ISRCTN08439795 https://doi.org/10.1186/ISRCTN08439795

Study to evaluate a smartphone application for raising diabetes risk awareness in urban India

Submission date
16/05/2012

Recruitment status
No longer recruiting

Registration date
31/05/2012

Overall study status
Completed

Last Edited
30/11/2015

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Diabetes is a lifelong condition that causes a person's blood sugar level to become too high. A large number of people in India do not realize they are at risk of developing diabetes or that they have the condition. A prototype smartphone application called D-Check has been designed to communicate personal diabetes risk and contains persuasive messages to motivate high-risk individuals to take action. The aim of this study is to assess whether D-Check has a beneficial educational and/or motivational effect for example on intentions to get a diabetes blood screening test.

Who can participate?
Healthy volunteers, aged 30-60, living in Mumbai or Chennai, who are at high risk of diabetes.

What does the study involve?
Participants complete questionnaires to assess diabetes general knowledge, beliefs, perceptions and motivation to take diabetes preventative action (i.e. go for a diabetes screening test, eat a healthy diet most of the time, take regular exercise). Two weeks later, all participants use a smartphone application at a test centre. Particpants are randomly allocated into two groups. Half the participants use the D-Check application and the other half use a commercially available financial app. After using the apps, all participants again answer questions about their diabetes beliefs, perceptions and motivation to take preventative action. Two weeks later, participants receive a follow-up visit to assess diabetes general knowledge.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Unilever Discover (UK).

When is the study starting and how long is it expected to run for?
May to July 2012.

Who is funding the study?
Unilever Discover (UK).

Who is the main contact?
1. Emma Bertenshaw
2. Dr.A.Ramachandran

Contact information

Type(s)
Scientific

Contact name
Dr Emma Bertenshaw

Contact details
Unilever Discover
Colworth Science Park
Sharnbrook
Bedford
United Kingdom
MK44 1LQ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SKN-APP-0328

Study information

Scientific Title
Exploratory pilot study to evaluate a diabetes risk awareness smartphone application with high risk individuals in urban India

Study objectives
D-Check - a prototype diabetes risk smartphone application (app) - will change diabetes perceptions and motivation to engage in preventative behaviour amongst high risk individuals, compared to a control condition.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Unilever Independent Ethics Committee, Bangalore, India, 02/04/2012, ref: ETH2012_ N02

Study design
Randomised parallel multi-centred single-blind controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

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

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

Interventions
Interventional group: provision of a D-Check diabetes smartphone application in a controlled environment.
Control group: provision of a commercially available financial application in a controlled environment.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Change in intention to engage in preventative action (i.e. blood screening, taking regular exercise and eating a healthy diet) from baseline to post intervention (two weeks later)
2. Change in diabetes risk perceptions and beliefs including susceptibility, perceived severity and perceived outcomes of taking diabetes preventative action, from baseline to post intervention
3. Change in Diabetes awareness & knowledge from baseline to follow-up (four weeks later)

Secondary outcome measures
1. Self-efficacy
2. Emotional response to the risk
3. Self-reported health information seeking and preventative behaviour
4. Qualitative appraisal of the app

Overall study start date
16/05/2012

Completion date
01/07/2012

Eligibility

Key inclusion criteria
1. Healthy volunteers
2. Female and male, between 30-60 years old
3. Living in Mumbai or Chennai
4. Regularly read in English
5. Have good vision
6. Use smartphone applications on a regular basis
7. At high risk of diabetes (defined by a risk score over 21)

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
200 participants

Key exclusion criteria
1. Diabetics
2. Had blood screened for diabetes - or any other tests of diabetes status - within the last year
3. Disability that impacts physical activity status or use of a mobile phone

Date of first enrolment
16/05/2012

Date of final enrolment
01/07/2012

Locations

Countries of recruitment
England

India

United Kingdom

Study participating centre

Unilever Discover
Bedford
United Kingdom
MK44 1LQ

Sponsor information

Organisation
Unilever Discover (UK)

Sponsor details
Colworth Science Park
Sharnbrook
Bedford
United Kingdom
MK44 1LQ

Sponsor type
Industry

Website
http://www.unilever.co.uk/

ROR
https://ror.org/05n8ah907

Funder(s)

Funder type
Industry

Funder Name
Unilever Discover (UK)

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