

A web-based self-management programme for people with type 2 diabetes: the HeLP-Diabetes research programme including RCT

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Declared competing interests of authors: Elizabeth Murray reports grants from the National Institute for Health Research (NIHR) and National School of Primary Care Research during the conduct of the study, and grants from NIHR outside the submitted work. She is also managing director of the not-for-profit HeLP Digital community interest company (CIC), which was established to disseminate the HeLP-Diabetes programme across the NHS. She does not take any remuneration for this work. Kingshuk Pal reports personal fees from HeLP Digital CIC outside the submitted work. Fiona Stevenson reports grants from the NIHR during the conduct of this study. Maria Barnard reports sponsorship for attendance at educational conferences from Novo Nordisk A/S, personal fees from Janssen Pharmaceutica NV and that Janssen-Cilag International NV Sponsor was a sponsor of the multicentre CREDENCE trial (which Whittington Health NHS Health Trust is a site for) outside the submitted work. Lucy Yardley reports grants from NIHR during the conduct of the study; grants from NIHR, the Engineering and Physical Sciences Research Council, Medical Research Council (MRC), medical charities and European Commission outside the submitted work; and

membership of the Health Technology Assessment Efficient Study Designs Board and Public Health Research Research Funding Board. Susan Michie reports grants during the conduct of the study from NIHR, the Engineering and Physical Sciences Research Council, MRC, the National Institute for Health and Care Excellence, the Department of Health and Social Care, Public Health England, Cancer Research UK, the British Psychological Society and EC outside the submitted work. David Patterson was one of the founders, and is now Chief Medical Officer, of Helicon Health Ltd, a spin-out company from UCL Business. He does not believe there is any actual conflict of interest between Helicon Health Ltd and this work – other than the fact that his knowledge of information technology and devices was growing during this academic work. Ghadah Alkhalidi reports personal fees from the Saudi Arabian Cultural Bureau, outside the submitted work. Brian Fisher reports that he is the Director of Patient Access to Electronic Record Systems Ltd (now Evergreen Life), which was intended to offer links from the HeLP-Diabetes programme to the patient record outside the submitted work. Orla O'Donnell reports working as the Chief Operating Officer for the HeLP Digital CIC from the end of the programme grant until 1 May 2017. Andrew Farmer reports grants from NIHR and MRC outside the submitted work.

Published September 2018

DOI: 10.3310/pgfar06050

Scientific summary

The HeLP-Diabetes research programme including RCT

Programme Grants for Applied Research 2018; Vol. 6: No. 5

DOI: 10.3310/pgfar06050

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Scientific summary

Background

Diabetes mellitus is a NHS priority; estimates suggest that around 6% of the UK population, 4 million people, have diabetes mellitus, of whom 90% have type 2 diabetes mellitus (T2DM), which accounts for 10% of NHS expenditure (£14B per annum). Most costs are as a result of treating complications.

Good self-management is key to preventing complications and improving health. Since 2008, it has been NHS policy that all people with diabetes mellitus should be referred at diagnosis to structured education to improve their self-management skills, with annual reinforcement thereafter.

Unfortunately, uptake remains low despite incentives for general practitioners (GPs) to refer people through the Quality and Outcomes Framework. Figures from the National Diabetes Audit suggest that although referral rates increased very substantially, from 7.6% in 2009–10 to 75.8% in 2014–15, uptake did not, with only 5.6% of eligible patients attending in 2014–15.

Almost all structured education in the UK is group based, which may not suit people who work, have caring commitments or do not like group-based formats. Moreover, patient needs vary with time and illness progression. A single education session at diagnosis is unlikely to meet these evolving needs, particularly as many people report being emotionally unable to engage with self-management in the months immediately after diagnosis. A decision to engage with self-management may result from specific triggers, such as an increase in medication or development of a complication.

Web-based self-management programmes offer some potential benefits. They can combine health information with behaviour-change, decision and emotional support, they are easily updated and convenient to use and their confidentiality and anonymity is valued by users. In the UK, in 2015, 86% of households had internet access, with 78% of adults accessing the internet daily or almost daily.

