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Title

Sensing Interstitial Glucose to Nudge Active Lifestyles (SIGNAL): Feasibility of combining novel self-monitoring technologies for persuasive behaviour change

Corresponding author

Maxine Whelan

National Centre for Sport and Exercise Medicine,

Loughborough University,

LE11 3TU

m.e.whelan@lboro.ac.uk

Authors

Maxine Whelan[1,2]; Andrew Kingsnorth[1,2]; Mark Orme[3]; Lauren Sherar[1,2,4]; Dale Esliger[1,2,4]

Affiliations

(1) National Centre for Sport and Exercise Medicine, UK

(2) School of Sport, Exercise and Health Sciences, Loughborough University, UK

(3) Centre for Exercise and Rehabilitation Science, NIHR Leicester Biomedical Research Centre - Respiratory, Leicester, UK.

(4) NIHR Leicester Biomedical Research Centre – Lifestyle, Leicester, UK

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Keywords

Flash glucose monitoring; type 2 diabetes; physical activity; prevention; activity trackers; bio-behavioural feedback.

ABSTRACT

Introduction: Increasing physical activity (PA) reduces the risk of developing diabetes, highlighting the role of preventive medicine approaches. To date, efforts are limited because encouraging people to be more active has been the assumption that individuals are willing to change their lifestyles *today* to reduce the risk of developing disease *years or even decades later*. The self-monitoring technologies tested in this study will present PA feedback in real-time, parallel with acute physiological data. Presenting the immediate health benefits of being more physically active may help enact change by observing the immediate consequences of that behaviour. The present study aims to assess user engagement with the self-monitoring technologies in individuals at moderate-to-high risk of developing type 2 diabetes.

Methods and analysis:

Forty-five individuals with a moderate-to-high risk, aged ≥40 years old and using a compatible smartphone, will be invited to take part in a seven-week protocol. Following one week of baseline measurements, participants will be randomised into one of three groups: Group 1, glucose feedback followed by bio-behavioural feedback (glucose plus PA); Group 2, PA feedback followed by bio-behavioural feedback; Group 3, bio-behavioural feedback. A PA monitor and a flash glucose monitor will be deployed during the intervention. Participants will wear both devices throughout the intervention but blinded to feedback depending on group allocation. The primary outcome is the level of participant engagement and will be assessed by device use and smartphone usage. Feasibility will be assessed by the practicality of the technology and screening for diabetes risk. Semi-structured interviews will be conducted to explore participant experiences using the technologies.

Ethics and dissemination: The Loughborough University Ethics Advisory Committee has provided ethical approval to conduct this study (research proposal R17-P049). Study results will be disseminated at international conferences and published in a peer-reviewed journal.

Trial registration: ISRCTN17545949. Registered on 15/05/2017.

Keywords: Flash glucose monitoring, type 2 diabetes, physical activity, prevention, activity trackers, bio-behavioural feedback.

Strengths and limitations of this study

- Our protocol has been reported in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines
- The study will involve the deployment of two novel, self-monitoring technologies to quantify and provide feedback on interstitial glucose and physical activity levels
- It is the first study to combine real-time feedback for both behaviour and the immediate physiological consequences of that behaviour
- This is a feasibility study and is not powered to determine effectiveness
- Results of the study will determine if a future RCT is warranted

INTRODUCTION

There is widespread concern regarding the increasing prevalence of non-communicable diseases such as type 2 diabetes (1). Type 2 diabetes currently imposes an annual cost of £23.7bn through its associated complications (2); however, this cost is likely to rise as it is projected to directly impact 592 million individuals worldwide by 2035 (3). Preventing the development of type 2 diabetes is an international priority moving forward (4) given that one in seven adults have impaired glucose regulation (a form of prediabetes) (5). Compared to individuals living with normal circulating glucose levels, pre-diabetics are five to ten times more likely to develop type 2 diabetes (6) with around 5-10% of people living with prediabetes becoming diabetic every year (7). Overall, diabetes is projected to be one of the ten leading causes of death worldwide (8); thus, preventing its onset is pivotal for early intervention.

A lack of physical activity is considered one of the major risk factors for non-communicable diseases and is comparable to the ill-effects of both obesity (9) and smoking (10);. Given that physical inactivity, where insufficient levels of physical activity are achieved, is attributed to an estimated 7% of type 2 diabetes cases (11), it is an important modifiable lifestyle behaviour to target. With the prevalence of impaired fasting glucose (another form of prediabetes) doubling in individuals at 40-59 years and remaining consistent beyond 60 years (12), targeting efforts toward specific age cohorts is crucial. Individuals with impaired glucose resistance are referred onto community-based lifestyle behaviour programmes such as The Healthier You: National Diabetes Prevention Programme (NDPP). Initiated in 2016, the programme aims to roll out nationally by 2020 as part of the NHS Five Year Forward plan (13). Aligning with the aims and objectives of the NDPP is a crucial component of the present study.

With widespread encouragement to integrate technology into usual care pathways, it is a crucial time to consider how self-monitoring technologies can play a key role in the management of chronic diseases. This approach is informed by Control Theory (14) whereby people compare a present state with a behavioural standard and how a series of self-regulatory feedback loops are actioned to achieve a desired outcome. In addition, a taxonomy produced by Michie and colleagues identified 93 discrete behaviour change techniques often used in behavioural interventions (15); produced to encourage researchers to state the specific techniques used within an intervention. Given recent advancements and widespread consumer interest (16), wearable self-monitoring technologies offer a digital platform to monitor behaviour and health through feedback and self-regulation. The majority of research to date has focused on the deployment of technology to self-monitor movement behaviours (e.g. (17)) or specific health markers (e.g. (18)) in isolation, and although these have shown to be beneficial to behaviour change in the short term, most user engagement is not sustained beyond six months (19). With a view to sustaining the "honeymoon period" of technology-bolstered behaviour change, a logical next step would be to deploy wearable technologies in combination. For example, delivering bio-behavioural feedback to users to educate them about the relationship between their movement behaviours and their acute health status (i.e. walking after a meal leads to marked reductions in glucose levels) may help sustain engagement with the self-monitoring technology and thereby maintain the healthy lifestyle behaviour change. To date, an important limitation of the efforts to encourage people to be

more physically active has been the assumption that we are willing to change our lifestyles *today* to reduce our risk of developing disease *years or even decades later*. Implementing specific behaviour change techniques such as self-monitoring, goal-setting and feedback (15), wearable devices could empower individuals to manage their health through a change in behaviour. Building on previous findings which observed greater levels of brain activation in response to personalised glucose related information (over behavioural information) [Whelan et al., *submitted*], the present study aims to examine the role of providing novel self-monitoring technologies presenting bio-behavioural feedback in those living at moderate-to-high risk of type 2 diabetes.

AIMS AND OBJECTIVES

Primary aim

The primary aim of this study is to investigate assess participant engagement using self-monitoring technologies for physical activity and interstitial glucose.

Secondary aims

The secondary aims of this study are to explore (i) the feasibility of the intervention trial at baseline, 1, 2, 3, 4, 5, and 6 weeks; (ii) levels of physical activity and interstitial glucose levels at baseline, 1, 2, 3, 4, 5, and 6 weeks; (iii) levels of technology readiness, health literacy, health status and attitudes towards one's own health at baseline and post self-monitoring.

METHODS AND ANALYSIS

Study setting

Participants will be identified within the community setting in Leicestershire, UK from May to November 2017. All appointments (three or four in total, depending on group allocation) will take place at the National Centre for Sport and Exercise Medicine at Loughborough University, UK.

Study design

The feasibility study protocol has been prepared in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) (20) with reference to the Template for Intervention Description and Replication (TIDieR) (21) (see supplementary material).

The study will aim to recruit 45 individuals with 15 participants randomly allocated to each of the three groups. No specific sample size has been calculated due to its feasibility status but study results will inform the sample size for a full-scale intervention.

The Sensing Interstitial Glucose to Nudge Active Lifestyle (SIGNAL) study will last seven weeks in total and is outlined in Figure 1. Following baseline (one week), participants will be randomised into one of three groups. Participants will be notified of their group allocation at the second appointment before starting the intervention period. Appointments will be arranged at the preceding appointment where possible. The study was registered on the International Standard Randomised Controlled Trial number (ISRCTN) Register (ISRCTN17545949) in May 2017.

Randomisation

Participants will be block randomised using a 1:1:1 study allocation ratio, coordinated by a remote internet-based service (http://www.sealedenvelope.com/). Randomisation will be done by a member of the research group, independent to the present study. Baseline measures will be conducted pre-randomisation. Participants will be notified of their group allocation at appointment two. In the event of participants originating from the same household, identical group allocation will be employed to avoid any cross-contamination.

Inclusion criteria

Participants will be aged at least 40 years old, have a moderate-to-high risk of developing type 2 diabetes (22), a HbA1c of <6.5% and use a compatible Android smartphone (with access to Wi-Fi, Bluetooth and Near Field Communication).

Exclusion criteria

Anyone reporting a clinical diagnosis of type 1 or type 2 diabetes or have suspected/confirmed pregnancy will be excluded. Participants unable/unwilling to provide informed consent, cannot/unwilling to adhere to the study protocol or cannot read/write English will also be excluded.

Recruitment procedure

Participants will be recruited at community sites through the distribution of posters and leaflets in community organisations and local businesses based in Leicestershire, UK. Individuals will also be recruited through an existing Movement Insights Lab participant database. All individuals will be directed to complete a brief survey to determine level of risk for type 2 diabetes. Participant information sheets will be provided (copies available at: http://www.lboro.ac.uk/research/mi-lab/research/signal/). The questions will be presented via an online survey platform (Qualtrics, Provo, UT) and will relate to gender, age, ethnic background, familial history of diabetes, waist circumference, body mass index and blood pressure. The validated survey (22) has been used in studies applying risk score algorithms on primary care electronic data (23). Waist circumference will be replaced with clothing size and fit following guidance offered by Battram and colleagues (24). Moderate-to-high risk individuals will be contacted by the research team to take part in the study. Ineligible individuals (i.e. low risk, increased risk or a moderate/high risk, but are not aged at least 40 years old nor use an Android smartphone) will be directed to Diabetes UK "Type 2 diabetes: What to do if you're at risk" information booklets (available at: https://www.diabetes.org.uk/Global/professionals/KYR%20Booklet.pdf).

Study procedure

First appointment and baseline

An outline of the study procedure is presented in Figure 1. Appointment one will involve informed consent, health measures (height, weight, percentage body fat, waist circumference, blood pressure, HbA1c, grip strength, quadriceps strength and aerobic fitness; full methodological details are provided in the measures section below) and a brief demographics questionnaire. Participants will complete a physical activity readiness questionnaire (25) before completing the aerobic fitness assessment for screening purposes. Participants will be

fitted with a waist-worn ActiGraph wGT3x-BT (ActiGraph, Florida, USA) and a wrist-worn Fitbit Charge 2 (Fitbit Inc., San Francisco, CA); measuring physical activity whilst also presenting an opportunity to validate the Fitbit Charge 2. Neither device will provide feedback to the participant during the seven consecutive days of wear. Participants will be asked to install two mobile applications onto a personal Android smartphone; in particular, the Ethica Health (Kitchener, Ontario, Canada) and Fitbit (Fitbit Inc., San Francisco, CA) applications. Both smartphone applications will sit idle on the smartphone for the duration of baseline. Participants will be asked to sync the Fitbit via the official Fitbit mobile application; switching on Wi-Fi and Bluetooth simultaneously at least once every five days for ≥1 hour to ensure the sync occurs.

Second appointment and intervention

One week later (following baseline), participants will attend appointment two where they will be informed of their group allocation. Participants will be asked to complete a brief questionnaire, to continue wearing the Fitbit during the intervention (settings may or may not be adjusted) and to return the ActiGraph. A Freestyle Libre flash glucose monitor (Abbott Diabetes Care, Alameda, CA) will be deployed to each participant on the posterior surface of the upper non-dominant arm to measure interstitial glucose levels. Participants will be provided with additional supplies of Freestyle Libre sensors to last for the four (Groups 1 and 2) or six weeks (Group 3) of the intervention. Accounts for both the Fitbit and Freestyle Libre will be connected to Diasend (Diasend Inc., Chicago, IL). An overview of the three groups is provided below.

Group 1 (glucose feedback followed by bio-behavioural feedback)

Real-time interstitial glucose feedback will be presented to participants for four weeks via the LibreLink application (Abbott Diabetes Care Inc., Alameda, CA). Participants will install the LibreLink mobile application (Abbott Diabetes Care Inc., Alameda, CA) onto a personal Android smartphone to interact with the Freestyle Libre via Near Field Communication (NFC) for measurement of interstitial glucose. The Freestyle Libre has a lifespan that restricts wear to 14 consecutive days. The application will remind participants to scan every seven hours and to remove/replace after 14 days. The LibreLink application will continuously display the number of days left.

Group 2 (physical activity feedback followed by bio-behavioural feedback)

Real-time physical activity feedback will be presented for four weeks via the Fitbit application. In contrast to Group 1, participants will not have the LibreLink application installed and so will not have access to glucose feedback. Participants will be informed that the sensor is functional (recording data) and participants will be asked to remove and replace the expired sensor with another sensor after 14 days.

Device unmasking for Groups 1 and 2 after four weeks

At the end of the first four weeks of the intervention, participants in Groups 1 and 2 will attend a brief appointment (up to one hour in duration). For Group 1, the researcher will adjust settings to reveal physical activity feedback via the Fitbit application and device. For Group 2, the researcher will install the LibreLink application to reveal glucose feedback. All

participants will be able to access bio-behavioural feedback for the remaining two weeks of the intervention.

Group 3 (bio-behavioural feedback)

Participants in Group 3 will receive bio-behavioural feedback for the full six weeks via the two independent LibreLink and Fitbit applications. Participants will install the LibreLink mobile application onto a personal Android smartphone to interact with the Freestyle Libre to measure interstitial glucose. The application will remind participants to scan every seven hours and to remove/replace the sensor after 14 days.

Final appointment

All participants (Groups 1, 2 and 3) will be asked to attend the final appointment at the end of the intervention where they will complete a questionnaire (identical to appointment 2, apart from the revised DKT) and a semi-structured interview. All participants will also receive a personalised health report containing results from the health measures conducted at appointment one.

Device masking

All email account and password combinations will be manually generated and managed by the research team. When required to prevent access to physical activity feedback the Fitbit will be masked. Tape will be applied to the screen; leaving only time and date viewable. Settings will be adjusted to remove physical activity metrics from the device screen and the smartphone application dashboard with notifications restricted. The Fitbit will also be set to *all day sync* to minimise data loss with data automatically transferred (Wi-Fi and Bluetooth must both be simultaneously switched on). When required to prevent access to glucose feedback, participants will wear the sensors for 14 day periods as normal but will not be asked to install the LibreLink application nor scan the sensor (i.e. no data will be collected). This will standardise wear across all three groups.

