cyclical and iterative way. The data provided by this implementation study will provide additional outcome data to that provided by the trial including data that will be essential for commissioners of care such as data on what happens in practice, and what actions and resources are needed for successful implementation and realisation of potential benefits.

Aim

To explore the implementation of *HeLP-Diabetes* within NHS GP surgeries and hospital and community based diabetes clinics.

Objectives

a. To describe the uptake and use of *HeLP-Diabetes* by NHS services and patients.
b. To identify factors which inhibit or facilitate implementation.
c. To identify the resources needed for effective implementation.

   d. To explore any effects of *HeLP-Diabetes* use on
      self-reported patient outcomes.

Theoretical framework

Literature on the transfer of research into clinical practice consistently reports the process as unpredictable, slow and haphazard [16]. The explicit use of theory in implementation research may support a better understanding of the generalisability and replicability of implementation interventions [17]. The MRC framework emphasises that the development, evaluation and implementation of health care interventions requires a strong theoretical foundation [15].

We have selected Normalisation Process Theory (NPT) [18,19] to provide a theoretical underpinning to this study. NPT can be used as a theoretical framework to identify factors that promote and inhibit the routine incorporation of complex interventions into everyday practice. It explains how these interventions work in practice (or fail to), looking not only at early implementation, but beyond this to the point where an intervention becomes so embedded into routine practice that it 'disappears' from view (i.e., it is normalised) [20]. We will use NPT as an explanatory framework to explore the implementation process and to guide interviews with NHS staff. The use of NPT will provide a transferable understanding of the success or failure of the *HeLP-Diabetes* integration into routine NHS practice, providing learning opportunities for future studies.

Methods/Design

Design

This will be a longitudinal cohort study using qualitative and quantitative methods.

Setting

The study will be conducted in GP surgeries, community diabetes clinics and hospital based diabetes clinics within two inner city London boroughs: There are approximately 80 GP surgeries, two services providing a range of community diabetes clinics and three hospitals running diabetes clinics within these two boroughs. Our aim is to make *HeLP-Diabetes* available to up to 30 GP surgeries and all diabetes clinics. Within these boroughs there are 16,223 people on GP registers with a recorded diagnosis of diabetes [21]. Since T2DM accounts for 90% of all diabetes cases, there are up to 14,601 potential users of *HeLP-Diabetes* within these two boroughs.

Procedure

The use of *HeLP-Diabetes* will be offered to GP surgeries and diabetes clinics free of charge for the duration of the study (30 months). *HeLP-Diabetes* will be made available to batches of GP surgeries and clinics (approx.

2 or 3 at a time). This will allow learning and experience gained from the implementation at each batch of sites to be transferred to subsequent ones. Once organisations have agreed to use *HeLP-Diabetes* they will be asked to opt-in to the research evaluation study. Organisations who opt-out of the research evaluation will still be free to use *HeLP-Diabetes* without participation in the research.

Staff working in services that agree to use *HeLP-Diabetes* will be asked to recommend its use to all suitable patients with T2DM and refer them to a training appointment with a researcher or a member of the clinical team. Suitable times to recommend the use of *HeLP-Diabetes* may include at annual diabetes reviews and when a patient is newly diagnosed. Staff will also be encouraged to maintain engagement with *HeLP-Diabetes* by encouraging patients to use it at appropriate times during routine consultations.

During training appointments patients will be registered on the *HeLP-Diabetes* site and shown how to use it. Each appointment will be tailored to the specific needs of the patient and will focus on an aspect of diabetes self-management important to the patient. At the end of the training appointment patients will be invited to take part in the research study evaluating the implementation of *HeLP-Diabetes*. Patients who agree to take part in the evaluation study will be asked to sign a consent form after reading the participant information sheet and having the opportunity to ask any questions. Patients who opt-out of the research evaluation will still be free to use *HeLP-Diabetes* without participation in the research.

Ethical consideration

Ethical approval for this study was gained from the NRES Committee East Midlands-Leicester ref: 13/EM/0033.

Recruitment

Recruitment will happen at both organisational and patient level.

Both organisations and patients will be recruited firstly to use *HeLP-Diabetes* and secondly to take part in the research evaluation of the implementation.

Organisational

Strategies being explored to recruit organisations to use *HeLP-Diabetes* include engagement of the Clinical Commissioning Groups (CCG), direct contacts with hospital and community based clinics and the assistance of the North Central London Research Consortium (NoCLOR) to recruit GP surgeries.

Staff in participating services who opt in to the research evaluation will be invited to take part in research

activities on an opportunistic basis throughout the study period.