There are, however, potential disadvantages to this type of programme, including the 'digital divide' (the divide between those who do and do not have access to, or make use of, the internet), uncertainties around clinical effectiveness and a track record of significant problems with the implementation of digital interventions in the NHS.

Aims and objectives

The overall aim of this programme grant, which started in March 2011, was to develop, evaluate and implement a web-based self-management programme for people with T2DM (at any stage of their illness journey), with the goal of improving access to, and uptake of, self-management support and, hence, improving health outcomes in a cost-effective manner. Particular attention was paid to working with users [patients and health-care professionals (HCPs)] to identify and meet user 'wants and needs', to overcoming the digital divide and to ensuring that the intervention could be easily implemented within routine NHS care.

The specific objectives were to:

Development

1. Determine patients' perspectives of the essential and desirable features of the intervention (wants and needs).
2. Determine HCPs' perspectives of the essential and desirable features of the intervention that would encourage uptake and use in the NHS.
3. Determine the overall content and function of the intervention.
4. Determine the optimal facilitation required to encourage use of the intervention.
5. Determine feasibility and acceptability of facilitated access to the intervention.

Evaluation

6. Determine the effect of the intervention on clinical outcomes and health-related quality of life in people with T2DM.
7. Determine the incremental cost-effectiveness of the intervention compared with usual care, from the perspectives of health and personal social services and wider public sector resources.

Implementation

8. Implement the intervention in two primary care trusts [since renamed clinical commissioning groups (CCGs)].
9. Determine the uptake, use and effects of the intervention in an unselected population in routine care.
10. Determine factors that inhibit or facilitate integration into existing services and uptake of the intervention by users.
11. Determine the resources needed for effective implementation.

Methods

We designed five linked work packages (WPs). WPs A and B used qualitative methods to address objectives 1 and 4 (WP A), and objectives 2 and 4 (WP B). WP C addressed objectives 3 and 5, combining a process of participatory design with evidence synthesis and applying theoretical frameworks. WP D addressed objectives 6 and 7 in an individually randomised controlled trial in primary care. WP E addressed objectives 8–11 using mixed methods.

Work package A

Participants in WP A were people with T2DM, who were purposively sampled for variability in age, ethnicity, duration of diabetes mellitus since diagnosis and internet experience. Data were collected in focus groups and analysed thematically by a multidisciplinary group in parallel with data collection, which continued until thematic saturation was reached.

Work package B

Participants in WP B were HCPs who are involved in caring for people with T2DM, including GPs, practice nurses, diabetes specialist nurses, consultants in diabetic medicine and dietitians. Data were collected through focus groups and semistructured individual interviews and analysed thematically by a multidisciplinary group in parallel with data collection, which continued until thematic saturation was reached. Following thematic analysis, data were mapped onto normalisation process theory (NPT).

Work package C

Development of the programme, called the Healthy Living for People with Type 2 Diabetes (HeLP-Diabetes) programme, involved combining multiple data sources to create content and functionality. We used the

Corbin and Strauss model of the tasks faced by people living with long-term conditions, namely medical management (adopting healthy behaviours, working with health professionals, taking medicines, keeping appointments and engaging with self-monitoring), emotional management (managing the strong negative emotions that accompany such conditions, including anger, guilt, shame and despair) and role management (coming to terms with the disruption of one's biographical narrative).

The NPT was used as a framework to plan for implementation, and a taxonomy of behaviour change techniques was used to target specific behaviours. We synthesised available evidence on T2DM (diagnosis, natural history and treatments), factors associated with clinical effectiveness in internet-based interventions, optimal techniques for presenting information in an accessible and comprehensible format, and enhancing usability and engagement with internet interventions. We combined these data sources with the data from WPs A and B to determine initial content and functionality, and then worked with user panels (patients and HCPs), software engineers and web designers to develop, refine and optimise content and function through participatory design. We subsequently undertook usability testing to refine the navigation and presentation.

