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Combining novel self-monitoring technologies for persuasive behaviour change in people at moderate or high risk of developing Type 2 diabetes

Submission date
12/05/2017

Recruitment status
No longer recruiting

Registration date
15/05/2017

Overall study status
Completed

Last Edited
15/06/2023

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Type 2 diabetes mellitus (T2DM) is a growing problem worldwide. People with T2DM have difficulty controlling their blood sugar (glucose) as they do not produce enough insulin to function properly (insulin deficiency), or that the body's cells don't react to insulin as they should do (insulin resistance). Prediabetes is a condition where a person's blood sugar levels are higher than normal, but nor high enough to be classified as T2DM. If left untreated, then prediabetes can turn into T2DM. It is estimated that 11% of the population have prediabetes. Type 2 diabetes costs the NHS £23.7 billion every year and there are an estimated 174.8 million individuals are living with undiagnosed Type 2 diabetes globally. Therefore, early treatment to prevent the onset of Type 2 diabetes is needed. Lack of regular physical activity has been shown to directly cause 7% of Type 2 diabetes cases worldwide and is an established risk factor to developing the disease. However current efforts to increase population physical activity levels have been unsuccessful. Providing individuals at risk of developing Type 2 diabetes with feedback on both their physical activity as well as the immediate consequence of that behaviour on their health (blood sugar levels) could be a good solution. The aim of this study is to test this strategy to find out if people engage with the technology to see the feedback, and whether they believe it helps motivate them to be more physically active, in order to see if a full scale study would be possible.

Who can participate?
Adults aged 40 years or older with a moderate or high risk of developing T2DM who own an Android smartphone

What does the study involve?
Participants are randomly allocated to one of three groups. At the start of the study, participants in all groups undergo a range of measurements to assess their body composition, fitness and background information. Those in the first group receive feedback about their blood sugar levels for four weeks. Those in the second group receive feedback about their physical

activity levels for four weeks. Those in the third group receive feedback about their blood sugar levels and physical activity levels for four weeks. After the programme, participants are asked to take part in an interview about their experience using the technology and to complete questionnaires. Participants also wear a special device which repeatedly measures their blood sugar levels to measure the change over a period of time.

What are the possible benefits and risks of participating?
Participants may benefit from improved health in terms of blood sugar control and increased physical activity. No risks are foreseen but participants may experience skin irritation or slight discomfort when wearing the blood glucose monitor.

Where is the study run from?
National Centre for Sport and Exercise Medicine, Loughborough University (UK)

When is the study starting and how long is it expected to run for?
January 2017 to December 2017

Who is funding the study?
1. The Movement Insights Lab (UK)
2. Loughborough University (UK)

Who is the main contact?
Miss Maxine Whelan
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number

R17-P049

Study information

Scientific Title
The Sensing Interstitial Glucose to Nudge Active Lifestyles (SIGNAL) Study: Combining novel self-monitoring technologies for persuasive behaviour change in people at moderate or high risk of developing Type 2 diabetes

Acronym
SIGNAL

Study objectives
1. Providing individuals with both behavioural and physiological feedback will encourage greater engagement with the self-monitoring technology than providing individuals with only one feedback component
2. The level of user engagement with the self-monitoring technology will be related to the extent to which individuals increase their physical activity

Ethics approval required
Old ethics approval format

Ethics approval(s)
Loughborough University Ethics Advisory Committee, 21/04/2017, ref: R17-P049

Study design
Interventional three arm randomised parallel trial

Primary study design
Interventional

Study type(s)
Prevention

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

Interventions
Following enrolment, participants' baseline physical activity will be measured for one week using two devices, an ActiGraph GT3x-BT and a Fitbit Charge 2. No feedback will be provided during free-living wear. Following completion of baseline, participants will be block randomised to one of three groups (1:1:1).

Group 1: Participants will receive a flash glucose monitor (Freestyle Libre; providing feedback) and a physical activity monitor (Fitbit; not providing feedback) for four weeks.