User engagement

Time spent on the official Fitbit and LibreLink applications will be quantified using Ethica Data (Kitchener, Ontario, Canada) as well as time-stamped data relating to when the smartphone screen was turned on and off. In combination, these two data sources will reveal the proportion of time that the applications were used in relation to total smartphone use. These data will be recorded at either a day level (e.g. aggregate time) or event level (e.g. record of each time an application was opened) depending on the Android smartphone model. Number of syncs and scans using the Fitbit and Freestyle Libre, respectively, will also be recorded. *Compulsory engagement* will be participants having to sync the Fitbit at least once every five days and scan the Freestyle Libre at least once every seven hours. The number of syncs and scans recorded over and above *compulsory engagement* will reflect *optional engagement*. Identifying when and how often syncs and scans happen and how these patterns change over the course of the intervention will indicate engagement with the technology. We will also identify when participants decide to change the settings for goals relating to steps, floors climbed, active minutes on the Fitbit application. These settings will be checked on a daily basis between the hours of 18:00-19:00 by the research team and changes will be flagged with details of the original and new setting logged.

Remote monitoring of participant glucose and physical activity will be completed using Diasend (Diasend Inc., Chicago, IL) and Fitabase (Small Steps Labs LLC., San Diego, CA), respectively. Diasend will connect with the Freestyle Libre via the LibreLink application. Additional data sources to be monitored by Ethica Data include battery status (i.e. smartphone plugged in? Charging?), Bluetooth and Wi-Fi (turned on or off). Quantifying these data sources will provide valuable insight into participant behaviour (e.g. Do participants only use Wi-Fi and Bluetooth for the purpose of our intervention? Are participants charging it more often in the intervention compared with baseline?). Ethica Data will also monitor location (GPS), motion (pedometer, accelerometer, gravity, gyroscope, linear acceleration, magnetic field, orientation) and survey responses. These digital streams will monitor smartphone usage and will provide detailed data on human behaviour during a free-living, naturalistic setting. In total, fourteen data sources will be monitored. In the event a participant raises concerns relating to the number and/or type of data sources being monitored, a *restricted* coverage option of only three data sources (application usage, screen state and survey responses) will be offered and implemented.

Feasibility

Guidelines used to assess the feasibility of this study were informed by Bowen and colleagues (26). Both qualitative and quantitative data will be collected to assess feasibility of deploying novel self-monitoring technologies in parallel. In total, we will assess intervention feasibility as outlined in Table 1.

Table 1. An overview of the feasibility components to be assessed.

Feasibility component	Data source (indicator of feasibility)
Practicality of technology/intervention	• Qualitative interviews • Fitabase (sync compliance, missing data and response to haptic prompt) • LibreLinkUp (scan compliance) • Diasend (missing data, identification of Freestyle Libre sensor-related issues) • Project records (identification of need to dispatch additional Freestyle Libre sensors, number of individuals screened, rate of eligibility, study uptake and retention) • Ethica Data (data sources, enrolment into full* or restricted^{+} coverage)
Acceptability of technology/intervention	• Qualitative interviews • Fitabase (Fitbit wear time) • Diasend (Freestyle Libre wear time, digital footprint of time taken to move onto the next Freestyle Libre sensor i.e. sensor delay?) • Project records (changes to goal settings, manual withdrawals, attendance at appointments, retention to follow-up) • Ethica Data (digital footprint of application usage, Bluetooth and Wi-Fi status, battery status, electronic withdrawal)

**Full coverage: application usage, screen state, Bluetooth, Wi-Fi, GPS, pedometer, accelerometer, gravity, gyroscope, linear acceleration, magnetic field, orientation, battery and survey responses.*
+Restricted coverage: application usage, screen state and survey responses.

Behaviour change techniques

Prior to starting the intervention, the researcher will implement the default settings for levels of physical activity (i.e. 10,000 steps and 10 floors climbed) (BCT 1.1: Goal setting (behaviour)) and glucose (4.0-5.9 mmol/L) (BCT 1.3: Goal setting (outcome)). Participants will be informed that they will be able to change the settings for physical activity as preferred (i.e. should the default value be too easy/difficult) via the Fitbit application. Participants will be advised to not make any changes via the LibreLink application for the target glucose range. In relation to the deployment of self-monitoring technologies, participants will be able to monitor physical activity levels using the Fitbit Charge 2 (BCT: 2.3 Self-monitoring of behaviour) and glucose levels using the Freestyle Libre (BCT: 2.4: Self-monitoring of outcome(s) of behaviour) which is a minimally-invasive device that presents feedback about glucose (BCT: Biofeedback). Participants will also receive haptic feedback (a gentle vibration) on the Fitbit Charge 2 device 10 minutes prior to the end of each hour (09:00-18:00) if the hourly goal of 250 steps is not achieved (BCT 7.1: Prompts/cues).

Measures

ActiGraph

The ActiGraph wGT3X-BT accelerometer will quantify time spent sedentary, in light and moderate-to-vigorous intensity physical activity as well as step count. Participants will be asked to wear the device during waking hours and to remove for any water-based activities (e.g. showering and swimming). Data from the ActiGraph will be collected at 100 Hz resolution and integrated into 60 second epochs using ActiLife (ActiGraph, Pensacola, FL, USA) and processed using Kinesoft (Kinesoft, Loughborough, UK).

Fitbit

The Fitbit Charge 2 will be worn on the wrist associated with the non-dominant arm and, whilst being sweat, rain and splash proof, participants will be asked to remove the device for water-based activities. The Fitbit records minutes spent lightly active, fairly active and very active in addition to heart rate and steps. Heart rate will be assessed using Fitbit's proprietary PurePulse optical heart rate technology. To examine changes in physical activity, data from the Fitbit will be analysed in 60 second epochs following export from Fitabase (Small Steps Labs LLC., San Diego, CA). Participants will be requested to sync the Fitbit at least once every five days (rather than the company recommendations of seven days) to minimise data loss. These syncs will either occur automatically (i.e. without the application open) or will be user-driven (i.e. with the application open) depending on how the *all day sync* is set and heart rate will be set to automatic (only record heart rate when device is worn).

Freestyle Libre

The minimally-invasive Freestyle Libre flash glucose monitor will be covered with Tegaderm (3M Health Care, St. Paul, MN) to help maintain position and adhesion during the 14 day sensor lifespan. Three strips of Tegaderm will be provided to participants per sensor to allow for replacement when the Tegaderm becomes dirty. Participants will be asked to wear the device continuously without removal for water-based activities. Participants will be requested to scan the glucose monitor at least once every seven hours (rather than the company recommendations of eight hours) to minimise data loss. If participants experience skin irritation on the non-dominant arm in the region of application, participants will be advised to switch to their dominant arm. Interstitial glucose data will be downloaded in 15 minute epochs using Diasend (Diasend Inc., Chicago, IL), an online platform connected to the LibreLink application. Participant accounts will be linked to Diasend Clinic from the point of LibreLink application installation. Figure 2 illustrates how the numerous components connect to achieve the primary and secondary aims.

Qualitative interview

If a participant decides to withdraw from the study at any time prior to the final appointment, they will be able to leave the study via (i) the Ethica Health application on their personal smartphone (aligning with a dynamic consenting process (27)) or by (ii) contacting the research team via telephone or email. Participants that decide to withdraw via Ethica Health will be directed to complete a brief exit survey on the application. The research team will contact all participants for an optional exit interview (5-10 minutes) via telephone. This will be recorded using Tapeacall (http://www.tapeacall.com/) and will explore reasons for not completing the study.

For participants who complete the six-week intervention, a semi-structured interview will be completed (20-40 minutes) during the final appointment at the National Centre for Sport and Exercise Medicine, Loughborough University, UK. The interview will aim to identify potential barriers and facilitators to using self-monitoring technologies. In particular, how participants experience receiving feedback relating to behaviour and/or health. These interviews will explore individual experiences using the device(s) and mobile application(s), adherence to syncing (Fitbit) and scanning (Freestyle Libre), wearing multiple devices and the perceived effect of viewing feedback on actual behaviour. In addition, we will ask participants about future intentions to continue wearing self-monitoring devices and identify any recommended changes for future study designs.

Demographics

Self-reported age, sex, ethnic background, employment, household income, postcode (to provide an Index of Multiple Deprivation score) and education will be recorded.

Health, physical functioning and fitness

A measure of height will be conducted using a Seca stadiometer (Seca, Hamburg, Germany) and weight and body fat percentage will be measured using Tanita scales (Tokyo, Japan). Two measures of waist circumference will be taken at the midpoint between the lowest rib and top of the iliac crest; if the difference exceeds 1 cm, the two measurements will be repeated (28). Glycated haemoglobin (HbA1c) will be assessed using an Afinion AS100 Analyser (Alere Inc., Waltham, MA) with readings of 5.7-6.4% identified as pre-diabetic (29). Three measures of blood pressure will be recorded using an Omron digital monitor (Omron Corporation, Kyoto, Japan) with the first measure taken after the participant has

remained seated for ten minutes. Grip strength will be assessed using a handheld Takei dynamometer (Takei Scientific Instruments, Tokyo, Japan) whilst standing with hands positioned down each side. Quadriceps strength will be assessed using the DAVID G200 knee extension machine (David Health Solutions Ltd., Helsinki, Finland). Aerobic fitness will be assessed using the modified Canadian Aerobic Fitness Test (mCAFT) (30). Participants' scores for aerobic fitness will be defined according to the following formula: 17.2 + (1.29 x oxygen cost at the final stage) - (0.09 x weight in kg) - (0.18 x age in years) (30).

Questionnaire measures

All questionnaires will be completed electronically using an online platform for immediate data entry (http://www.onlinesurveys.ac.uk/; Bristol, UK). At appointment two, quality of life will be assessed via the 26 item EQ-5D-5L (31), technology readiness via the 16 item Technology Readiness Index (TRI 2.0) (32), health literacy via the 8 item eHealth Literacy Scale (e-HEALs) (33), diabetes knowledge via the 20 item revised diabetes knowledge test (DKT) (34) and general attitude toward developing diabetes via the 8 item general attitudes section of the Risk Perception Survey for Developing Diabetes (RPS-DD) (35).

Quantitative data analysis

Analysis of primary outcomes

Ethica Data (Kitchener, Ontario, Canada) will be used to provide time-stamped data relating to engagement. The number of scans and syncs will be unobtrusively assessed using the free LibreLinkUp mobile application (Abbott Diabetes Care Inc., Alameda, CA) and Fitabase (Small Steps Labs LLC., San Diego, CA), respectively. Fitabase is a fee-for-service platform that permits access to high resolution Fitbit data and remote monitoring of multiple Fitbit devices. Identification of moments where participants have decided to change the goal settings will be completed by accessing the online Fitbit account. The researchers will remotely access participants' accounts daily between 18:00-19:00 to note goal settings; recording the date and live/current settings for all metrics (e.g. step count) to help identify any changes.

Analysis of secondary outcomes

To assess eligibility, uptake and retention, we will manually record how many individuals complete the screening survey, how many meet our inclusion criteria and of these how many decide to enrol. Identifying nonusage attrition and dropout attribution is crucial to assess the feasibility of an intervention as they are both important but distinct constructs (36). Nonusage attrition, where participants have disengaged from the intervention but have not dropped out, will be defined as participants who attend appointment two but do not sync the Fitbit or scan the Freestyle Libre. Dropout attrition will be defined as participants who explicitly withdraw from the study via Ethica Health or direct contact with the research team. The number of participants who enrol into the full (all 14 data sources monitored) or restricted (only three data sources) coverage for Ethica Data will also be recorded.

Descriptive statistics of the sample will be conducted and between-group comparisons and within-group comparisons using repeated ANCOVAs (both controlling for physical activity).

All data will be analysed using Statistical Package for Social Sciences (SPSS Inc. Chicago, IL).

Qualitative data analysis

All interviews will be audio recorded (with informed consent), transcribed verbatim and analysed using thematic analysis. This will involve standard thematic data analysis procedures; identifying emerging patterns in the interview (37). Transcripts will be analysed using constant comparison with initial free coding and emergent themes interrogated (38). The interview schedule and coding schedule will be modified to follow new leads until new themes no longer emerge. The analysis will create a coding frame that 'fits' the data (38). Transcripts will be uploaded into NVivo qualitative data analysis software (QSR International Pty, Ltd, Victoria, Australia).

DISSEMINATION

This work will inform a full-scale randomised-controlled trial by enabling a sample size calculation. The full-scale RCT will primarily aim to investigate changes in physical activity and interstitial glucose levels in individuals randomised into the three groups. Overall, the findings seek to encourage the implementation of technologies into usual pre-clinical care pathways; in particular, how engaging with self-monitoring technologies (providing bio-behavioural feedback) may positively influence rates of uptake, adherence, retention and behaviour change.

We will publicise study findings online, present them at international conferences relating to diabetes, physical activity and digital health and publish via a peer-reviewed journal.

DECLARATIONS

Competing interests

None declared.

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Author contributions

All authors have contributed to the design of the work, acquisition and analysis plan. MW, AK, MO, LS and DE were involved in the development of the intervention and design of the trial. MW, AK, MO, LS and DE have been involved in drafting the work or revising it critically for important intellectual content.

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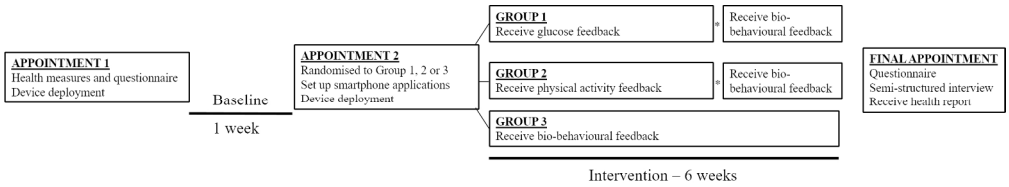

Figure 1. An illustration of the intervention design (*indicates a brief appointment at 4 weeks).

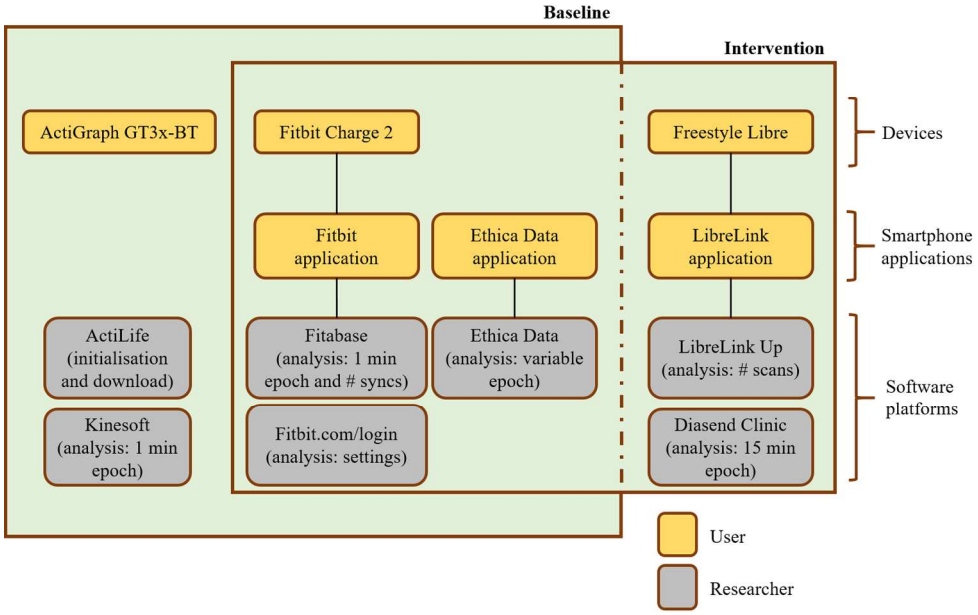

Figure 2. A schematic of how the multiple wearable technologies, mobile applications and software are integrated.

Supplementary material

Table 1. Intervention description using the Template for Intervention Description and Replication (TIDieR) checklist

1. Brief name	The Sensing Interstitial Glucose to Nudge Active Lifestyles Study.
2. Why	Nudging people to become more physically active offers a wealth of benefits for everyone. With widespread prevalence of type 2 diabetes, a non-communicable disease largely attributed to poor lifestyle choices, people living with prediabetes should access early lifestyle intervention to prevent disease onset. Self-monitoring is a recognised behaviour change technique that aligns well with the influx of mobile health (mHealth) technologies; however, more needs to be done to improve sustained use of these devices. Given the contribution of behaviour to type 2 diabetes, deploying self-monitoring technologies that present behavioural (physical activity) and physiological (interstitial glucose) information in parallel could be a persuasive behaviour change method. Understanding how people use these devices is paramount to assess feasibility of deployment and levels of engagement over time.
3. What - materials	All participants, regardless of group allocation, will wear two devices simultaneously for the full six weeks of the intervention. The first device, the Freestyle Libre (Abbott, Diabetes Care, Alameda, CA), will present interstitial glucose levels and the second, the Fitbit Charge 2 (Fitbit Inc., San Francisco, CA), will present physical activity feedback. If the device is to be masked, the participants will either have the device taped with access to metrics restricted or have no access to the data at all.
4. What - procedures	Engagement will be recorded using Ethica Data (Kitchener, Ontario, Canada), Fitabase (Small Steps Labs LLC., San Diego, CA) and LibreLinkUp (Abbott, Diabetes Care, Alameda, CA). Ethica Data will quantify smartphone application usage, Fitabase will record the number of times participants sync the Fitbit and LibreLinkUp will time-stamp when participants scan the Freestyle

	Libre. The Ethica Health application will also allow participants to withdraw from the study at any point during the intervention. Semi-structured interviews will be conducted to discuss the feasibility of the intervention.
5. Who provided	A team of early career academics will deliver the intervention.
6. How	The intervention will be delivered via two self-monitoring technology devices. The Freestyle Libre will present feedback relating to interstitial glucose levels and the Fitbit Charge 2 will present feedback relating to physical activity levels.
7. Where	The intervention will be delivered in Leicestershire, UK. Appointments will take place at the National Centre for Sport and Exercise Medicine, Loughborough University, UK.
8. When and how much	Participants will be requested to attend up to four face-to-face appointments. Following baseline (seven days), participants will be randomised into one of three groups. Group 1 will receive interstitial glucose feedback, Group 2 will receive physical activity feedback and Group 3 will receive bio-behavioural feedback (interstitial and physical activity feedback). For the remaining two weeks of the intervention, Groups 1 and 2 will receive bio-behavioural feedback (both interstitial and physical activity feedback).
9. Tailoring	The self-monitoring technologies will provide personalised data relating to interstitial glucose and physical activity levels during the intervention. Participants will be able to adjust goals based on individual preference for the Fitbit (e.g. number of steps).

Table 2. Spirit 2013 Checklist.

Section/Item	Item Number	Included in manuscript (Y/N) or described below
Administrative Information		
Title	1	Y
Trial registration	2a	Y
	2b	Y
Protocol version	3	Y – Version 2, 15/05/2017
Funding	4	Y
Roles and responsibilities	5a	Y
	5b	Y - Contact details can be found via the ISRCTN registration.
	5c	Y
	5d	Y - The steering committee is comprised of the study authors.
Introduction		
Background and rationale	6a	Y
	6b	Y
Objectives	7	Y
Trial design	8	Y
Methods		
Study setting	9	Y
Eligibility criteria	10	Y
Interventions	11a	Y
	11b	
	11c	Y
	11d	
Outcomes	12	Y
Participant timeline	13	Y
Sample size	14	Y
Recruitment	15	Y
Assignment of interventions		
Allocation		
Sequence generation	16a	Y
Allocation concealment mechanism	16b	Y
Implementation	16c	Y
Blinding (masking)	17a	Y - The PI will be blinded during health measures at baseline. The PI will be informed of group allocations prior to appointment 2. Outcome assessments will not be blinded.
	17b	Y
Data collection methods	18a	Y - Data collection forms can be obtained on request.
	18b	Y
Data management	19	Y - Data will be entered into a password protected secure

		Microsoft Excel spreadsheet. Data will be manually checked against source documents throughout the study.
Statistical methods	20a	Y
	20b	Y
	20c	Y
Monitoring		
Data monitoring	21a	Y – A DMC is not needed on this occasion as it is a feasibility study.
	21b	N/A – no interim analyses are planned as the trial is low risk.
Harms	22	Y - Any adverse events will be recorded and reported to the ethics committees along with any protocol amendments.
Auditing	23	Y
Ethics and dissemination		
Research ethics approval	24	Y
Protocol amendments	25	Y - Amendments will be communicated to the ethics committee and trial registry, if needed.
Consent or assent	26a	Y
	26b	N/A
Confidentiality	27	Y - All participants will be assigned a unique registration number used on data collection forms.
Declaration of interests	28	Y - No competing interests reported.
Access to data	29	Y - Study authors will have access to the final trial dataset.
Ancillary and post-trial care	30	Y
Dissemination policy	31a	Y - Study team intend to share results with participants following data analysis.
	31b	Y - No intention to use professional writers.
	31c	Y - The dataset will be made available to others upon request.
Appendices		
Informed consent materials	32	Y – Version 2
Biological specimens	33	Y - Described in consent form

BMJ Open

Sensing Interstitial Glucose to Nudge Active Lifestyles (SIGNAL): Feasibility of combining novel self-monitoring technologies for persuasive behaviour change.

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Primary Subject Heading:	Public health
Secondary Subject Heading:	Diabetes and endocrinology
Keywords:	Flash glucose monitoring, type 2 diabetes, physical activity, prevention, activity trackers, bio-behavioural feedback

Title

Sensing Interstitial Glucose to Nudge Active Lifestyles (SIGNAL): Feasibility of combining novel self-monitoring technologies for persuasive behaviour change

Corresponding author

Maxine Whelan

National Centre for Sport and Exercise Medicine,

Loughborough University,

LE11 3TU

m.e.whelan@lboro.ac.uk

Authors

Maxine E Whelan[1,2]; Andrew P Kingsnorth[1,2]; Mark W Orme[3]; Lauren B Sherar[1,2,4]; Dale W Esliger[1,2,4]

Affiliations

(1) National Centre for Sport and Exercise Medicine, Loughborough University, UK

(2) School of Sport, Exercise and Health Sciences, Loughborough University, UK

(3) Centre for Exercise and Rehabilitation Science, NIHR Leicester Biomedical Research Centre - Respiratory, Leicester, UK.

(4) NIHR Leicester Biomedical Research Centre – Lifestyle, Leicester, UK

Word count

5,404

Keywords

Flash glucose monitoring; type 2 diabetes; physical activity; prevention; activity trackers; bio-behavioural feedback.

ABSTRACT

Introduction: Increasing physical activity (PA) reduces the risk of developing diabetes, highlighting the role of preventive medicine approaches. Changing lifestyle behaviours is difficult and is often predicated on the assumption that individuals are willing to change their lifestyles *today* to reduce the risk of developing disease *years or even decades later*. The self-monitoring technologies tested in this study will present PA feedback in real-time, parallel with acute physiological data. Presenting the immediate health benefits of being more physically active may help enact change by observing the immediate consequences of that behaviour. The present study aims to assess user engagement with the self-monitoring technologies in individuals at moderate-to-high risk of developing type 2 diabetes.

Methods and analysis:

Forty-five individuals with a moderate-to-high risk, aged ≥40 years old and using a compatible smartphone, will be invited to take part in a seven-week protocol. Following one week of baseline measurements, participants will be randomised into one of three groups: Group 1, glucose feedback followed by bio-behavioural feedback (glucose plus PA); Group 2, PA feedback followed by bio-behavioural feedback; Group 3, bio-behavioural feedback. A PA monitor and a flash glucose monitor will be deployed during the intervention. Participants will wear both devices throughout the intervention but blinded to feedback depending on group allocation. The primary outcome is the level of participant engagement and will be assessed by device use and smartphone usage. Feasibility will be assessed by the practicality of the technology and screening for diabetes risk. Semi-structured interviews will be conducted to explore participant experiences using the technologies.

Ethics and dissemination: The Loughborough University Ethics Advisory Committee has provided ethical approval to conduct this study (research proposal R17-P049). Study results will be disseminated at international conferences and published in a peer-reviewed journal.

Trial registration: ISRCTN17545949. Registered on 15/05/2017.

Keywords: Flash glucose monitoring, type 2 diabetes, physical activity, prevention, activity trackers, bio-behavioural feedback.

Strengths and limitations of this study

- The study will present real-time biological and behavioural information to participants using wearable technologies; a novel concept which has not been utilised in physical activity research.
- The study will be the first to deploy flash glucose monitors to people at risk of developing Type 2 diabetes.
- We will employ quantitative and qualitative methodologies to explore user engagement with the technology.
- A validated survey will be utilised to identify individuals at moderate-to-high risk of developing Type 2 diabetes, among which we expect a proportion to have prediabetes.
- Whilst the duration of the intervention (six continuous weeks) will permit the examination of change in engagement over time, the absence of additional follow-ups

prevents the assessment of long-term use engagement and behaviour change maintenance.

- Recruitment of at-risk individuals from the community aligns with the National Diabetes Prevention Programme.
- Cost-effectiveness analysis will not be undertaken in this study.
- Due to the nature of feasibility studies, this study will not be powered for effectiveness.

INTRODUCTION

There is widespread concern regarding the increasing prevalence of non-communicable diseases such as type 2 diabetes (1). Type 2 diabetes currently imposes an annual cost of £23.7bn through its associated complications (2); however, this cost is likely to rise as it is projected to directly impact 592 million individuals worldwide by 2035 (3). Another imposing challenge is the proportion of the population living with undiagnosed diabetes (current prevalence estimated at 45.8%) (4); which is possibly, in part, attributable to its asymptomatic state prior to the presentation of complications. Regardless of diagnosis status, preventing the development of type 2 diabetes is an international priority moving forward (5). Prediabetes, categorised as either impaired fasting glucose or impaired glucose tolerance represents abnormal glucose homeostasis and is placed between diabetes and normal regulation. Impaired fasting glucose has been defined as elevated fasting plasma glucose (100-126 mg/dl) whilst impaired glucose tolerance is characterised by an elevated two hour plasma glucose concentration (140-199 mg/dl) following intake of a 75g glucose load (6). One in seven adults have impaired glucose regulation (7) and, compared to individuals living with normal circulating glucose levels, pre-diabetics are five to ten times more likely to develop type 2 diabetes (8) with 5-10% of people becoming diabetic annually (9). Diabetes is projected to be one of ten leading causes of death worldwide (10); thus, identification and prevention are crucial for early intervention.A lack of physical activity is considered one of the major risk factors for non-communicable diseases and is comparable to the ill-effects of obesity (11) and smoking (12) individually. Given that physical inactivity, where insufficient levels of physical activity are achieved, is attributed to an estimated 7% of type 2 diabetes cases (13), it is an important modifiable lifestyle behaviour to target. With the prevalence of impaired fasting glucose doubling in individuals at 40-59 years and remaining consistent beyond 60 years (14), targeting efforts toward specific age cohorts is crucial. Individuals with abnormal glucose homeostasis are referred onto community-based lifestyle behaviour programmes such as The Healthier You: National Diabetes Prevention Programme (NDPP). Initiated in 2016, the programme aims to roll out nationally by 2020 as part of the NHS Five Year Forward plan (15). The present study intends to implement a community screening approach, monitor participant retention and to investigate whether self-monitoring technologies providing feedback about physical activity and interstitial glucose levels play a role in the prevention pathway (which may be amenable to the NDPP framework).

With increasing recognition toward the integration of technology into usual care pathways (i.e. emergence of NHS Digital), it is a crucial time to consider how technologies could contribute to the management of chronic diseases. Given recent consumer interest (16), wearable technologies permit people to self-monitor behaviour and health. Gardner and

colleagues (17) reviewed behavioural interventions and identified self-monitoring of behaviour as a particularly promising behaviour change technique. Similarly, continuous glucose monitoring technology has shown promise for longer term physiological outcomes (including glycated haemoglobin (HbA1c)) (18); supporting the suggestion that more frequent engagement leads to better health outcomes (19). Self-monitoring of both behaviour and outcomes are listed within the taxonomy alongside 91 other ingredients (i.e. feedback and goal-setting) in behavioural interventions (20) As well as delivering key behaviour change techniques, self-monitoring technologies also support Control Theory (21). More specifically, people are presented with information about a present state via feedback (e.g. 9,000 steps) and are often provided a set goal to achieve (i.e. 10,000 steps). Equipped with this information, people may make efforts to achieve the goal or desired outcome (i.e. ≥10,000 steps) because they have been informed how they are performing relative to it. The majority of research to date has focused on the deployment of technologies to self-monitor movement behaviours (e.g. (22)) or specific health markers (e.g. (23)) in isolation. Although these approaches have shown to be beneficial to behaviour change in the short term, most user engagement is not sustained beyond six months (24). Despite research conducted on short-term improvements, it is not yet clear whether results are sustained with prolonged use (25; 26). However, the rationale is that when provided with information about their current levels of activity, people may feel motivated to improve their behaviour.

With a view to sustaining the "honeymoon period" of technology-bolstered behaviour change, a logical next step would be to deploy wearable technologies in combination. For example, studies investigating the acute effects of brief physical activity bouts or interruptions to prolonged sedentary behaviour on glucose levels in controlled settings have found reductions in postprandial glucose as a result of increased movement (e.g. (27–30)). As a result, the present study proposes that delivering behavioural and physiological feedback in parallel may be more persuasive rather than when delivered in isolation. This approach may offer a platform for people to self-educate themselves about the relationship between movement and acute health status (i.e. walking after a meal leads to marked reductions in glucose levels); which may help sustain engagement with self-monitoring technologies.. With ongoing developments, technologies such as flash glucose monitoring offer a wealth of information to users without the need for invasive fingerprick samples; offering a useful tool for non-diabetic individuals (who are not accustomed to regular fingerprick blood samples) (31). To date, an important limitation of the efforts to encourage people to be more physically active has been the assumption that we are willing to change our lifestyles *today* to reduce our risk of developing disease *years or even decades later*. Implementing specific behaviour change techniques such as self-monitoring, goal-setting and feedback (20), wearable devices could empower individuals to manage their health through a change in behaviour by recognising movement patterns and observing influences on health. Building on previous findings which observed greater levels of brain activation in response to personalised glucose related information (over behavioural information) [Whelan et al., *submitted*], the present study aims to examine the role of providing novel self-monitoring technologies presenting bio-behavioural feedback in those living at moderate-to-high risk of type 2 diabetes.

AIMS AND OBJECTIVES

Primary aim

The primary aim of this study is to investigate participant engagement using self-monitoring technologies for physical activity and interstitial glucose.

Secondary aims

The secondary aims of this study are to explore (i) the feasibility of the intervention trial at baseline, 1, 2, 3, 4, 5, and 6 weeks; (ii) levels of physical activity and interstitial glucose levels at baseline, 1, 2, 3, 4, 5, and 6 weeks; (iii) levels of technology readiness, health literacy, health status and attitudes towards one's own health at baseline and post self-monitoring.

METHODS AND ANALYSIS

Study setting

Participants will be recruited from the community in Leicestershire, UK from May to November 2017. All appointments (three or four in total, depending on group allocation) will take place at the National Centre for Sport and Exercise Medicine at Loughborough University, UK.

Study design

The feasibility study protocol has been prepared in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) (32) with reference to the Template for Intervention Description and Replication (TIDieR) (33) (see supplementary material).

The study will aim to recruit 45 individuals with 15 participants randomly allocated to each of the three groups. No specific sample size has been calculated due to its feasibility status but study results will inform the sample size for a full-scale intervention.

The Sensing Interstitial Glucose to Nudge Active Lifestyle (SIGNAL) study will last seven weeks in total and is outlined in Figure 1. Following baseline (one week), participants will be randomised into one of three groups. Participants will be notified of their group allocation at the second appointment before starting the intervention period. Appointments will be arranged at the preceding appointment where possible. The study was registered on the International Standard Randomised Controlled Trial number (ISRCTN) Register (ISRCTN17545949) in May 2017.

Randomisation

Participants will be block randomised using a 1:1:1 study allocation ratio, coordinated by a remote internet-based service (http://www.sealedenvelope.com/). Randomisation will be done by a member of the research group, independent to the present study. Baseline measures will be conducted pre-randomisation. Participants will be notified of their group allocation at appointment two. In the event of participants originating from the same household, identical group allocation will be employed to avoid any cross-contamination.

Inclusion criteria

Participants will be at least 40 years old, be at moderate-to-high risk of developing type 2 diabetes (34) and use a compatible Android smartphone.

Compatible smartphones at the time of the study will be defined as having the following characteristics: An Android operating system of 4.0 or higher, Near Field Communication (NFC), a screen resolution of 480x800 to 1080x1920 and a screen size of 8.9-14.5cm. Exceptions at the time of the study are the Samsung Galaxy 7, Samsung S8, Nexus 5X and Nexus 6P which cannot install the LibreLink application.

Exclusion criteria

Individuals with a clinical diagnosis of type 1 or type 2 diabetes, a HbA1c of ≥6.5%, or have suspected/confirmed pregnancy will be excluded. Participants unable/unwilling to provide informed consent, cannot/unwilling to adhere to the study protocol or cannot read/write English will also be excluded.

Recruitment procedure

Participants will be recruited at community sites through the distribution of posters and leaflets in community organisations and local businesses based in Leicestershire, UK. Individuals will also be recruited through an existing Movement Insights Lab participant database. All individuals will be directed to complete a brief survey to determine level of risk for type 2 diabetes. Participant information sheets will be provided (copies available upon request). The questions will be presented via an online survey platform (Qualtrics, Provo, UT) and will relate to gender, age, ethnic background, familial history of diabetes, waist circumference, body mass index and blood pressure. The validated survey (34) has been used in studies applying risk score algorithms on primary care electronic data (35). Waist circumference will be replaced with clothing size and fit following guidance offered by Battram and colleagues (36). Moderate-to-high risk individuals will be contacted by the research team to take part in the study. Ineligible individuals (i.e. low risk, increased risk or a moderate/high risk, but are not aged at least 40 years old nor use an Android smartphone) will be directed to Diabetes UK "Type 2 diabetes: What to do if you're at risk" information booklets (available at: https://www.diabetes.org.uk/Global/professionals/KYR%20Booklet.pdf).

Study procedure

First appointment and baseline

An outline of the study procedure is presented in Figure 1. Appointment one will involve informed consent, health measures (height, weight, percentage body fat, waist circumference, blood pressure, HbA1c, grip strength, quadriceps strength and aerobic fitness; full methodological details are provided in the measures section below) and a brief demographics questionnaire. Participants will complete a physical activity readiness questionnaire (37) before completing the aerobic fitness assessment for screening purposes. Participants will be fitted with a waist-worn accelerometer and a wrist-worn activity tracker; measuring physical activity whilst also presenting an opportunity to validate the activity tracker. Neither device will provide feedback to the participant during the seven consecutive days of wear. Participants will be asked to install two mobile applications onto a personal Android smartphone. Both smartphone applications will sit idle on the smartphone for the duration of baseline. Participants will be asked to sync the activity tracker via the smartphone application; switching on Wi-Fi and Bluetooth simultaneously at least once every five days for ≥1 hour to ensure the sync occurs.

Second appointment and intervention

One week later (following baseline), participants will attend appointment two where they will be informed of their group allocation. Participants will be asked to complete a brief questionnaire, to continue wearing the activity tracker during the intervention (settings may or may not be adjusted) and to return the accelerometer. A glucose sensor will be deployed to each participant to measure interstitial glucose levels. Participants will be provided with additional supplies of glucose sensors to last for the four (Groups 1 and 2) or six weeks (Group 3) of the intervention. Accounts for both the activity tracker and glucose sensor will be connected to Diasend (Diasend Inc., Chicago, IL). An overview of the three groups is provided below.

Group 1 (glucose feedback followed by bio-behavioural feedback)

Real-time interstitial glucose feedback will be presented to participants for four weeks via the LibreLink application (Abbott Diabetes Care Inc., Alameda, CA). Participants will install the LibreLink mobile application (Abbott Diabetes Care Inc., Alameda, CA) onto a personal Android smartphone to interact with the Freestyle Libre via Near Field Communication (NFC) for measurement of interstitial glucose. The glucose monitor has a lifespan that restricts wear to 14 consecutive days. The application will remind participants to scan every seven hours and to remove/replace after 14 days. The LibreLink application will continuously display the number of days left.

Group 2 (physical activity feedback followed by bio-behavioural feedback)

Real-time physical activity feedback will be presented for four weeks via the Fitbit application. In contrast to Group 1, participants will not have the LibreLink application installed and so will not have access to glucose feedback. Participants will be informed that the glucose sensor is functional (recording data) and participants will be asked to remove and replace the expired sensor with another sensor after 14 days.

Device unmasking for Groups 1 and 2 after four weeks

At the end of the first four weeks of the intervention, participants in Groups 1 and 2 will attend a brief appointment (up to one hour in duration). For Group 1, the researcher will adjust settings to reveal physical activity feedback via the Fitbit application and device. For Group 2, the researcher will install the LibreLink application to reveal glucose feedback. All participants will be able to access bio-behavioural feedback for the remaining two weeks of the intervention.

Group 3 (bio-behavioural feedback)

Participants in Group 3 will receive bio-behavioural feedback for the full six weeks via the two independent LibreLink and Fitbit applications. Participants will install the LibreLink mobile application onto a personal Android smartphone to interact with the Freestyle Libre to measure interstitial glucose. The application will remind participants to scan every seven hours and to remove/replace the sensor after 14 days.

Final appointment

All participants (Groups 1, 2 and 3) will be asked to attend the final appointment at the end of the intervention where they will complete a questionnaire (identical to appointment 2, apart

from the revised Diabetes Knowledge Test) and a semi-structured interview. All participants will also receive a personalised health report containing results from the health measures conducted at appointment one.

Device masking

All email accounts and password combinations will be manually generated and managed by the research team to prevent use of identifiable information. During baseline wear, the activity tracker will be physically masked using black tape applied to the screen; leaving only time and date viewable. Participants will be asked not to tamper with the screen; however, if they do manipulate the masking, it should be readily apparent to the research team. Settings on the application will also be adjusted to remove physical activity metrics from the device screen and notifications fully restricted on their phone and activity tracker. However, participants will not be locked out of the application due to the requirement to sync the device. Time spent on the Fitbit application will be inspected using Ethica Data (Kitchener, Ontario, Canada) to identify potential unauthorised use. The activity tracker will also be set to *all day sync* to minimise data loss with data automatically transferred (Wi-Fi and Bluetooth must both be simultaneously switched on). When required to prevent access to glucose feedback, participants will wear the glucose sensors for 14 day periods as normal but will not be asked to install the LibreLink application nor scan the sensor (i.e. no data will be collected). This will standardise wear across all three groups.

Data management and storage procedures

All data collected will be anonymised by assigning a participant ID. Accounts with the three applications (Fitbit, LibreLink and Ethica Health) will be setup using study-specific ('dummy') email addresses and passwords (accessible only to the research team) to minimise use of personalised information. All data will be stored securely on the Loughborough University server, as password protected, encrypted documents and original paperwork kept in locked storage. No directly personally identifiable information will be collected through these platforms. GPS (global positioning system) will be collected via Ethica Data which could theoretically be 'reverse-engineered' to re-identify individuals; however, all participants will be explicitly informed about all information monitored as part of the study. For individuals who do not wish to have their location services monitored, we will set up a 'reduced access' version of Ethica Data (application usage, screen state and survey responses only).

Primary outcomes

User engagement: Quantitative

Time spent on the official free Fitbit and LibreLink applications will be quantified using Ethica Data as well as time-stamped data relating to when the smartphone screen was turned on and off. In combination, these two data sources will reveal the proportion of time that the devices' applications were used in relation to total smartphone use. These data will be recorded at either a day level (e.g. aggregate time) or event level (e.g. record of each time an application was opened) depending on the Android smartphone model. How often and how much time spent on the two applications compared with other applications on participants' smartphones will also be quantified. Number of times the activity tracker syncs (occurs when the application is opened, assumed to see feedback about physical activity) and scans of the

glucose sensor (occurs when the participant scans and to see feedback about interstitial glucose levels) will also be recorded. *Compulsory engagement* will be participants having to sync the activity tracker at least once every five days and scan the glucose snros at least once every seven hours. The number of syncs and scans recorded over and above *compulsory engagement* will reflect *optional engagement*. Identifying when and how often syncs and scans happen and how these patterns change over the course of the intervention (from week one to six) will indicate engagement with the technology. We will also identify if participants change the goal settings relating to steps, floors climbed and active minutes on the Fitbit application. These settings will be checked daily between the hours of 18:00-19:00 by the research team and changes will be flagged with details of the original and new setting logged. In addition, assessing whether participants responded to prompts offered by the activity tracker will also be conducted (i.e. did participants achieve 250 steps/hour? See Behaviour Change Techniques section for further detail).

Remote monitoring of participant glucose and physical activity will be completed using Diasend (Diasend Inc., Chicago, IL) and Fitabase (Small Steps Labs LLC., San Diego, CA), respectively. Diasend will connect with the Freestyle Libre via the LibreLink application and data will be recorded and accessed through this software. Additional data sources to be monitored by Ethica Data include battery status (i.e. smartphone plugged in? Charging?), Bluetooth and Wi-Fi (turned on or off). Quantifying these data sources will provide valuable insight into participant behaviour (e.g. Do participants only use Wi-Fi and Bluetooth for the purpose of our intervention? Are participants charging it more often in the intervention compared with baseline?). Ethica Data will also monitor location (GPS), motion (pedometer, accelerometer, gravity, gyroscope, linear acceleration, magnetic field, orientation) and survey responses. These digital streams will monitor smartphone usage and will provide detailed data on human behaviour during a free-living, naturalistic setting. In total, fourteen data sources will be monitored. In the event a participant raises concerns relating to the number and/or type of data sources being monitored, a *restricted* coverage option of only three data sources (application usage, screen state and survey responses) will be offered.

User engagement: Qualitative

For participants who complete the six-week intervention, a semi-structured interview will be completed (20-40 minutes) during the final appointment at the National Centre for Sport and Exercise Medicine, Loughborough University, UK. The interview will aim to identify potential barriers and facilitators to using self-monitoring technologies. In particular, how participants experience receiving feedback relating to physical activity and interstitial glucose levels. These interviews will explore individual experiences using the device(s) and mobile application(s), adherence to syncing (Fitbit) and scanning (Freestyle Libre), wearing multiple devices and the perceived effect of viewing feedback on actual behaviour. In addition, participants will be asked about future intentions to continue wearing self-monitoring devices and identify any recommended changes for future study designs.

If a participant decides to withdraw from the study at any time prior to the final appointment, they will be able to leave the study via (i) the Ethica Health application on their personal smartphone (aligning with a dynamic consenting process (38)) or by (ii) contacting the research team via telephone or email. Participants that decide to withdraw via Ethica Health will be directed to complete a brief exit survey on the application. The research team will contact all participants for an optional exit interview (5-10 minutes) via telephone. This will

be recorded using Tapeacall (http://www.tapeacall.com/) and will explore reasons for not completing the study.

Secondary Outcomes

Feasibility

Guidelines used to assess the feasibility of this study were informed by Bowen and colleagues (39). Both qualitative and quantitative data will be collected to assess feasibility of deploying novel self-monitoring technologies in parallel. In total, we will assess intervention feasibility as outlined in Table 1.

Table 1. An overview of the feasibility components to be assessed.

Feasibility component	Data source (indicator of feasibility)
Practicality of technology/intervention	• Qualitative interviews • Fitabase (sync compliance, missing data and response to haptic prompt) • LibreLinkUp (scan compliance) • Diasend (missing data, identification of glucose sensor sensor-related issues) • Project records (identification of need to dispatch additional glucose sensors, number of individuals screened, rate of eligibility, study uptake and retention) • Ethica Data (data sources, enrolment into full* or restricted+ coverage)
Acceptability of technology/intervention	• Qualitative interviews • Fitabase (activity tracker wear time) • Diasend (glucose sensor wear time, digital footprint of time taken to move onto the next glucose sensor i.e. sensor delay?) • Project records (changes to goal settings, manual withdrawals, attendance at appointments, retention to follow-up) • Ethica Data (digital footprint of application usage, Bluetooth and Wi-Fi status, battery status, electronic withdrawal)

**Full coverage: application usage, screen state, Bluetooth, Wi-Fi, GPS, pedometer, accelerometer, gravity, gyroscope, linear acceleration, magnetic field, orientation, battery and survey responses.*
+Restricted coverage: application usage, screen state and survey responses.

Physical activity levels

ActiGraph

The ActiGraph wGT3X-BT (ActiGraph, Pensacola, FL, USA) accelerometer will quantify time spent sedentary, in light and moderate-to-vigorous physical activity (MVPA) as well as step count. Participants will be asked to wear the device on their waist over the right hip

(mid-clavicular line) during waking hours and to remove for any water-based activities (e.g. showering and swimming). ActiGraph accelerometers were deployed because they have been shown to offer high validity and reliability in free-living settings (40). Data from the ActiGraph will be collected at 100 Hz and integrated into 60 second epochs using ActiLife (ActiGraph, Pensacola, FL, USA) and processed using Kinesoft (Kinesoft, Loughborough, UK). Non-wear will be defined as 60 minutes of consecutive zeros (allowing for up to two minutes of interruptions) with a minimum wear of 600 waking minutes used to define a valid day (41). A minimum of 4 valid days will be used to define a valid file with sedentary time classified as <100cpm, light activity as 100-2019cpm and MVPA as >= 2020cpm (41).

Fitbit

The Fitbit Charge 2 (Fitbit Inc., San Francisco, CA) will be worn on the wrist associated with the non-dominant arm and, whilst being sweat, rain and splash proof, participants will be asked to remove the device for water-based activities. The Fitbit records intensity (i.e. minutes spent lightly active, fairly active and very active) in addition to heart rate and step count. Heart rate will be assessed using Fitbit's proprietary PurePulse optical heart rate technology. To examine changes in physical activity over the study duration, participants will be requested to wear the device for the full seven weeks and data will be analysed in 60 second epochs following export from Fitabase. Previous models of the Fitbit have been validated for step count (42). Free-living concurrent validation of the Fitbit Charge 2 will be conducted and reported with the results of the trial. A waking protocol will be implemented with non-wear defined as a loss of a heart rate signal. Participants will be requested to sync the Fitbit at least once every five days (rather than the company recommendations of seven days) to minimise data loss. Syncs beyond seven days will result in day level data rather than minute level data. These syncs will either occur automatically (i.e. without the application open) or will be user-driven (i.e. with the application open) depending on how the *all day sync* is set and heart rate will be set to automatic (only record heart rate when device is worn).

