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Content and delivery modes of prompts to engage users with a digital intervention (HeLP-Diabetes)

Submission date
17/05/2016

Recruitment status
No longer recruiting

Registration date
25/05/2016

Overall study status
Completed

Last Edited
06/06/2018

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Diabetes is a life-long condition where a person is unable to control their blood sugar levels. An important part of diabetes management is maintaining a healthy lifestyle, namely eating well, exercising and taking medication properly. Digital interventions (programs) are an effective tool for health promotion and helping people to manage long-term conditions. However, their effectiveness is limited by low usage rates, with non-engagement posing a major challenge. Technological prompts (e.g. emails) are one method of encouraging people to better engage with the material, however the specific effect of their characteristics (e.g. delivery mode, content) on engagement has not previously been thoroughly investigated. This will be investigated in two similar studies, which test different content and delivery modes on promoting engagement with a digital intervention called HeLP-Diabetes. HeLP-Diabetes is a digital intervention that aims to promote self-management among people with diabetes.

Who can participate?
In the first study, registered users of HeLP-Diabetes who have subscribed to email prompts are able to take part. In the second study, registered users of HeLP-Diabetes who have subscribed to email and text message prompts are able to take part.

What does the study involve?
In the first study, participants are randomly allocated to one of two groups. Participants in the first group receive an email containing and email prompt with news and updates. This includes a new research article about how diabetes education programmes can help patients lower their blood sugar as well as links of videos of people discussing how diabetes brought some positive changes into their lives and reminders and tips on how to help control Type 2 Diabetes more easily. Participants in the second group receive the email prompt without news and updates, which includes the video links and reminders and tips only. Over the next five days, the number of participants in both groups who visited the HeLP-Diabetes website and those who opened the email prompt are recorded.
In the second study, participants are randomly allocated to one of two groups. Participants in the first group receive an email containing a link to a specific webpage. Those in the second

group receive a text message prompt containing a link to a specific webpage. Over the next five days, the number of participants in both groups who visited the HeLP-Diabetes website are recorded.

What are the possible benefits and risks of participating?
Participants can benefit from the content of the prompts they receive, as the information can help them to better control their diabetes. There are no major risks involved with participating, although some participants may not like the content of the prompts or feel annoyed by them.

Where is the study run from?
The study is run from University College London and takes place on the internet (UK)

When is the study starting and how long is it expected to run for?
September 2015 to April 2016

Who is funding the study?
1. Saudi Arabian Cultural Bureau in London (UK)
2. HeLP-Diabetes was funded by National Institute for Health Research (UK)

Who is the main contact?
Mrs Ghadah Alkhadi

Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
1.1

Study information

Scientific Title
Testing content and delivery modes of HeLP-Diabetes prompts on user visits: two pilot randomised controlled trials

Study objectives
Trial 1:
Email prompt with news and updates will be associated with a higher proportion of participants visiting the digital intervention(HeLP-Diabetes) compared to an email prompt that does not have news and updates.

Trial 2:
The use of an email prompt will be associated with a higher proportion of participants visiting the digital intervention (HeLP-Diabetes) compared to the use of a text message prompt.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The email and text message prompts were included as a part of the HeLP-Diabetes website intervention that was developed following the results of this study (Development, evaluation and implementation of a computer-based self-management programme for people with Type 2 Diabetes, REC reference: North West London Research Ethics Committee, 10/01/2011, ref: 10 /H0722/86). Users who were registered to use the HeLP-Diabetes programme had actively agreed to the original Terms and Conditions when signing up to receive prompts via emails and text messages as part of the intervention and that their usage data including website visits would be stored anonymously and used for analysis.

As no new users were recruited, it was advised that ethical approval for this study was not required as no participant was actively recruited for this study, only participants who had been using the website before the start of this study and who subscribed to emails and text messages were enrolled.

Primary study design
Interventional

Study design
Two sequential randomised two-arm pilot trials

Study type(s)
Other

Health condition(s) or problem(s) studied
Diabetes mellius

Interventions
Randomisation for both Trial 1 and 2:
Randomisation was done by extracting only user identification numbers from the HeLP-Diabetes database then using the website (https://www.random.org/), to generate two lists of

randomised identification numbers. 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.

Trial 1:
Arm 1: At baseline (19/10/2015), participants receive an email prompt with news and updates. This includes a new research article about how diabetes education programmes can help patients to decrease their blood glucose level, as well as a link to videos of people discussing how diabetes brought some positive changes into their lives and reminders and tips on how to help control Type 2 Diabetes more easily.
Arm 2: At baseline (19/10/2015), participants receive an email prompt without news and updates. This includes a link to videos of people discussing how diabetes brought some positive changes into their lives and reminders and tips on how to help control Type 2 Diabetes more easily.

Participants in both groups are followed up for five days

Trial 2:
Arm 1: At baseline (26/10/2015), participants receive an email prompt that contained a link to a specific webpage, for example, a link to a sugar-free recipe.
Arm 2: At baseline (26/10/2015), participants receive a text message prompt that contained a link to a specific webpage (the same link as provided to the group receiving the email).

Participants in both groups are followed up for five days

Intervention Type
Behavioural

Primary outcome(s)
Trial 1 and 2:
Proportion of participants who visited HeLP-Diabetes at least once after receiving prompts during a period of 5 days is measured objectively through HeLP-Diabetes.

Key secondary outcome(s)
Trial 1:
Proportion of participants who opened an email prompt at least once up to 5 days after receiving Trial 1 email prompts is measured objectively through HeLP-Diabetes.

Completion date
30/04/2016

Eligibility

Key inclusion criteria
Trial 1 :
1. Registered users of HeLP-Diabetes
2. Subscribers to email prompts

Trial 2:
1. Registered users of Help-Diabetes who provided cell phone numbers and agreed to receive

text message prompts
2. Subscribers to email prompts
3. Included in trial 1

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Trial 1 and 2:
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 randomised controlled trial plan (as this group of users cannot be randomised to receive different prompts until the end of the trial in early 2016)

Date of first enrolment
30/09/2015

Date of final enrolment
05/10/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University College London
Royal Free Campus
Rowland Hill Street
London
United Kingdom
NW3 2PF

Sponsor information

Organisation
University College London (UCL)

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
Saudi Arabian Cultural Bureau in London

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	22/08/2017		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes