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Web-based support for self-management of diabetes

Submission date	Recruitment status	[X] Prospectively registered
26/03/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/03/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/01/2017	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
The aim of this study is to look for better ways to make web-pages to help people with diabetes. New web-pages have been developed and this study tests whether or not these are easier to use than standard information.

Who can participate?
Adults with type 2 diabetes

What does the study involve?
This study compares different types of web-pages for people with diabetes to see which is more helpful. To find this out, participants are randomly allocated into two groups and each group is given different web-pages to look at. This study takes about 30 minutes in total. Participants answer a questionnaire, are shown the web-pages, and afterwards fill in another questionnaire.

What are the possible benefits and risks of participating?
Taking part in this study will help identify better ways to make web-pages to help people with diabetes. The main risk is that participants may not like the web-pages.

Where is the study run from?
This study is organised by researchers at the University of Southampton, but the study will be carried out over the internet.

When is the study starting and how long is it expected to run for?
July 2014 to July 2015

Who is funding the study?
This study is part of a bigger project to improve the health of people with diabetes that is funded by the European Council.

Who is the main contact?
Dr Ingrid Muller
I.Muller@soton.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Ingrid Muller

Contact details
University Road
Southampton
United Kingdom
SO17 1BJ
-
I.Muller@soton.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14189

Study information

Scientific Title
Developing and testing accessible web-based support for patient self-management of diabetes

Study objectives
The aim of this work-package is to develop and trial web-based support suitable for people with lower levels of health literacy. In particular, it will examine the potential for web-based materials and tools to provide enhanced support (compared with standard written materials) by:

1. Tailoring the material to the particular needs, abilities and perspective of the user
2. Employing engaging audio-visual presentation and quiz formats
3. Providing simple interactive tools to support self-management tasks (e.g. guidance for choosing and planning lifestyle changes).

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES London Hampstead Committee,18/03/2013, ref: 13/LO/0316

Study design

Randomised; Interventional; Design type: Process of Care

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Interventions
Current interventions as of 17/04/2014:
1. Interactive web-based materials: web-based-materials that are tailored, interactive and includes interactive tools
2. Static web-based materials: static version of the interactive web-based materials

Previous interventions:
1. Interactive web-based materials: web-based-materials that are tailored, interactive and includes interactive tools
2. Standard written materials: materials currently available
3. Static web-based materials: static version of the interactive web-based materials

Intervention Type
Other

Phase
Phase I/II

Primary outcome measure
Current primary outcome measures as of 17/04/2014:
User engagement, measured by intervention completion rates

Previous primary outcome measures:
Patient enablement; Timepoint(s): immediately post intervention

Secondary outcome measures
Current secondary outcome measures as of 17/04/2014:
1. Physical activity attitudes and intentions
2. Patient enablement
3. Website satisfaction

4. Diabetes and physical activity knowledge
All of these will be measured immediately post intervention

Previous secondary outcome measures:
1. Comprehension and satisfaction with materials; Timepoint(s): immediately post intervention
2. Health literacy; Timepoint(s): immediately post intervention
3. Intention to take part in physical activity; Timepoint(s): immediately post intervention

Overall study start date
01/07/2014

Completion date
01/07/2015

Eligibility

Key inclusion criteria
1. Adults (male & female; upper age limit 120 years; lower age limit 18 years) with Type 2 diabetes
2. Able to consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
120 Years

Sex
Both

Target number of participants
Planned Sample Size: 250; UK Sample Size: 250

Key exclusion criteria
GPs will screen lists of potential participants to exclude individuals where there may be potential difficulties, for instance:
1. Severe mental health problems
2. Palliative care
3. Recent bereavement
4. Known opposition to involvement in research or inability to complete research measures, e.g. learning disability, inability to read/speak English

Date of first enrolment
01/07/2014

Date of final enrolment
01/07/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Road
Southampton
United Kingdom
SO17 1BJ

Sponsor information

Organisation
University of Southampton (UK)

Sponsor details
Aldermoor Health Centre
Southampton
England
United Kingdom
SO17 1BJ

Sponsor type
University/education

Website
http://www.southampton.ac.uk/

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
Seventh Framework Programme

Alternative Name(s)
EC Seventh Framework Programme, European Commission Seventh Framework Programme, EU Seventh Framework Programme, European Union Seventh Framework Programme, FP7

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/01/2017		Yes	No
HRA research summary			28/06/2023	No	No