Patient

Once a GP surgery or diabetes clinic has agreed to use *HeLP-Diabetes*, recruitment to use *HeLP-Diabetes* at the patient level will begin. Health professionals in participating GP surgeries and clinics will be asked to recommend the use of *HeLP-Diabetes* to all patients with T2DM who meet the inclusion criteria and to refer them to a training appointment. At the end of training appointments, eligible patients will be asked to participate in the research study evaluating the implementation of *HeLP-Diabetes*.

Sample
Staff

A range of staff from GP surgeries and diabetes clinics including consultants, salaried doctors, junior hospital doctors, general practice partners, general practice managers, practice nurses, community nurses, hospital diabetes nurses and reception staff will be recruited to participate in the research evaluation study. The aim is to represent a range of perspectives of the staff who contribute to the care of patients with T2DM on the implementation of *HeLP-Diabetes*.

Patient

To use *HeLP-Diabetes* and participate in the evaluation study, patients must be 18 or above, registered at participating GP surgeries, community diabetes clinics or hospital based diabetes clinics and have a diagnosis of T2DM. Patients will be excluded from the research evaluation if they are unable to provide informed consent, e.g. due to psychosis, dementia or severe learning disabilities, are terminally ill (life expectancy less than 12 months), unable to use a computer due to physical or mental impairment or possess English language skills insufficient to use the intervention.

Implementation plan

An implementation plan has been devised by the research team which will be offered to all services. This plan includes the following steps; an initial meeting at the GPsurgery or clinic to explain the new *HeLP-Diabetes* service, a demonstration of *HeLP-Diabetes*, training for staff who will be using *HeLP-Diabetes* top-up training and support as necessary, training patients to use *HeLP-Diabetes*, follow up contact with patients, continued monitoring and feedback to staff, and the provision of training materials to staff and patients. Each GP surgery and diabetes clinic will be invited to work with researchers to tailor the implementation plan to the individual setting.

The researcher will spend time with staff to implement *HeLP-Diabetes* and to provide support and facilitate patient training appointments. Formal feedback from interviews with staff and patients and informal feedback such as lessons learned from training staff and patients will be used by the researcher to develop and refine the implementation procedures. The iterative design will allow the implementation plan to be tested out on a small scale, the researcher to learn from the experience and modifications to be made to plan before testing it on a another small number of services. This method will allow for difficulties and challenges to be explored and addressed, which may otherwise be missed by widespread implementation. Through the process of modifying the implementation plan based on feedback from patients and staff and by allowing the implementation plan to be tailored to individual sites, we hope to increase buy-in and ownership of *HeLP-Diabetes* by staff and reduce barriers to successful implementation.

Outcomes

The study objectives will be addressed in the following ways.

a. To describe the uptake and use of *HeLP-Diabetes* by NHS services and patients.

The number of GP surgeries and diabetes clinics *HeLP-Diabetes* is offered to, and the numbers who take it up will be recorded. To describe the types of services that take up *HeLP-Diabetes* we will collect data including: the number of patients registered at the surgery or who attend the clinic (overall numbers and those with T2DM), socio demographics of the patient population and the number of staff. For GP surgeries we will also collect: Quality and Outcomes Framework (QOF) achievement and whether it is a training or non-training practice.

The number of patients who register on *HeLP-Diabetes* will be recorded and patient registration data will be used to describe the characteristics of patients who sign up. This data will include; year of birth, gender, ethnicity, the surgery or clinics they attend, duration of diabetes, existence of complications, how diabetes is currently managed; what help the patient would like with self-management, smoking status, internet access (home/public) and use of computer (basic/intermediate/advanced).

Data on *HeLP-Diabetes* use will be recorded automatically by the website software and Google Analytics and will include number of logins, length of time patients use *HeLP-Diabetes* per visit, pages that are visited and those that are not, and the

tools, assessments, educational modules that are
used and how often.

b. To identify factors which inhibit or facilitate
implementation.

Semi-structured interviews will be conducted with
key informants, both patients and health
professionals and will be focussed on exploring the
barriers and facilitators to implementation. The
researcher will also keep detailed notes on the
implementation process and document any
challenges and successes.

c. To identify the resources needed for effective
implementation.

A proforma will be used to collect quantitative data
on the resources spent on implementing *HeLP-
Diabetes*, which are predicted to be largely made up
of staff and researcher time. Semi-structured inter-
views will be conducted with key informants, both
patients and health professionals, to investigate the
resources needed for effective implementation.

d. To explore the effects of *HeLP-Diabetes* on
self-reported patient outcomes.

