

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

<b>Submission date</b> 16/05/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 31/05/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 30/11/2015	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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. Participants 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