Work package D

We conducted an individually randomised controlled trial in primary care, with co-primary outcomes of diabetes mellitus control [as measured by glycated haemoglobin (HbA_{1c}) levels] and diabetes mellitus-related distress [as measured by the Problem Areas in Diabetes (PAID) scale]. Outcomes were measured at baseline and at 3 months and 12 months. A health economic analysis was included.

Work package E

An implementation study was developed using mixed methods, combining quantitative data on adoption and uptake at CCG, general practice and patient levels with interview data from commissioners, HCPs and patients and observation data from individual practices. The impact that the HeLP-Diabetes programme had on people with T2DM was to have been determined using self-completed questionnaires at baseline and follow-up, but an insufficient number of people consented to this for the data to be useful.

Results

Work package A

Thematic saturation was reached after four focus groups and one interview, which involved 20 participants. The data generated indicated that there was a strong shared sense of the overwhelming burden that living with diabetes mellitus placed on participants, which had severe negative impacts on their emotional well-being, work, social life and physical health. Participants stated that many of their needs could not be met by current health services and that a web-based self-management support programme could help with these unmet needs. Participants had clear views about the features of such a programme that they would want or need, features that would help generate trust and encourage engagement and, conversely, features that would be off-putting and lead to disengagement. They were in favour of HCPs facilitating access to the programme and of patient access to electronic medical records (EMRs).

Work package B

Thematic saturation was reached after four focus groups and seven individual interviews, which involved a total of 18 HCPs. All data mapped easily onto NPT. The potential benefits of our proposed web-based self-management programme were appreciated by participants, who understood the need for self-management support, the problems with current service provision and the advantages of a web-based approach. This appreciation led to a perception that overall, HCPs would support the implementation of such a programme, as long as the impact that it had on workload was acceptable. They also had clear views about the types and range of evidence that HCPs would require to continue to engage with the programme once it had been implemented.

Views about facilitating access to the programme were more nuanced. Although some participants understood what facilitation would require, many were unconvinced of the potential benefits and felt that the impact it would have on workload could not be justified and was not an appropriate use of scarce resources in general practice. Similarly, there was considerable disquiet about patient access to EMRs, with participants being unsure about what information would be accessed or what the benefits might be and having significant concerns about adverse outcomes, including risks to privacy and confidentiality, increased patient anxiety and an increase in workload.

Work package C

The overall goals of the HeLP-Diabetes programme were to improve health outcomes and reduce diabetes mellitus-related distress.

All content drew on evidence on the management of T2DM, promoting behaviour change and emotional well-being and maximising acceptability reach and uptake of web-based interventions. There were information sections on T2DM; how T2DM is treated; possible complications; possible impacts that T2DM could have on relationships at home and at work; dealing with parties, holidays, travelling or shift work; and which lifestyle modifications will improve health. There were sections addressing skills and behaviour change, including behaviour change modules on eating healthily, losing weight, being more physically active, smoking cessation, moderating alcohol consumption, managing medicines, glycaemic control and blood pressure control. Users could set the programme to send themselves reminder text messages or e-mails and could specify the content and frequency of such reminders.

The third strand of components focused on emotional well-being, with self-help tools based on cognitive-behavioural therapy (used with a licence from Living Life to the Full) and mindfulness. There were multiple personal stories (used with a licence from HealthTalkOnline) and a moderated forum. Participants were free to use the programme as much or as little as they chose. Engagement with the programme was promoted through initial registration and facilitation by HCP and regular newsletters, e-mails and short message services containing updates on the latest diabetes mellitus-related research or practice, seasonally relevant advice and links to specific relevant parts of the programme (sent by the HeLP-Diabetes team).

Work package D

Of the 374 participants randomised between September 2013 and December 2014, 185 were allocated to the intervention group and 189 to the control group. Final (12-month) follow-up data for HbA_{1c} levels were available for 318 (85%) participants and for 337 (90%) participants for PAID scores. Of these, 291 (78%) and 321 (86%) responses, respectively, were recorded within the predefined window of 10–14 months. At 12 months, participants in the intervention group had lower HbA_{1c} levels than those in the control group [mean difference –0.24%, 95% confidence interval (CI) –0.44% to –0.049%; $p = 0.014$]. There was no significant difference between groups for the PAID score (mean difference –1.5 points; 95% CI –3.9 to 0.9 points; $p = 0.25$), but the subgroup analysis suggested that, among people who had been diagnosed more recently, PAID scores fell more in the intervention group than in the control group ($p = 0.004$).

The within-trial health economic analysis showed that adjusted incremental costs were lower in the intervention group than the control group (mean difference –£111; 95% CI –£384 to £136) and quality-adjusted life-years (QALYs) were higher (mean difference 0.02, 95% CI 0.000 to 0.044), meaning that the intervention dominated the comparator, that is, it was less costly and more effective.

Work package E

The HeLP-Diabetes programme was successfully implemented in one CCG in north London. It was adopted by the diabetes services in the main hospital serving the local population, in both community clinics and in 22 out of the 34 (65%) general practices open at the end of the study. A total of 205 people were registered to use the HeLP-Diabetes programme between March 2013 and August 2015. Of these, around half ($n = 107$, 52%) were male and 52% ($n = 107$) were from ethnicities other than white British, with

African, Caribbean, Bangladeshi, Indian and other ethnicities represented. There was a wide spread of ages (19–81 years) and of educational levels, with one-third (31%, $n = 64$) having no education after school-leaving age and over one-third (38.5%, $n = 79$) describing their computer skills as basic. The duration of diabetes mellitus since diagnosis ranged from < 1 year to > 20 years. Over half of the visits to the programme occurred outside normal working hours.

Although most services were keen for the HeLP-Diabetes programme to be available to their patients, many found that it was difficult to manage the workload associated with signing people up and requested a patient self-sign up model. This patient self-sign up model was provided; however, data comparing those who received support in signing up from HCPs with those who signed themselves up suggest that the self-sign-up model was associated with users who were better educated and had rated their computer skills as advanced. Interview data confirmed that users placed great weight on the fact that the HeLP-Diabetes programme had been recommended by a HCP, and that this was a major factor in deciding to use it.

Additional information

A number of other CCGs requested access to the HeLP-Diabetes programme. To meet these requests, and to help ensure ongoing sustainability and implementation of the programme, we established a not-for-profit community interest company to maintain and disseminate the HeLP-Diabetes programme.

Conclusions

The HeLP-Diabetes programme is an effective web-based self-management programme for people with T2DM that leads to improved glycaemic control. It is highly cost-effective. It can be implemented into routine health care, and, with minimal support from HCPs, can be used by people from a wide range of demographic backgrounds. As we initially hypothesised, HCP support does appear to be important in overcoming the digital divide and encouraging uptake and use. We believe that the care taken during the development process, including the emphasis on participatory design, theoretical underpinning and future implementation were vital in obtaining the results shown.

The HeLP-Diabetes programme is currently available for commissioning by individual CCGs; our results suggest that a central commissioning model would be more cost-effective.

Trial registration

This trial is registered as CSP 62330 and Research Ethics Committee reference number 10/H0722/86 for WPs A–C; CSP 113285, Research Ethics Committee reference number 10/LO/1571 and UK Clinical Research Network/National Institute for Health Research Portfolio 13563 for WP D; and CSP 115774 and Research Ethics Committee 13/EM/0033 for WP E. In addition, for WP D, the study was registered with the International Standard Randomised Controlled Trial Register as reference number ISRCTN02123133.

Funding details

Funding for this study was provided by the Programme Grants for Applied Research programme of the National Institute for Health Research.

Programme Grants for Applied Research

ISSN 2050-4322 (Print)

ISSN 2050-4330 (Online)

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

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This report

The research reported in this issue of the journal was funded by PGfAR as project number RP-PG-0609-10135. The contractual start date was in March 2011. The final report began editorial review in November 2016 and was accepted for publication in July 2017. As the funder, the PGfAR programme agreed the research questions and study designs in advance with the investigators. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The PGfAR editors and production house have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the final report document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, CCF, NETSCC, PGfAR or the Department of Health and Social Care. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the PGfAR programme or the Department of Health and Social Care.

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