Patient participants will be asked to complete two
self-report measures. The first will be the Problem
Areas in Diabetes (PAID) scale [22] which is a
health related quality of life and emotional distress
measure. It is comprised of 20 items focusing on
areas that cause difficulty for people living with
diabetes including; social situations, food, friends
and family, diabetes treatment, emotions,
relationships with healthcare professionals and
social support. The second measure will be the
Diabetes Management Self-Efficacy Scale
(DMSES-UK) [23] which measures the individual's
efficacy expectations for engaging in 20 diabetes
self-management activities, for example, taking
daily exercise and keeping to a healthy eating plan
when away from home. A sample size of 100 pa-
tients will detect a 3.5 point difference in the mean
PAID score from baseline and a 9 point difference
in the mean DMSES score from baseline. These
calculations are based on 90% power ($\alpha = 0.05$).
Additional self-report measures may be introduced
to new cohorts of patients in order to test
developing hypotheses generated by interviews with
patients and staff. For example, if a theme emerges
from the interviews suggesting that using *HeLP-
Diabetes* may increase patients' levels of physical
activity, we may administer a physical activity
self-report measure to a new cohort of patients at
baseline, 3 months and 12 months to quantitatively
explore this. Power and sample size will be
calculated for each new measure prior to it being
administered.

Data collection

After consenting to take part in the evaluation research
study, patient participants will be allocated a unique study
ID number and complete baseline measures. Participants
will be asked to provide their email address, postal address
and contact number for data collection purposes. They
will be sent a link in an email to a web-based case report
form which will host the data collection measures. The
data entered into this form will be anonymous and only
linked to the patient by the unique ID number. Parti-
cipants will be asked to complete socio-demographic in-
formation at baseline and self-report measures at baseline,
3 months and 12 months. Socio-demographic information
will be collected to describe the sample, and to compare
intervention use and self-report measure data.

Both patient and health professional participants will
be asked to take part in semi-structured interviews.
Each participant may be interviewed several times
throughout the course of the study. We will sample
until saturation is reached. In order to capture a
breadth of experiences interviews will be conducted
with patients from a range of ethnic backgrounds, ages,
socio-demographic statuses, length of time with dia-
betes, treatment types, and associated complications,
as well as a range of experience with computers and
the internet. Similarly, to capture a range of staff expe-
riences, we will seek to interview consultants, salaried
doctors, junior hospital doctors, general practice part-
ners, general practice managers, practice nurses, com-
munity nurses, hospital diabetes nurses and reception
staff from GP surgeries and diabetes clinics. It is likely
that there will be different levels of engagement with
HeLP-Diabetes and with the evaluation research study
between different members of staff and between differ-
ent services and sites. Therefore, not all interviews will
be face to face; initial interviews and follow-up en-
counters with some participants may be short, highly
focused telephone interviews. These will minimise the
demand on participants, and is likely to be much more
cost effective. However, more in-depth, semi struc-
tured interviews will be conducted with participants
wherever possible. Participants may be sampled pur-
posefully at times to ensure that we have captured a
range of experiences and opinions.

Data on intervention use will be recorded automati-
cally by the intervention software and Google Analytics
and will be downloaded into a spread sheet. Data on
the type of GP surgeries and diabetes clinics that take
up *HeLP-Diabetes* will be collected from Population
Manager Data, Public Health Observatories [21] data
and a data collection form to be completed by the
Practice Manager or Clinic Lead at each site. The time
spent by individuals involved in the implementation of
HeLP-Diabetes will be recorded on a proforma.

Anaylsis

The proportion of GP surgeries and clinics offered *HeLP-Diabetes* who adopt it, the number of patients who register on *HeLP-Diabetes*, the socio-demographic characteristics of the patients who take part in the evaluation study and the characteristics of the clinics and GP surgeries that adopt *HeLP-Diabetes* will be described using descriptive statistics. SPSS statistical software [24] will be used for coding and analysing these data. Descriptive statistics will also be used to explain how patients make use of *HeLP-Diabetes* including counts of pages accessed, number of logins, the times of use, the duration of use and the patterns of use by different users. This data will be recorded automatically by the website software. The time and other resources expended on implementing *HeLP-Diabetes* will be recorded on a proforma and these will be collated on a spread sheet and data described descriptively.

The cost of health professional input from the GP surgeries and clinics will be based on national average rates using Personal Social Services Research Unit estimates. Estimates of the additional time required from the general practice and clinic staff where *HeLP-Diabetes* is implemented will be calculated from responses in the qualitative interviews. Resources required in training individual patients to use *HeLP-Diabetes* will be estimated.

