

# Web-based support for self-management of diabetes

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

I.Muller@soton.ac.uk

# Contact information

## Type(s)

Scientific

## Contact name

Dr Ingrid Muller

## Contact details

University Road  
Southampton  
United Kingdom  
SO17 1BJ

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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?
<a href="#">Results article</a>	results	23/01/2017		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No