Interstitial glucose levels

Freestyle Libre

The minimally-invasive Freestyle Libre flash glucose monitor (Abbott Diabetes Care, Alameda, CA) will be covered with Tegaderm (3M Health Care, St. Paul, MN) to help maintain position and adhesion during the 14 day sensor lifespan. Three strips of Tegaderm will be provided to participants per sensor to allow for replacement when the Tegaderm becomes dirty. Participants will be asked to wear the device continuously without removal for water-based activities. The Freestyle Libre demonstrates consistent accuracy throughout the 14 days with a mean absolute relative difference of 11.4% compared with capillary blood glucose, a lag time of 4.5-4.8 minutes and is not impacted by physical characteristics including age, BMI and HbA1c (31). Participants will be requested to scan the glucose monitor at least once every seven hours (rather than the company recommendations of eight hours) to minimise data loss. If participants experience skin irritation on the non-dominant arm in the region of application, participants will be advised to switch to their dominant arm. Interstitial glucose data will be downloaded in 15 minute epochs using Diasend, an online platform connected to the LibreLink application. Participant accounts will be linked to Diasend from the point of LibreLink application installation. Figure 2 illustrates how the numerous components connect to achieve the primary and secondary aims.

Levels of technology readiness, health status and attitude

All questionnaires will be completed electronically using an online platform for immediate data entry (http://www.onlinesurveys.ac.uk/; Bristol, UK). At appointment two, quality of life will be assessed via the 26 item EQ-5D-5L (43), technology readiness via the 16 item Technology Readiness Index (TRI 2.0) (44), health literacy via the 8 item eHealth Literacy Scale (e-HEALs) (45), diabetes knowledge via the 20 item revised diabetes knowledge test (46) and general attitude toward developing diabetes via the 8 item general attitudes section of the Risk Perception Survey for Developing Diabetes (RPS-DD) (47).

Other measures

Participant Characteristics

Self-reported age, sex, ethnic background, employment, household income, postcode (to provide an Index of Multiple Deprivation score) and education will be recorded.

Health, physical functioning and fitness

HbA1c will be assessed at the first appointment using a point-of-care system, (Afinion AS100 Analyser, Alere Inc., Waltham, MA). Results will be processed immediately following collection. Participants receiving a result ≥6.5% will be ineligible, readings of 5.7-6.4% classified as pre-diabetic (48) and readings of <5.7% classified as euglycemic. A measure of height will be conducted using a Seca stadiometer (Seca, Hamburg, Germany) and weight and body fat percentage will be measured using Tanita scales (Tokyo, Japan). Two measures of waist circumference will be taken at the midpoint between the lowest rib and top of the iliac crest; if the difference exceeds 1 cm, the two measurements will be repeated (49). Three measures of blood pressure will be recorded using an Omron digital monitor (Omron Corporation, Kyoto, Japan) with the first measure taken after the participant has remained seated for ten minutes. Grip strength will be assessed using a handheld Takei dynamometer (Takei Scientific Instruments, Tokyo, Japan) whilst standing with hands positioned down each side. Quadriceps strength will be assessed using the DAVID G200 knee extension machine (David Health Solutions Ltd., Helsinki, Finland). Aerobic fitness will be assessed using the modified Canadian Aerobic Fitness Test (mCAFT) (50). The mCAFT is a sub-maximal step-test protocol with participants instructed to complete ≥1 three-minute stages of stepping at a speed dictated by an audio track. Heart rate will be monitored throughout with the stepping stages continued until heart rate ≥85% of age-predicted maximal heart rate. Participants' scores for aerobic fitness will be defined according to the following formula*:* 17.2 + (1.29 x oxygen cost at the final stage) - (0.09 x weight in kg) - (0.18 x age in years) (50).

Behaviour change techniques

Prior to starting the intervention, the researcher will implement the default settings for levels of physical activity (BCT 1.1: Goal setting (behaviour)) (i.e. 10,000 steps and 10 floors climbed) and glucose (BCT 1.3: Goal setting (outcome)) (i.e. 4.0-5.9 mmol/L). Participants will be fully informed that they can freely change the goals set for physical activity as preferred (i.e. should the default value be too easy/difficult) via the Fitbit application. However, participants will be advised to not make any changes via the LibreLink application for the target glucose range. Attainment of a goal will be assessed as either complete or

incomplete. Participants will be asked to sync the Fitbit (at least once every five days) and scan the Freestyle Libre (at least once every seven hours) if they are in the respective group to receive feedback from these devices. This action has a dual purpose; to minimise data loss and to encourage continued engagement with the technologies. Participants will also receive haptic feedback (BCT 7.1: Prompts/cues; i.e. a gentle vibration) as a reminder to move by the Fitbit 10 minutes prior to the end of each hour (default 09:00-18:00) if 250 steps have not been taken. The reminder to move prompt aims to encourage interruptions in prolonged sedentary bouts as is recommended by the UK Physical Activity Guidelines (51). In relation to the other behaviour change techniques, participants will be able to monitor physical activity levels using the Fitbit Charge 2 (BCT: 2.3 Self-monitoring of behaviour) and glucose levels using the Freestyle Libre (BCT: 2.4: Self-monitoring of outcome(s) of behaviour) which is a minimally-invasive device that presents feedback about glucose (BCT: Biofeedback).

Quantitative data analysis

Analysis of primary outcomes

Ethica Data is a fee-for-service platform that will be used to provide time-stamped data relating to application usage. This is an application installed on participants' phones and sits idle during the study period. The number of scans and syncs will be unobtrusively assessed using the free LibreLinkUp mobile application (Abbott Diabetes Care Inc., Alameda, CA) and Fitabase (Small Steps Labs LLC., San Diego, CA), respectively. Fitabase is a fee-for-service platform that permits access to download 60 second epoch Fitbit data (i.e. levels of physical activity) and remote monitoring of Fitbit devices (e.g. battery level and time since last sync event) via Bluetooth and Wi-Fi. Identification of moments where participants have decided to change the goal settings will be completed by accessing the online Fitbit account. The researchers will remotely access participants' accounts daily between 18:00-19:00 to note goal settings; recording the date and live/current settings for all metrics (e.g. step count) to help identify any changes.

Analysis of secondary outcomes

To assess eligibility, uptake and retention, we will manually record how many individuals complete the screening survey, how many meet our inclusion criteria and of these how many decide to enrol. In addition, the screening survey will also identify recruitment sources. Identifying nonusage attrition and dropout attribution is crucial to assess the feasibility of an intervention as they are both important but distinct constructs (52). Nonusage attrition, where participants have disengaged from the intervention but have not dropped out, will be defined as participants who attend appointment two but do not sync the Fitbit or scan the Freestyle Libre. Dropout attrition will be defined as participants who explicitly withdraw from the study via Ethica Health or direct contact with the research team. The number of participants who enrol into the full coverage (all 14 data sources monitored) or restricted coverage (only three data sources monitored) for Ethica Data will also be recorded. Diasend is a fee-for-service platform that permits access to download 15 minute epoch data from the Freestyle Libre and remote monitoring of multiple LibreLink accounts. Descriptive statistics of the sample will be conducted. In addition, two-way repeated measures ANCOVAs will be conducted to assess changes in engagement (dependent) according to group (independent) having adjusted for participant characteristics. Similarly, two-way repeated measures

ANCOVAs will be conducted to assess changes in physical activity (dependent) according to group (independent) having adjusted for baseline physical activity, Fitbit wear time and participant characteristics. All data will be analysed using Statistical Package for Social Sciences (SPSS Inc. Chicago, IL).

Qualitative data analysis

All interviews will be audio recorded (with informed consent), transcribed verbatim and analysed using thematic analysis. This will involve standard thematic data analysis procedures; identifying emerging patterns in the interview (53). Transcripts will be analysed using constant comparison with initial free coding and emergent themes interrogated (54). The interview schedule and coding schedule will be modified to follow new leads until new themes no longer emerge. The analysis will create a coding frame that 'fits' the data (54). Transcripts will be uploaded into NVivo qualitative data analysis software (QSR International Pty, Ltd, Victoria, Australia).

DISSEMINATION

This work will inform a full-scale randomised-controlled trial by enabling a sample size calculation. The full-scale RCT will primarily aim to investigate changes in physical activity and interstitial glucose levels in individuals randomised into the three groups. Overall, the findings seek to encourage the implementation of technologies into usual pre-clinical care pathways; in particular, how engaging with self-monitoring technologies (providing bio-behavioural feedback) may positively influence rates of uptake, adherence, retention and behaviour change.

We will publicise study findings online, present them at international conferences relating to diabetes, physical activity and digital health and publish via a peer-reviewed journal.

DECLARATIONS

Competing interests

None declared.

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Author contributions

All authors have contributed to the design of the work, acquisition and analysis plan. MW, AK, MO, LS and DE were involved in the development of the intervention and design of the trial. MW, AK, MO, LS and DE have been involved in drafting the work or revising it critically for important intellectual content.

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Figure 1. An illustration of the intervention design (*indicates a brief appointment at 4 weeks).

Figure 2. A schematic of how the wearable technologies, mobile applications and software connect.

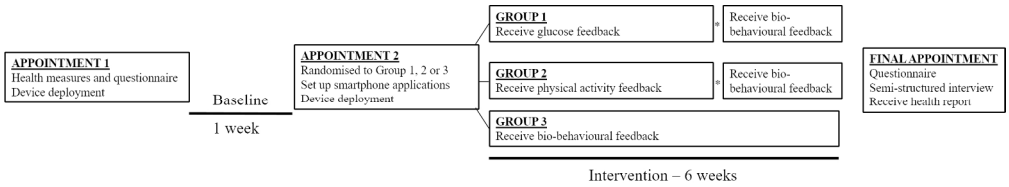

Figure 1. An illustration of the intervention design (*indicates a brief appointment at 4 weeks).

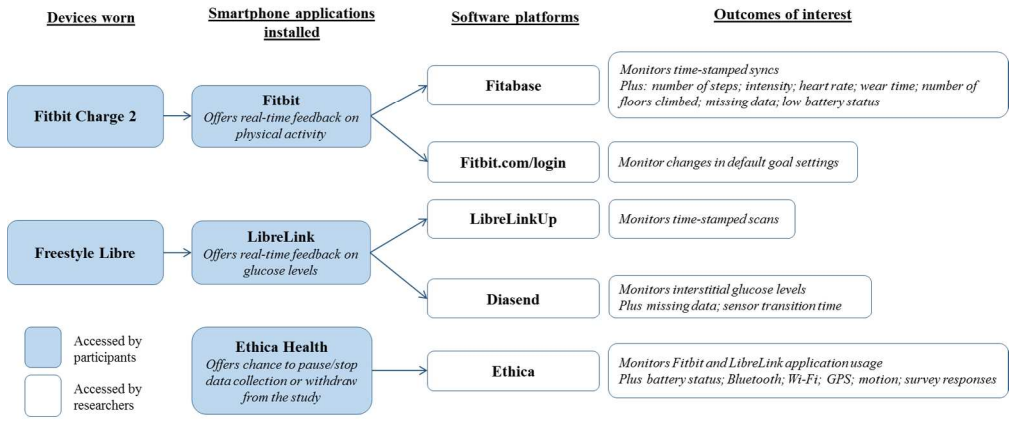

Figure 2. A schematic of how the wearable technologies, mobile applications and software connect.

Supplementary material

Table 1. Intervention description using the Template for Intervention Description and Replication (TIDieR) checklist

1. Brief name	The Sensing Interstitial Glucose to Nudge Active Lifestyles Study.
2. Why	Encouraging people to become more physically active offers a wealth of benefits for everyone. With widespread prevalence of type 2 diabetes, a non-communicable disease largely attributed to poor lifestyle choices, people living with prediabetes should access early lifestyle intervention to prevent disease onset. Self-monitoring is a recognised behaviour change technique that aligns well with the influx of mobile health (mHealth) technologies; however, more needs to be done to improve sustained use of these devices. Given the contribution of behaviour to type 2 diabetes, deploying self-monitoring technologies that present behavioural (physical activity) and physiological (interstitial glucose) information in parallel could be a persuasive behaviour change method. Understanding how people use these devices is paramount to assess feasibility of deployment and levels of engagement over time.
3. What - materials	All participants, regardless of group allocation, will wear two devices simultaneously for the full six weeks of the intervention. The first device, the Freestyle Libre (Abbott, Diabetes Care, Alameda, CA), will present interstitial glucose levels and the second, the Fitbit Charge 2 (Fitbit Inc., San Francisco, CA), will present physical activity feedback. If the device is to be masked, the participants will either have the device taped with access to metrics restricted or have no access to the data at all.
4. What - procedures	Engagement will be recorded using Ethica Data (Kitchener, Ontario, Canada), Fitabase (Small Steps Labs LLC., San Diego, CA) and LibreLinkUp (Abbott, Diabetes Care, Alameda, CA). Ethica Data will quantify smartphone application usage, Fitabase will record the number of times participants sync the Fitbit and LibreLinkUp will time-stamp when participants scan the Freestyle Libre. The Ethica

	Health application will also allow participants to withdraw from the study at any point during the intervention. Semi-structured interviews will be conducted to discuss the feasibility of the intervention.
5. Who provided	A team of early career academics will deliver the intervention.
6. How	The intervention will be delivered via two self-monitoring technology devices. The Freestyle Libre will present feedback relating to interstitial glucose levels and the Fitbit Charge will present feedback relating to physical activity levels.
7. Where	The intervention will be delivered in Leicestershire, UK. Appointments will take place at the National Centre for Sport and Exercise Medicine, Loughborough University, UK.
8. When and how much	Participants will be requested to attend up to four face-to-face appointments. Following baseline (seven days), participants will be randomised into one of three groups. Group 1 will receive interstitial glucose feedback, Group 2 will receive physical activity feedback, and Group 3 will receive bio-behavioural feedback (interstitial and physical activity feedback). For the remaining two weeks of the intervention, Groups 1 and 2 will receive bio-behavioural feedback (both interstitial and physical activity feedback).
9. Tailoring	The self-monitoring technologies will provide personalised data relating to interstitial glucose and physical activity levels during the intervention. Participants will be able to adjust goals based on individual preference for the Fitbit (e.g. number of steps).

Table 2. Spirit 2013 Checklist.