Participant scores on the PAID and DSMSE-UK scales will be compared statistically at the different time points using a repeated measures analysis of variance test using time as the independent variable. If a statistically significant effect is found post-hoc tests will be used to explore this further. Follow up PAID and DSMSE-UK scores will be adjusted for initial scores and other baseline covariates including age, gender, and duration of diabetes. Group effects including gender and age will be assessed using mixed-between within subjects analysis of variance.

With respondents' consent, all semi-structured interviews will be audio-recorded, transcribed (and edited to ensure anonymity of respondent) and data will be subjected to formal analysis. Patient and staff interviews will be analysed inductively to identify themes and categories, a process of constant comparison will be used to establish analytical categories. Atlas. ti [25] data collation and management software will be used to aid data management and analysis.

Discussion

This study will explore what happens when a new internet-based self-management intervention for patients with T2DM is introduced into existing NHS services. Quantitative data will describe the use of *HeLP-Diabetes* by NHS organisations and patients and allow us to determine the socio-demographic characteristics of users

and the type of service that take up *HeLP-Diabetes.* We will determine the cost of implementation and the resources needed for successful implementation. Qualitative data will allow us to understand the implementation process and explore barriers and facilitators to implementing *HeLP-Diabetes* into existing services. We will explore the possible impact of *HeLP-Diabetes* use on patient-reported health-related quality of life, emotional wellbeing and self-efficacy to self-manage T2DM. This study will produce findings useful for those embarking on the implementation of an internet based resource within the NHS.

Translating research into routine clinical practice is often a difficult task. Implementation research is often focused on the early stages of the implementation process [26] however, there is also a need to examine later stages of implementation, including the integration of innovations into the norms and practices of organisations. Exploring the implementation of *HeLP-Diabetes* with a longitudinal study over 30 months will provide an opportunity to examine issues and challenges that emerge during the many stages of implementation including the less researched later stages.

There are several strengths of the design of this study. Data on the implementation of *HeLP-Diabetes* will be collected from staff across diabetes services and from a range of staff within these services. This will include both management and front-line staff as these groups may have very different viewpoints and perceptions of organisational change [27].

The iterative design of the study will allow for the implementation plan to change and develop in line with experiential learning and feedback from those involved in the implementation process. This is important in creating a final implementation procedure that is fit for purpose and effective. The mixed method design will aid the process of exploring the impact of *HeLP-Diabetes* on patient outcomes. By conducting interviews with patients throughout the study, emerging themes pertaining to the possible benefits of *HeLP-Diabetes* can be explored in greater detail with further interviews. We can also test emerging hypotheses about the mechanisms of action borne out of the interviews by administering further self-report measures to new cohorts of patients at baseline, 3 month and 12 month follow up.

The study faces some potential methodological and practical challenges. The study is limited to two inner London boroughs; the patient population and the services within which we are seeking to implement *HeLP-Diabetes* which may limit the generalizability of findings. In terms of studying the patient experience of *HeLP-Diabetes*, only the views of those patients who agree to take part in the research evaluation will be included. The views of those who don't use *HeLP-Diabetes* and

those using it but not taking part in the research study will not be represented.

The need for patients to attend a training appointment to use *HeLP-Diabetes* may be a potential bottle-neck to uptake. However, we believe that this tailored appointment will ensure that patients can use *HeLP-Diabetes* optimally. A research question to be addressed within this study is what is the most effective and viable way to ensure *HeLP-Diabetes* is a useful, effective and sustainable resource for patients and the evaluation of this training appointment will be central to that.

It is likely that internet-based health interventions will become increasingly widespread, not just for diabetes but for other long term physical conditions and mental health problems. There is a need to understand the implementation process of these interventions including the uptake by health organisations and patients, the facilitators and barriers to use and the resources needed for successful implementation and normalization. This study will offer a contribution to this.

Abbreviations
CCG: Clinical Commissioning Group; DMSES-UK: Diabetes management self efficacy scale; GP: General practice; NHS: National Health Service; NICE: National Institute for Health and Clinical Excellence; NPT: Normalisation process theory; PAID: Problem Areas in Diabetes; T2DM: Type 2 diabetes mellitus.

Competing interests
The authors declare that they have no competing interests.

Authors' contributions
All authors have made substantial contributions to conception and design of this study. JR developed the manuscript draft. All authors have read and given final approval of the version to be published.

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