

Web-based support for self-management of diabetes

Submission date 26/03/2013	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 26/03/2013	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 25/01/2017	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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
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Contact information

Type(s)

Scientific

Contact name

Dr Ingrid Muller

Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Quality of life

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

120 years

Sex

All

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**

United Kingdom

England

Study participating centre

University Road
Southampton
United Kingdom
SO17 1BJ

Sponsor information

Organisation

University of Southampton (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

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?
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Results article	results	23/01/2017	Yes	No
HRA research summary		28/06/2023	No	No