Section	Included in manuscript (Y/N) or described here.	Manuscript page number
Administrative Information		
1. Title	Y	1
2a. Trial registration	Y	2, 5
2b.	Y – provided within manuscript, via ISRCTN http://www.isrctn.com/ISRCTN17545949 or via study website www.lboro.ac.uk/research/mi-lab/research/signal/	2-15
3. Protocol version	Version 2, 15/05/2017	
4. Funding	Y	14
5a. Roles and responsibilities	Y	14
5b.	Contact details can be found via the ISRCTN registration.	
5c.	Y	14
5d.	The steering committee is comprised of the study authors.	
Introduction		
6a. Background and rationale	Y	3-4
6b.	Y	3-4
7. Objectives	Y	4-5
8. Trial design	Y	5-8
Methods		
9. Study setting	Y	5
10. Eligibility criteria	Y	5-6
11a. Interventions	Y	7
11b.	Y – participants originating from the same household will be allocated to an identical group (to avoid any cross-contamination).	5
11c.	Y	8-9
11d.	No relevant concomitant care nor interventions.	N/A
12. Outcomes	Y	8-10
13. Participant timeline	Y	5 and Fig. 1
14. Sample size	Y	5
15. Recruitment	Y	5
Assignment of interventions Allocation		
16a. Sequence generation	Y	5
16b. Allocation concealment mechanism	Y	5
16c. Implementation	Y	5
17a. Blinding (masking)	Y – The PI will be blinded during health measures at baseline. The PI will be informed of group allocations prior to	8

	appointment 2. Outcome assessments will not be blinded.	
17b.	Y – Participants and researcher will be unblinded following baseline measures.	5
18a. Data collection methods	Data collection forms can be obtained on request.	N/A
18b.	Y	13
19. Data management	Y - Data will be entered into password protected spreadsheets. Data will be manually checked against source documents throughout the study.	8
20a. Statistical methods	Y	13-14
20b.	Y	13-14
20c.	Y	13-14
Monitoring		
21a. Data monitoring	DMC is not needed on this occasion as it is a feasibility study.	N/A
21b.	No interim analyses are planned as the trial is low risk.	N/A
22. Harms	Any adverse events will be recorded and reported to the ethics committees along with any protocol amendments.	N/A
23. Auditing	No intention to conduct audit of trial conduct. The study team of investigators will regularly meet to discuss progress.	N/A
Ethics and dissemination		
24. Research ethics approval	Y	2
25. Protocol amendments	Amendments will be communicated to the ethics committee and trial registry, if needed.	N/A
26a. Consent or assent	Y	6
26b.	N/A	N/A
27. Confidentiality	Y - All participants will be assigned a unique registration number used on data collection forms.	8
28. Declaration of interests	Y	14
29. Access to data	Study authors will have access to the final trial dataset.	N/A
30. Ancillary and post-trial care	Y – there is no ancillary or post-trial care to be offered.	8
31a. Dissemination policy	Y – Study team intend to share results with participants following data analysis.	14
31b.	No intention to use professional writers.	N/A
31c.	The dataset will be made available to others upon request.	N/A
Appendices		
32. Informed consent materials	N – Copy of consent form can be accessed via www.lboro.ac.uk/research/mi-lab/research/signal/	N/A

33. Biological specimens	N - Described in consent form, can be accessed via www.lboro.ac.uk/research/mi-lab/research/signal/	N/A

BMJ Open

Sensing Interstitial Glucose to Nudge Active Lifestyles (SIGNAL): Feasibility of combining novel self-monitoring technologies for persuasive behaviour change.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-018282.R2
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Primary Subject Heading:	Public health
Secondary Subject Heading:	Diabetes and endocrinology
Keywords:	Flash glucose monitoring, type 2 diabetes, physical activity, prevention, activity trackers, bio-behavioural feedback

Title

Sensing Interstitial Glucose to Nudge Active Lifestyles (SIGNAL): Feasibility of combining novel self-monitoring technologies for persuasive behaviour change

Corresponding author

Maxine Whelan

National Centre for Sport and Exercise Medicine,

Loughborough University,

LE11 3TU

m.e.whelan@lboro.ac.uk

Authors

Maxine E Whelan[1,2]; Andrew P Kingsnorth[1,2]; Mark W Orme[3]; Lauren B Sherar[1,2,4]; Dale W Esliger[1,2,4]

Affiliations

(1) National Centre for Sport and Exercise Medicine, Loughborough University, UK

(2) School of Sport, Exercise and Health Sciences, Loughborough University, UK

(3) Centre for Exercise and Rehabilitation Science, NIHR Leicester Biomedical Research Centre - Respiratory, Leicester, UK.

(4) NIHR Leicester Biomedical Research Centre – Lifestyle, Leicester, UK

Word count

5,405

Keywords

Flash glucose monitoring; type 2 diabetes; physical activity; prevention; activity trackers; bio-behavioural feedback.

ABSTRACT

Introduction: Increasing physical activity (PA) reduces the risk of developing diabetes, highlighting the role of preventive medicine approaches. Changing lifestyle behaviours is difficult and is often predicated on the assumption that individuals are willing to change their lifestyles *today* to reduce the risk of developing disease *years or even decades later*. The self-monitoring technologies tested in this study will present PA feedback in real-time, parallel with acute physiological data. Presenting the immediate health benefits of being more physically active may help enact change by observing the immediate consequences of that behaviour. The present study aims to assess user engagement with the self-monitoring technologies in individuals at moderate-to-high risk of developing type 2 diabetes.

Methods and analysis:

Forty-five individuals with a moderate-to-high risk, aged ≥40 years old and using a compatible smartphone, will be invited to take part in a seven-week protocol. Following one week of baseline measurements, participants will be randomised into one of three groups: Group 1, glucose feedback followed by bio-behavioural feedback (glucose plus PA); Group 2, PA feedback followed by bio-behavioural feedback; Group 3, bio-behavioural feedback. A PA monitor and a flash glucose monitor will be deployed during the intervention. Participants will wear both devices throughout the intervention but blinded to feedback depending on group allocation. The primary outcome is the level of participant engagement and will be assessed by device use and smartphone usage. Feasibility will be assessed by the practicality of the technology and screening for diabetes risk. Semi-structured interviews will be conducted to explore participant experiences using the technologies.

Ethics and dissemination: The Loughborough University Ethics Advisory Committee has provided ethical approval to conduct this study (research proposal R17-P049). Study results will be disseminated at international conferences and published in a peer-reviewed journal.

Trial registration: ISRCTN17545949. Registered on 15/05/2017.

Keywords: Flash glucose monitoring, type 2 diabetes, physical activity, prevention, activity trackers, bio-behavioural feedback.

Strengths and limitations of this study

- The study will present real-time biological and behavioural information to participants using wearable technologies; a novel concept which has not been utilised in physical activity research.
- The study will be the first to deploy flash glucose monitors to people at risk of developing Type 2 diabetes.
- We will employ quantitative and qualitative methodologies to explore user engagement with the technology.
- A validated survey will be utilised to identify individuals at moderate-to-high risk of developing Type 2 diabetes, among which we expect a proportion to have prediabetes.
- Whilst the duration of the intervention (six continuous weeks) will permit the examination of change in engagement over time, the absence of additional follow-ups

prevents the assessment of long-term use engagement and behaviour change maintenance.

- Recruitment of at-risk individuals from the community aligns with the National Diabetes Prevention Programme.
- Cost-effectiveness analysis will not be undertaken in this study.
- Due to the nature of feasibility studies, this study will not be powered for effectiveness.

INTRODUCTION

There is widespread concern regarding the increasing prevalence of non-communicable diseases such as type 2 diabetes (1). Type 2 diabetes currently imposes an annual cost of £23.7bn through its associated complications (2); however, this cost is likely to rise as it is projected to directly impact 592 million individuals worldwide by 2035 (3). Another imposing challenge is the proportion of the population living with undiagnosed diabetes (current prevalence estimated at 45.8%) (4); which is possibly, in part, attributable to its asymptomatic state prior to the presentation of complications. Regardless of diagnosis status, preventing the development of type 2 diabetes is an international priority moving forward (5). Prediabetes, categorised as either impaired fasting glucose or impaired glucose tolerance represents abnormal glucose homeostasis and is placed between diabetes and normal regulation. Impaired fasting glucose has been defined as elevated fasting plasma glucose (100-126 mg/dl) whilst impaired glucose tolerance is characterised by an elevated two hour plasma glucose concentration (140-199 mg/dl) following intake of a 75g glucose load (6). One in seven adults have impaired glucose regulation (7) and, compared to individuals living with normal circulating glucose levels, pre-diabetics are five to ten times more likely to develop type 2 diabetes (8) with 5-10% of people becoming diabetic annually (9). Diabetes is projected to be one of ten leading causes of death worldwide (10); thus, identification and prevention are crucial for early intervention. A lack of physical activity is considered one of the major risk factors for non-communicable diseases and is comparable to the ill-effects of obesity (11) and smoking (12) individually. Given that physical inactivity, where insufficient levels of physical activity are achieved, is attributed to an estimated 7% of type 2 diabetes cases (13), it is an important modifiable lifestyle behaviour to target. With the prevalence of impaired fasting glucose doubling in individuals at 40-59 years and remaining consistent beyond 60 years (14), targeting efforts toward specific age cohorts is crucial. Individuals with abnormal glucose homeostasis are referred onto community-based lifestyle behaviour programmes such as The Healthier You: National Diabetes Prevention Programme (NDPP). Initiated in 2016, the programme aims to roll out nationally by 2020 as part of the NHS Five Year Forward plan (15). The present study intends to implement a community screening approach, monitor participant retention and to investigate whether self-monitoring technologies providing feedback about physical activity and interstitial glucose levels play a role in the prevention pathway (which may be amenable to the NDPP framework).

With increasing recognition toward the integration of technology into usual care pathways (i.e. emergence of NHS Digital), it is a crucial time to consider how technologies could contribute to the management of chronic diseases. Given recent consumer interest (16), wearable technologies permit people to self-monitor behaviour and health. Gardner and

colleagues (17) reviewed behavioural interventions and identified self-monitoring of behaviour as a particularly promising behaviour change technique. Similarly, continuous glucose monitoring technology has shown promise for longer term physiological outcomes (including glycated haemoglobin (HbA1c)) (18); supporting the suggestion that more frequent engagement leads to better health outcomes (19). Self-monitoring of both behaviour and outcomes are listed within the taxonomy alongside 91 other ingredients (i.e. feedback and goal-setting) in behavioural interventions (20) As well as delivering key behaviour change techniques, self-monitoring technologies also support Control Theory (21). More specifically, people are presented with information about a present state via feedback (e.g. 9,000 steps) and are often provided a set goal to achieve (i.e. 10,000 steps). Equipped with this information, people may make efforts to achieve the goal or desired outcome (i.e. ≥10,000 steps) because they have been informed how they are performing relative to it. The majority of research to date has focused on the deployment of technologies to self-monitor movement behaviours (e.g. (22)) or specific health markers (e.g. (23)) in isolation. Although these approaches have shown to be beneficial to behaviour change in the short term, most user engagement is not sustained beyond six months (24). Despite research conducted on short-term improvements, it is not yet clear whether results are sustained with prolonged use (25; 26). However, the rationale is that when provided with information about their current levels of activity, people may feel motivated to improve their behaviour.

With a view to sustaining the "honeymoon period" of technology-bolstered behaviour change, a logical next step would be to deploy wearable technologies in combination. For example, studies investigating the acute effects of brief physical activity bouts or interruptions to prolonged sedentary behaviour on glucose levels in controlled settings have found reductions in postprandial glucose as a result of increased movement (e.g. (27–30)). As a result, the present study proposes that delivering behavioural and physiological feedback in parallel may be more persuasive rather than when delivered in isolation. This approach may offer a platform for people to self-educate themselves about the relationship between movement and acute health status (i.e. walking after a meal leads to marked reductions in glucose levels); which may help sustain engagement with self-monitoring technologies.. With ongoing developments, technologies such as flash glucose monitoring offer a wealth of information to users without the need for invasive fingerprick samples; offering a useful tool for non-diabetic individuals (who are not accustomed to regular fingerprick blood samples) (31). To date, an important limitation of the efforts to encourage people to be more physically active has been the assumption that we are willing to change our lifestyles *today* to reduce our risk of developing disease *years or even decades later*. Implementing specific behaviour change techniques such as self-monitoring, goal-setting and feedback (20), wearable devices could empower individuals to manage their health through a change in behaviour by recognising movement patterns and observing influences on health. Building on previous findings which observed greater levels of brain activation in response to personalised glucose related information (over behavioural information) [Whelan et al., *submitted*], the present study aims to examine the role of providing novel self-monitoring technologies presenting bio-behavioural feedback in those living at moderate-to-high risk of type 2 diabetes.

AIMS AND OBJECTIVES

Primary aim

The primary aim of this study is to investigate participant engagement using self-monitoring technologies for physical activity and interstitial glucose.

Secondary aims

The secondary aims of this study are to explore (i) the feasibility of the intervention trial at baseline, 1, 2, 3, 4, 5, and 6 weeks; (ii) levels of physical activity and interstitial glucose levels at baseline, 1, 2, 3, 4, 5, and 6 weeks; (iii) levels of technology readiness, health literacy, health status and attitudes towards one's own health at baseline and post self-monitoring.

METHODS AND ANALYSIS

Study setting

Participants will be recruited from the community in Leicestershire, UK from May to November 2017. All appointments (three or four in total, depending on group allocation) will take place at the National Centre for Sport and Exercise Medicine at Loughborough University, UK.

Study design

The feasibility study protocol has been prepared in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) (32) with reference to the Template for Intervention Description and Replication (TIDieR) (33) (see supplementary material).

The study will aim to recruit 45 individuals with 15 participants randomly allocated to each of the three groups. No specific sample size has been calculated due to its feasibility status but study results will inform the sample size for a full-scale intervention.

The Sensing Interstitial Glucose to Nudge Active Lifestyle (SIGNAL) study will last seven weeks in total and is outlined in Figure 1. Following baseline (one week), participants will be randomised into one of three groups. Participants will be notified of their group allocation at the second appointment before starting the intervention period. Appointments will be arranged at the preceding appointment where possible. The study was registered on the International Standard Randomised Controlled Trial number (ISRCTN) Register (ISRCTN17545949) in May 2017.

Randomisation

Participants will be block randomised using a 1:1:1 study allocation ratio, coordinated by a remote internet-based service (http://www.sealedenvelope.com/). Randomisation will be done by a member of the research group, independent to the present study. Baseline measures will be conducted pre-randomisation. Participants will be notified of their group allocation at appointment two. In the event of participants originating from the same household, identical group allocation will be employed to avoid any cross-contamination.

Inclusion criteria

Participants will be at least 40 years old, be at moderate-to-high risk of developing type 2 diabetes (34) and use a compatible Android smartphone.

Compatible smartphones at the time of the study will be defined as having the following characteristics: An Android operating system of 4.0 or higher, Near Field Communication (NFC), a screen resolution of 480x800 to 1080x1920 and a screen size of 8.9-14.5cm. Exceptions at the time of the study are the Samsung Galaxy 7, Samsung S8, Nexus 5X and Nexus 6P which cannot install the LibreLink application.

Exclusion criteria

Individuals with a clinical diagnosis of type 1 or type 2 diabetes, a HbA1c of ≥6.5%, or have suspected/confirmed pregnancy will be excluded. Participants unable/unwilling to provide informed consent, cannot/unwilling to adhere to the study protocol or cannot read/write English will also be excluded.

Recruitment procedure

Participants will be recruited at community sites through the distribution of posters and leaflets in community organisations and local businesses based in Leicestershire, UK. Individuals will also be recruited through an existing Movement Insights Lab participant database. All individuals will be directed to complete a brief survey to determine level of risk for type 2 diabetes. Participant information sheets will be provided (copies available upon request). The questions will be presented via an online survey platform (Qualtrics, Provo, UT) and will relate to gender, age, ethnic background, familial history of diabetes, waist circumference, body mass index and blood pressure. The validated survey (34) has been used in studies applying risk score algorithms on primary care electronic data (35). Waist circumference will be replaced with clothing size and fit following guidance offered by Battram and colleagues (36). Moderate-to-high risk individuals will be contacted by the research team to take part in the study. Ineligible individuals (i.e. low risk, increased risk or a moderate/high risk, but are not aged at least 40 years old nor use an Android smartphone) will be directed to Diabetes UK "Type 2 diabetes: What to do if you're at risk" information booklets (available at: https://www.diabetes.org.uk/Global/professionals/KYR%20Booklet.pdf).

Study procedure

First appointment and baseline

An outline of the study procedure is presented in Figure 1. Appointment one will involve informed consent, health measures (height, weight, percentage body fat, waist circumference, blood pressure, HbA1c, grip strength, quadriceps strength and aerobic fitness; full methodological details are provided in the measures section below) and a brief demographics questionnaire. Participants will complete a physical activity readiness questionnaire (37) before completing the aerobic fitness assessment for screening purposes. Participants will be fitted with a waist-worn accelerometer and a wrist-worn activity tracker. Neither device will provide feedback to the participant during the seven consecutive days of wear. Participants will be asked to install two mobile applications onto a personal Android smartphone. Both smartphone applications will sit idle on the smartphone for the duration of baseline. Participants will be asked to sync the activity tracker via the smartphone application; switching on Wi-Fi and Bluetooth simultaneously at least once every five days for ≥1 hour to ensure the sync occurs.

Second appointment and intervention

One week later (following baseline), participants will attend appointment two where they will be informed of their group allocation. Participants will be asked to complete a brief questionnaire, to continue wearing the activity tracker during the intervention (settings may or may not be adjusted) and to return the accelerometer. A glucose sensor will be deployed to each participant to measure interstitial glucose levels. Participants will be provided with additional supplies of glucose sensors to last for the four (Groups 1 and 2) or six weeks (Group 3) of the intervention. Accounts for both the activity tracker and glucose sensor will be connected to Diasend (Diasend Inc., Chicago, IL). An overview of the three groups is provided below.

Group 1 (glucose feedback followed by bio-behavioural feedback)

Real-time interstitial glucose feedback will be presented to participants for four weeks via the LibreLink application (Abbott Diabetes Care Inc., Alameda, CA). Participants will install the LibreLink mobile application (Abbott Diabetes Care Inc., Alameda, CA) onto a personal Android smartphone to interact with the Freestyle Libre via Near Field Communication (NFC) for measurement of interstitial glucose. The glucose monitor has a lifespan that restricts wear to 14 consecutive days. The application will remind participants to scan every seven hours and to remove/replace after 14 days. The LibreLink application will continuously display the number of days left.

Group 2 (physical activity feedback followed by bio-behavioural feedback)

Real-time physical activity feedback will be presented for four weeks via the Fitbit application. In contrast to Group 1, participants will not have the LibreLink application installed and so will not have access to glucose feedback. Participants will be informed that the glucose sensor is functional (recording data) and participants will be asked to remove and replace the expired sensor with another sensor after 14 days.

Device unmasking for Groups 1 and 2 after four weeks

At the end of the first four weeks of the intervention, participants in Groups 1 and 2 will attend a brief appointment (up to one hour in duration). For Group 1, the researcher will adjust settings to reveal physical activity feedback via the Fitbit application and device. For Group 2, the researcher will install the LibreLink application to reveal glucose feedback. All participants will be able to access bio-behavioural feedback for the remaining two weeks of the intervention.

Group 3 (bio-behavioural feedback)

Participants in Group 3 will receive bio-behavioural feedback for the full six weeks via the two independent LibreLink and Fitbit applications. Participants will install the LibreLink mobile application onto a personal Android smartphone to interact with the Freestyle Libre to measure interstitial glucose. The application will remind participants to scan every seven hours and to remove/replace the sensor after 14 days.

Final appointment

All participants (Groups 1, 2 and 3) will be asked to attend the final appointment at the end of the intervention where they will complete a questionnaire (identical to appointment 2, apart

from the revised Diabetes Knowledge Test) and a semi-structured interview. All participants will also receive a personalised health report containing results from the health measures conducted at appointment one.

Device masking

All email accounts and password combinations will be manually generated and managed by the research team to prevent use of identifiable information. During baseline wear, the activity tracker will be physically masked using black tape applied to the screen; leaving only time and date viewable. Participants will be asked not to tamper with the screen; however, if they do manipulate the masking, it should be readily apparent to the research team. Settings on the application will also be adjusted to remove physical activity metrics from the device screen and notifications fully restricted on their phone and activity tracker. However, participants will not be locked out of the application due to the requirement to sync the device. Time spent on the Fitbit application will be inspected using Ethica Data (Kitchener, Ontario, Canada) to identify potential unauthorised use. The activity tracker will also be set to *all day sync* to minimise data loss with data automatically transferred (Wi-Fi and Bluetooth must both be simultaneously switched on). When required to prevent access to glucose feedback, participants will wear the glucose sensors for 14 day periods as normal but will not be asked to install the LibreLink application nor scan the sensor (i.e. no data will be collected). This will standardise wear across all three groups.

Data management and storage procedures

All data collected will be anonymised by assigning a participant ID. Accounts with the three applications (Fitbit, LibreLink and Ethica Health) will be setup using study-specific ('dummy') email addresses and passwords (accessible only to the research team) to minimise use of personalised information. All data will be stored securely on the Loughborough University server, as password protected, encrypted documents and original paperwork kept in locked storage. No directly personally identifiable information will be collected through these platforms. GPS (global positioning system) will be collected via Ethica Data which could theoretically be 'reverse-engineered' to re-identify individuals; however, all participants will be explicitly informed about all information monitored as part of the study. For individuals who do not wish to have their location services monitored, we will set up a 'reduced access' version of Ethica Data (application usage, screen state and survey responses only).

Primary outcomes

User engagement: Quantitative

Time spent on the official free Fitbit and LibreLink applications will be quantified using Ethica Data as well as time-stamped data relating to when the smartphone screen was turned on and off. In combination, these two data sources will reveal the proportion of time that the devices' applications were used in relation to total smartphone use. These data will be recorded at either a day level (e.g. aggregate time) or event level (e.g. record of each time an application was opened) depending on the Android smartphone model. How often and how much time spent on the two applications compared with other applications on participants' smartphones will also be quantified. Number of times the activity tracker syncs (occurs when the application is opened, assumed to see feedback about physical activity) and scans of the

glucose sensor (occurs when the participant scans and to see feedback about interstitial glucose levels) will also be recorded. *Compulsory engagement* will be participants having to sync the activity tracker at least once every five days and scan the glucose sensors at least once every seven hours. The number of syncs and scans recorded over and above *compulsory engagement* will reflect *optional engagement*. Identifying when and how often syncs and scans happen and how these patterns change over the course of the intervention (from week one to six) will indicate engagement with the technology. We will also identify if participants change the goal settings relating to steps, floors climbed and active minutes on the Fitbit application. These settings will be checked daily between the hours of 18:00-19:00 by the research team and changes will be flagged with details of the original and new setting logged. In addition, assessing whether participants responded to prompts offered by the activity tracker will also be conducted (i.e. did participants achieve 250 steps/hour? See Behaviour Change Techniques section for further detail).

Remote monitoring of participant glucose and physical activity will be completed using Diasend (Diasend Inc., Chicago, IL) and Fitabase (Small Steps Labs LLC., San Diego, CA), respectively. Diasend will connect with the Freestyle Libre via the LibreLink application and data will be recorded and accessed through this software. Additional data sources to be monitored by Ethica Data include battery status (i.e. smartphone plugged in? Charging?), Bluetooth and Wi-Fi (turned on or off). Quantifying these data sources will provide valuable insight into participant behaviour (e.g. Do participants only use Wi-Fi and Bluetooth for the purpose of our intervention? Are participants charging it more often in the intervention compared with baseline?). Ethica Data will also monitor location (GPS), motion (pedometer, accelerometer, gravity, gyroscope, linear acceleration, magnetic field, orientation) and survey responses. These digital streams will monitor smartphone usage and will provide detailed data on human behaviour during a free-living, naturalistic setting. In total, fourteen data sources will be monitored. In the event a participant raises concerns relating to the number and/or type of data sources being monitored, a *restricted* coverage option of only three data sources (application usage, screen state and survey responses) will be offered.

User engagement: Qualitative

For participants who complete the six-week intervention, a semi-structured interview will be completed (20-40 minutes) during the final appointment at the National Centre for Sport and Exercise Medicine, Loughborough University, UK. The interview will aim to identify potential barriers and facilitators to using self-monitoring technologies. In particular, how participants experience receiving feedback relating to physical activity and interstitial glucose levels. These interviews will explore individual experiences using the device(s) and mobile application(s), adherence to syncing (Fitbit) and scanning (Freestyle Libre), wearing multiple devices and the perceived effect of viewing feedback on actual behaviour. In addition, participants will be asked about future intentions to continue wearing self-monitoring devices and identify any recommended changes for future study designs.

If a participant decides to withdraw from the study at any time prior to the final appointment, they will be able to leave the study via (i) the Ethica Health application on their personal smartphone (aligning with a dynamic consenting process (38)) or by (ii) contacting the research team via telephone or email. Participants that decide to withdraw via Ethica Health will be directed to complete a brief exit survey on the application. The research team will contact all participants for an optional exit interview (5-10 minutes) via telephone. This will

be recorded using Tapeacall (http://www.tapeacall.com/) and will explore reasons for not completing the study.

Secondary Outcomes

Feasibility

Guidelines used to assess the feasibility of this study were informed by Bowen and colleagues (39). Both qualitative and quantitative data will be collected to assess feasibility of deploying novel self-monitoring technologies in parallel. In total, we will assess intervention feasibility as outlined in Table 1.

Table 1. An overview of the feasibility components to be assessed.

Feasibility component	Data source (indicator of feasibility)
Practicality of technology/intervention	• Qualitative interviews • Fitabase (sync compliance, missing data and response to haptic prompt) • LibreLinkUp (scan compliance) • Diasend (missing data, identification of glucose sensor sensor-related issues) • Project records (identification of need to dispatch additional glucose sensors, number of individuals screened, rate of eligibility, study uptake and retention) • Ethica Data (data sources, enrolment into full* or restricted+ coverage)
Acceptability of technology/intervention	• Qualitative interviews • Fitabase (activity tracker wear time) • Diasend (glucose sensor wear time, digital footprint of time taken to move onto the next glucose sensor i.e. sensor delay?) • Project records (changes to goal settings, manual withdrawals, attendance at appointments, retention to follow-up) • Ethica Data (digital footprint of application usage, Bluetooth and Wi-Fi status, battery status, electronic withdrawal)

**Full coverage: application usage, screen state, Bluetooth, Wi-Fi, GPS, pedometer, accelerometer, gravity, gyroscope, linear acceleration, magnetic field, orientation, battery and survey responses.*
+Restricted coverage: application usage, screen state and survey responses.

Physical activity levels

ActiGraph

In an effort to determine the physical activity levels of the participants relative to general population, participants will be asked to wear an ActiGraph wGT3X-BT (ActiGraph, Pensacola, FL, USA) accelerometer for seven days during waking hours and to remove for

any water-based activities (e.g. showering and swimming). The waist-worn (i.e. over the right hip, mid-clavicular line) ActiGraph will quantify time spent sedentary, in light and moderate-to-vigorous physical activity (MVPA) as well as daily step counts and will function as a data logger (i.e. no feedback provided). ActiGraph accelerometers have been validated (40,41) and extensively deployed (42–44) to measure physical activity under free-living conditions. Data from the ActiGraph will be collected at 100 Hz and integrated into 60 second epochs using ActiLife (ActiGraph, Pensacola, FL, USA) and processed using Kinesoft (Kinesoft, Loughborough, UK). Non-wear will be defined as 60 minutes of consecutive zeros (allowing for up to two minutes of interruptions) with a minimum wear of 600 waking minutes used to define a valid day (43). A minimum of 4 valid days will be used to define a valid file with sedentary time classified as <100cpm, light activity as 100-2019cpm and MVPA as >= 2020cpm (43).

Fitbit

The Fitbit Charge 2 (Fitbit Inc., San Francisco, CA) will be worn on the wrist associated with the non-dominant arm and, whilst being sweat, rain and splash proof, participants will be asked to remove the device for water-based activities. The Fitbit records intensity (i.e. minutes spent lightly active, fairly active and very active) in addition to heart rate and step count. Heart rate will be assessed using Fitbit's proprietary PurePulse optical heart rate technology. To examine changes in physical activity over the study duration, participants will be requested to wear the device for the full seven weeks and data will be analysed in 60 second epochs following export from Fitabase. Previous models of the Fitbit have been validated for step count (45). A waking protocol will be implemented with non-wear defined as a loss of a heart rate signal. Participants will be requested to sync the Fitbit at least once every five days (rather than the company recommendations of seven days) to minimise data loss. Syncs beyond seven days will result in day level data rather than minute level data. These syncs will either occur automatically (i.e. without the application open) or will be user-driven (i.e. with the application open) depending on how the *all day sync* is set and heart rate will be set to automatic (only record heart rate when device is worn).

Interstitial glucose levels

Freestyle Libre

The minimally-invasive Freestyle Libre flash glucose monitor (Abbott Diabetes Care, Alameda, CA) will be covered with Tegaderm (3M Health Care, St. Paul, MN) to help maintain position and adhesion during the 14 day sensor lifespan. Three strips of Tegaderm will be provided to participants per sensor to allow for replacement when the Tegaderm becomes dirty. Participants will be asked to wear the device continuously without removal for water-based activities. The Freestyle Libre demonstrates consistent accuracy throughout the 14 days with a mean absolute relative difference of 11.4% compared with capillary blood glucose, a lag time of 4.5-4.8 minutes and is not impacted by physical characteristics including age, BMI and HbA1c (31). Participants will be requested to scan the glucose monitor at least once every seven hours (rather than the company recommendations of eight hours) to minimise data loss. If participants experience skin irritation on the non-dominant arm in the region of application, participants will be advised to switch to their dominant arm. Interstitial glucose data will be downloaded in 15 minute epochs using Diasend, an online platform connected to the LibreLink application. Participant accounts will be linked to

Diasend from the point of LibreLink application installation. Figure 2 illustrates how the numerous components connect to achieve the primary and secondary aims.

Levels of technology readiness, health status and attitude

All questionnaires will be completed electronically using an online platform for immediate data entry (http://www.onlinesurveys.ac.uk/; Bristol, UK). At appointment two, quality of life will be assessed via the 26 item EQ-5D-5L (46), technology readiness via the 16 item Technology Readiness Index (TRI 2.0) (47), health literacy via the 8 item eHealth Literacy Scale (e-HEALs) (48), diabetes knowledge via the 20 item revised diabetes knowledge test (49) and general attitude toward developing diabetes via the 8 item general attitudes section of the Risk Perception Survey for Developing Diabetes (RPS-DD) (50).

Other measures

Participant Characteristics

Self-reported age, sex, ethnic background, employment, household income, postcode (to provide an Index of Multiple Deprivation score) and education will be recorded.

Health, physical functioning and fitness

HbA1c will be assessed at the first appointment using a point-of-care system, (Afinion AS100 Analyser, Alere Inc., Waltham, MA). Results will be processed immediately following collection. Participants receiving a result ≥6.5% will be ineligible, readings of 5.7-6.4% classified as pre-diabetic (51) and readings of <5.7% classified as euglycemic. A measure of height will be conducted using a Seca stadiometer (Seca, Hamburg, Germany) and weight and body fat percentage will be measured using Tanita scales (Tokyo, Japan). Two measures of waist circumference will be taken at the midpoint between the lowest rib and top of the iliac crest; if the difference exceeds 1 cm, the two measurements will be repeated (52). Three measures of blood pressure will be recorded using an Omron digital monitor (Omron Corporation, Kyoto, Japan) with the first measure taken after the participant has remained seated for ten minutes. Grip strength will be assessed using a handheld Takei dynamometer (Takei Scientific Instruments, Tokyo, Japan) whilst standing with hands positioned down each side. Quadriceps strength will be assessed using the DAVID G200 knee extension machine (David Health Solutions Ltd., Helsinki, Finland). Aerobic fitness will be assessed using the modified Canadian Aerobic Fitness Test (mCAFT) (53). The mCAFT is a sub-maximal step-test protocol with participants instructed to complete ≥1 three-minute stages of stepping at a speed dictated by an audio track. Heart rate will be monitored throughout with the stepping stages continued until heart rate ≥85% of age-predicted maximal heart rate. Participants' scores for aerobic fitness will be defined according to the following formula*:* 17.2 + (1.29 x oxygen cost at the final stage) - (0.09 x weight in kg) - (0.18 x age in years) (53).

Behaviour change techniques

Prior to starting the intervention, the researcher will implement the default settings for levels of physical activity (BCT 1.1: Goal setting (behaviour)) (i.e. 10,000 steps and 10 floors climbed) and glucose (BCT 1.3: Goal setting (outcome)) (i.e. 4.0-5.9 mmol/L). Participants will be fully informed that they can freely change the goals set for physical activity as preferred (i.e. should the default value be too easy/difficult) via the Fitbit application.

However, participants will be advised to not make any changes via the LibreLink application for the target glucose range. Attainment of a goal will be assessed as either complete or incomplete. Participants will be asked to sync the Fitbit (at least once every five days) and scan the Freestyle Libre (at least once every seven hours) if they are in the respective group to receive feedback from these devices. This action has a dual purpose; to minimise data loss and to encourage continued engagement with the technologies. Participants will also receive haptic feedback (BCT 7.1: Prompts/cues; i.e. a gentle vibration) as a reminder to move by the Fitbit 10 minutes prior to the end of each hour (default 09:00-18:00) if 250 steps have not been taken. The reminder to move prompt aims to encourage interruptions in prolonged sedentary bouts as is recommended by the UK Physical Activity Guidelines (54). In relation to the other behaviour change techniques, participants will be able to monitor physical activity levels using the Fitbit Charge 2 (BCT: 2.3 Self-monitoring of behaviour) and glucose levels using the Freestyle Libre (BCT: 2.4: Self-monitoring of outcome(s) of behaviour) which is a minimally-invasive device that presents feedback about glucose (BCT: Biofeedback).

Quantitative data analysis

Analysis of primary outcomes

Ethica Data is a fee-for-service platform that will be used to provide time-stamped data relating to application usage. This is an application installed on participants' phones and sits idle during the study period. The number of scans and syncs will be unobtrusively assessed using the free LibreLinkUp mobile application (Abbott Diabetes Care Inc., Alameda, CA) and Fitabase (Small Steps Labs LLC., San Diego, CA), respectively. Fitabase is a fee-for-service platform that permits access to download 60 second epoch Fitbit data (i.e. levels of physical activity) and remote monitoring of Fitbit devices (e.g. battery level and time since last sync event) via Bluetooth and Wi-Fi. Identification of moments where participants have decided to change the goal settings will be completed by accessing the online Fitbit account. The researchers will remotely access participants' accounts daily between 18:00-19:00 to note goal settings; recording the date and live/current settings for all metrics (e.g. step count) to help identify any changes.

Analysis of secondary outcomes

To assess eligibility, uptake and retention, we will manually record how many individuals complete the screening survey, how many meet our inclusion criteria and of these how many decide to enrol. In addition, the screening survey will also identify recruitment sources. Identifying nonusage attrition and dropout attribution is crucial to assess the feasibility of an intervention as they are both important but distinct constructs (55). Nonusage attrition, where participants have disengaged from the intervention but have not dropped out, will be defined as participants who attend appointment two but do not sync the Fitbit or scan the Freestyle Libre. Dropout attrition will be defined as participants who explicitly withdraw from the study via Ethica Health or direct contact with the research team. The number of participants who enrol into the full coverage (all 14 data sources monitored) or restricted coverage (only three data sources monitored) for Ethica Data will also be recorded. Diasend is a fee-for-service platform that permits access to download 15 minute epoch data from the Freestyle Libre and remote monitoring of multiple LibreLink accounts. Descriptive statistics of the sample will be conducted. In addition, two-way repeated measures ANCOVAs will be

conducted to assess changes in engagement (dependent) according to group (independent) having adjusted for participant characteristics. Similarly, two-way repeated measures ANCOVAs will be conducted to assess changes in physical activity (dependent) according to group (independent) having adjusted for baseline physical activity, Fitbit wear time and participant characteristics. All data will be analysed using Statistical Package for Social Sciences (SPSS Inc. Chicago, IL).

Qualitative data analysis

All interviews will be audio recorded (with informed consent), transcribed verbatim and analysed using thematic analysis. This will involve standard thematic data analysis procedures; identifying emerging patterns in the interview (56). Transcripts will be analysed using constant comparison with initial free coding and emergent themes interrogated (57). The interview schedule and coding schedule will be modified to follow new leads until new themes no longer emerge. The analysis will create a coding frame that 'fits' the data (57). Transcripts will be uploaded into NVivo qualitative data analysis software (QSR International Pty, Ltd, Victoria, Australia).

DISSEMINATION

This work will inform a full-scale randomised-controlled trial by enabling a sample size calculation. The full-scale RCT will primarily aim to investigate changes in physical activity and interstitial glucose levels in individuals randomised into the three groups. Overall, the findings seek to encourage the implementation of technologies into usual pre-clinical care pathways; in particular, how engaging with self-monitoring technologies (providing bio-behavioural feedback) may positively influence rates of uptake, adherence, retention and behaviour change.

We will publicise study findings online, present them at international conferences relating to diabetes, physical activity and digital health and publish via a peer-reviewed journal.

DECLARATIONS

Competing interests

None declared.

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Author contributions

All authors have contributed to the design of the work, acquisition and analysis plan. MW, AK, MO, LS and DE were involved in the development of the intervention and design of the trial. MW, AK, MO, LS and DE have been involved in drafting the work or revising it critically for important intellectual content.

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Figure 1. An illustration of the intervention design (*indicates a brief appointment at 4 weeks).

Figure 2. A schematic of how the wearable technologies, mobile applications and software connect.

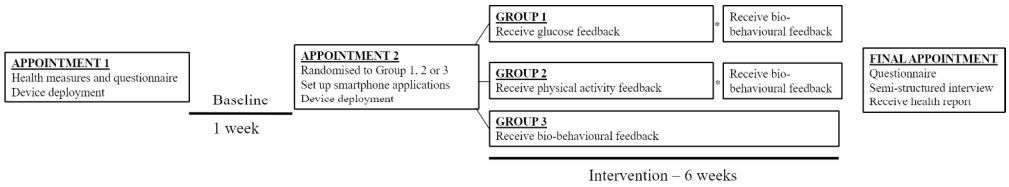

Figure 1. An illustration of the intervention design (*indicates a brief appointment at 4 weeks).

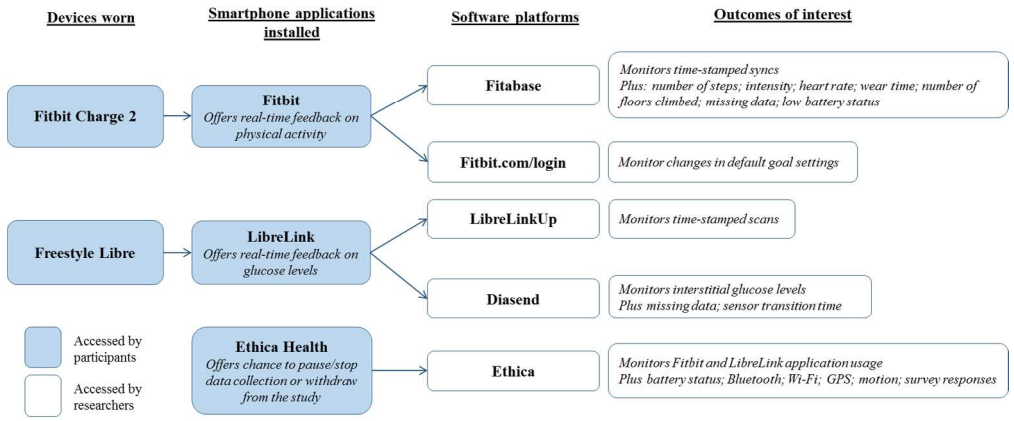

Figure 2. A schematic of how the wearable technologies, mobile applications and software connect.

Supplementary material

Table 1. Intervention description using the Template for Intervention Description and Replication (TIDieR) checklist

1. Brief name	The Sensing Interstitial Glucose to Nudge Active Lifestyles Study.
2. Why	Encouraging people to become more physically active offers a wealth of benefits for everyone. With widespread prevalence of type 2 diabetes, a non-communicable disease largely attributed to poor lifestyle choices, people living with prediabetes should access early lifestyle intervention to prevent disease onset. Self-monitoring is a recognised behaviour change technique that aligns well with the influx of mobile health (mHealth) technologies; however, more needs to be done to improve sustained use of these devices. Given the contribution of behaviour to type 2 diabetes, deploying self-monitoring technologies that present behavioural (physical activity) and physiological (interstitial glucose) information in parallel could be a persuasive behaviour change method. Understanding how people use these devices is paramount to assess feasibility of deployment and levels of engagement over time.
3. What - materials	All participants, regardless of group allocation, will wear two devices simultaneously for the full six weeks of the intervention. The first device, the Freestyle Libre (Abbott, Diabetes Care, Alameda, CA), will present interstitial glucose levels and the second, the Fitbit Charge 2 (Fitbit Inc., San Francisco, CA), will present physical activity feedback. If the device is to be masked, the participants will either have the device taped with access to metrics restricted or have no access to the data at all.
4. What - procedures	Engagement will be recorded using Ethica Data (Kitchener, Ontario, Canada), Fitabase (Small Steps Labs LLC., San Diego, CA) and LibreLinkUp (Abbott, Diabetes Care, Alameda, CA). Ethica Data will quantify smartphone application usage, Fitabase will record the number of times participants sync the Fitbit and LibreLinkUp will time-stamp when participants scan the Freestyle Libre. The Ethica

	Health application will also allow participants to withdraw from the study at any point during the intervention. Semi-structured interviews will be conducted to discuss the feasibility of the intervention.
5. Who provided	A team of early career academics will deliver the intervention.
6. How	The intervention will be delivered via two self-monitoring technology devices. The Freestyle Libre will present feedback relating to interstitial glucose levels and the Fitbit Charge will present feedback relating to physical activity levels.
7. Where	The intervention will be delivered in Leicestershire, UK. Appointments will take place at the National Centre for Sport and Exercise Medicine, Loughborough University, UK.
8. When and how much	Participants will be requested to attend up to four face-to-face appointments. Following baseline (seven days), participants will be randomised into one of three groups. Group 1 will receive interstitial glucose feedback, Group 2 will receive physical activity feedback, and Group 3 will receive bio-behavioural feedback (interstitial and physical activity feedback). For the remaining two weeks of the intervention, Groups 1 and 2 will receive bio-behavioural feedback (both interstitial and physical activity feedback).
9. Tailoring	The self-monitoring technologies will provide personalised data relating to interstitial glucose and physical activity levels during the intervention. Participants will be able to adjust goals based on individual preference for the Fitbit (e.g. number of steps).

Table 2. Spirit 2013 Checklist.

Section	Included in manuscript (Y/N) or described here.	Manuscript page number
Administrative Information		
1. Title	Y	1
2a. Trial registration	Y	2, 5
2b.	Y – provided within manuscript, via ISRCTN http://www.isrctn.com/ISRCTN17545949 or via study website www.lboro.ac.uk/research/mi-lab/research/signal/	2-15
3. Protocol version	Version 2, 15/05/2017	
4. Funding	Y	14
5a. Roles and responsibilities	Y	14
5b.	Contact details can be found via the ISRCTN registration.	
5c.	Y	14
5d.	The steering committee is comprised of the study authors.	
Introduction		
6a. Background and rationale	Y	3-4
6b.	Y	3-4
7. Objectives	Y	4-5
8. Trial design	Y	5-8
Methods		
9. Study setting	Y	5
10. Eligibility criteria	Y	5-6
11a. Interventions	Y	7
11b.	Y – participants originating from the same household will be allocated to an identical group (to avoid any cross-contamination).	5
11c.	Y	8-9
11d.	No relevant concomitant care nor interventions.	N/A
12. Outcomes	Y	8-10
13. Participant timeline	Y	5 and Fig. 1
14. Sample size	Y	5
15. Recruitment	Y	5
Assignment of interventions Allocation		
16a. Sequence generation	Y	5
16b. Allocation concealment mechanism	Y	5
16c. Implementation	Y	5
17a. Blinding (masking)	Y – The PI will be blinded during health measures at baseline. The PI will be informed of group allocations prior to	8

	appointment 2. Outcome assessments will not be blinded.	
17b.	Y – Participants and researcher will be unblinded following baseline measures.	5
18a. Data collection methods	Data collection forms can be obtained on request.	N/A
18b.	Y	13
19. Data management	Y - Data will be entered into password protected spreadsheets. Data will be manually checked against source documents throughout the study.	8
20a. Statistical methods	Y	13-14
20b.	Y	13-14
20c.	Y	13-14
Monitoring		
21a. Data monitoring	DMC is not needed on this occasion as it is a feasibility study.	N/A
21b.	No interim analyses are planned as the trial is low risk.	N/A
22. Harms	Any adverse events will be recorded and reported to the ethics committees along with any protocol amendments.	N/A
23. Auditing	No intention to conduct audit of trial conduct. The study team of investigators will regularly meet to discuss progress.	N/A
Ethics and dissemination		
24. Research ethics approval	Y	2
25. Protocol amendments	Amendments will be communicated to the ethics committee and trial registry, if needed.	N/A
26a. Consent or assent	Y	6
26b.	N/A	N/A
27. Confidentiality	Y - All participants will be assigned a unique registration number used on data collection forms.	8
28. Declaration of interests	Y	14
29. Access to data	Study authors will have access to the final trial dataset.	N/A
30. Ancillary and post-trial care	Y – there is no ancillary or post-trial care to be offered.	8
31a. Dissemination policy	Y – Study team intend to share results with participants following data analysis.	14
31b.	No intention to use professional writers.	N/A
31c.	The dataset will be made available to others upon request.	N/A
Appendices		
32. Informed consent materials	N – Copy of consent form can be accessed via www.lboro.ac.uk/research/mi-lab/research/signal/	N/A

33. Biological specimens	N - Described in consent form, can be accessed via www.lboro.ac.uk/research/mi-lab/research/signal/	N/A