Group 2: Participants will receive a Freestyle Libre (not providing feedback) and Fitbit (providing feedback) for four weeks. Following this, participants in groups 1 and 2 will have access to feedback from both devices for the remaining two weeks of the intervention.

Group 3: Participants will receive a Freestyle Libre (providing feedback) and Fitbit (providing feedback) for the full six weeks of the intervention.

The study design will allow comparisons between groups having access to feedback from only one device (Groups 1 and 2 during initial four weeks) and feedback from two devices (Groups 1 and 2 during final two weeks and Group 3 during the full six weeks). It will also allow for the quantification of any decay in device engagement over time.

Following the intervention, participants will complete a semi-structured qualitative interview (20-40 minutes) to discuss their experience using the technology and receiving feedback about physical activity and/or glucose levels. Interviews will be audio-recorded with permission and transcribed verbatim.

Intervention Type
Behavioural

Primary outcome(s)
Device engagement will be assessed by:
1. Time spent on the official LibreLink application using Ethica Data at 1, 2, 3, 4, 5, and 6 weeks
2. Time spent on the official Fitbit application using Ethica Data at 1, 2, 3, 4, 5, and 6 weeks
3. The number of Freestyle Libre scans using LibreLinkUp application at 1, 2, 3, 4, 5, and 6 weeks
4. The number of user-driven Fitbit syncs using Fitabase at 1, 2, 3, 4, 5, and 6 weeks
5. Semi-structured interviews at 6 weeks

Key secondary outcome(s)
1. Feasibility of delivering the intervention is measured using semi-structured interviews, researcher notes, Ethica Data, Fitabase, Diasend, LibreLinkUp at 1, 2, 3, 4, 5, and 6 weeks
2. Physical activity is measured using Fitbit Charge 2 at baseline and 1, 2, 3, 4, 5, and 6 weeks
3. Interstitial glucose levels are measured using Freestyle Libre at 1, 2, 3, 4, 5, and 6 weeks
4. Eligibility, uptake and retention is measured using researcher notes at baseline, 1, 2, 3, 4, 5, and 6 weeks
5. Changes in technology readiness is measured using the Technology Readiness Index 2.0 at baseline and 6 weeks
6. Health literacy is measured using the eHealth Literacy Scale at baseline and 6 weeks
7. Health status is measured using the 5Q-5D-5L at baseline and 6 weeks
8. Attitude about health is measured using the Risk Perception Survey – Developing Diabetes at baseline and 6 weeks

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. At least 40 years of age
2. Own a compatible Android smartphone [Version 4.3+ with access to internet, Bluetooth and near infrared communication (NFC))]
3. Have a moderate or high risk of developing Type 2 diabetes (score ≥16 points on a validated Type 2 diabetes screening survey)

Participant type(s)

Other

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
45

Key exclusion criteria
1. Have a clinical diagnosis of Type 1 or Type 2 diabetes or a HbA1c reading of >6.4%
2. Unable/unwilling to provide informed consent
3. Unable/unwilling to adhere to the study protocol
4. Unable to understand written/verbal English
5. Pregnant (suspected or confirmed)

Date of first enrolment
18/05/2017

Date of final enrolment
30/11/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
National Centre for Sport and Exercise Medicine
School of Sport, Exercise and Health Science
Loughborough University
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LE11 3TU

Sponsor information

Organisation

Loughborough University

ROR
https://ror.org/04vg4w365

Funder(s)

Funder type
University/education

Funder Name
The Movement Insights Lab (MI-Lab)

Funder Name
Loughborough University

Alternative Name(s)
Lboro

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from m.e.whelan@lboro.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/10/2019	30/10/2019	Yes	No
Results article	qualitative study results	12/01/2021	14/01/2021	Yes	No
Protocol article		08/10/2017	15/06/2023	Yes	No

Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes