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*Mo*bile Heal*th* B*i*ometrics to Enhance Exercise and Physical Acti*v*ity *A*dherence in *Type* 2 Diabetes (MOTIVATE-T2D): protocol for a feasibility randomised controlled trial

Katie Hesketh ,[1] Jonathan Low,[2] Robert Andrews,[3,4] Charlotte A Jones,[5] Helen Jones ,[1] Mary E Jung ,[2] Jonathan Little,[2] Ceu Mateus,[6] Richard Pulsford,[7] Joel Singer,[8] Victoria S Sprung ,[1,9] Alison M McManus,[2] Matthew Cocks[1]

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For numbered affiliations see end of article.

Correspondence to
Dr Matthew Cocks;
m.s.cocks@ljmu.ac.uk

ABSTRACT

Introduction Exercise and physical activity (PA) are fundamental to the treatment of type 2 diabetes. Current exercise and PA strategies for newly diagnosed individuals with type 2 diabetes are either clinically effective but unsuitable in routine practice (supervised exercise) or suitable in routine practice but clinically ineffective (PA advice). Mobile health (mHealth) technologies, offering biometric data to patients and healthcare professionals, may bridge the gap between supervised exercise and PA advice, enabling patients to engage in regular long-term physically active lifestyles. This feasibility randomised controlled trial (RCT) will evaluate the use of mHealth technology when incorporated into a structured home-based exercise and PA intervention, in those recently diagnosed with type 2 diabetes.

Methods and analysis This feasibility multicentre, parallel group RCT will recruit 120 individuals with type 2 diabetes (diagnosis within 5–24 months, aged 40–75 years) in the UK (n=60) and Canada (n=60). Participants will undertake a 6-month structured exercise and PA intervention and be supported by an exercise specialist (active control). The intervention group will receive additional support from a smartwatch and phone app, providing real-time feedback and enabling improved communication between the exercise specialist and participant. Primary outcomes are recruitment rate, adherence to exercise and loss to follow-up. Secondary outcomes include a qualitative process evaluation and piloting of potential clinical outcome measures for a future RCT.

Ethics and dissemination The trial was approved in the UK by the South East Scotland Research Ethics Committee 01 (20/SS/0101) and in Canada by the Clinical Research Ethics Board of the University of British Columbia (H20-01936), and is being conducted in accordance with the Declaration of Helsinki and Good Clinical Practice. Results will be published in peer-reviewed journals and presented at national and international scientific meetings.

Trial registration numbers ISRCTN14335124; ClinicalTrials.gov: NCT04653532.

Strengths and limitations of this study

- The MOTIVATE intervention potentially allows patients with newly diagnosed type 2 diabetes to co-design a personalised and progressive exercise programme with the support of an exercise specialist.
- The MOTIVATE intervention potentially allows participants to communicate regularly with an exercise specialist and gain feedback on the exercise they complete.
- Our active control group matches the contact time provided to the mobile health (mHealth) group in order to assess how the addition of mHealth technologies can increase exercise and physical activity (PA) adherence.
- The 12-month follow-up enables monitoring and evaluation of long-term adherence to an mHealth exercise and PA intervention.
- The MOTIVATE intervention is not embedded within current healthcare systems, as such, future work will be needed to address how the intervention could fit within current clinical care.

INTRODUCTION

Increasing physical activity (PA: movement that raises energy expenditure), both through exercise (planned and structured PAs with a goal of improving health and fitness) and habitual lifestyle behaviours such as walking and active travel, is fundamental to the initial treatment of type 2 diabetes,[1] and is recommended by international consensus.[2] Nevertheless, individuals with type 2 diabetes are less active and more sedentary than those without.[3 4] To address this issue, diabetes care pathways are prioritising personalised exercise and PA advice for those with newly diagnosed type 2 diabetes, (eg, the National

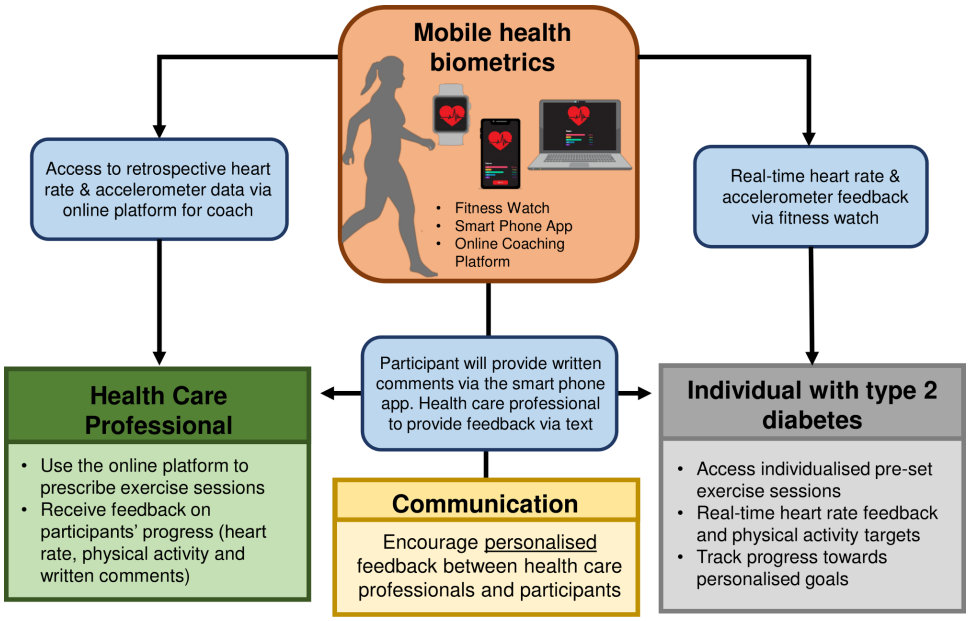

Figure 1 The use of mobile health biometrics to encourage communication between the healthcare providers and people with type 2 diabetes.

Health Service (NHS) Rightcare Pathway in UK[5] and Diabetes 360°[6] in Canada).

Previous research studies show supervised exercise interventions in individuals with type 2 diabetes are useful as they can increase total PA[7] and reduce glycated haemoglobin (HbA1c) by −0.67% (1.3 mmol/mol),[8] a reduction comparable with that observed with the addition of non-insulin glucose-lowering drugs.[9] However, the resources required to implement supervised exercise are not feasible as part of routine care in many countries.[10] Standard provision for individuals with newly diagnosed type 2 diabetes therefore is limited to PA advice alone. Importantly, a meta-analysis[8] suggests PA advice was not associated with changes in HbA1c in individuals with type 2 diabetes, unless it was combined with dietary advice.[7] Therefore, in order to provide effective exercise and PA support to individuals with type 2 diabetes, research is needed to develop clinically effective, cost-effective, scalable interventions which bridge the gap between supervised exercise and PA advice.

The emergence of mobile technologies and wearable sensors has enabled real-world monitoring of mobile health biometrics (mHealth). Devices incorporating biometrics such as habitual PA and heart rate (HR) could be a potential solution to bridge the gap between supervised exercise and PA advice (figure 1). The use of PA monitors (pedometers or accelerometers) is associated with increases in daily PA in individuals with type 2 diabetes,[11 12] which can be maintained for up to 12 months.[11] While some data suggest a sustained increase in PA may be beneficial for improving cardiovascular and general health,[13] PA monitoring in combination with advice has not yielded clinically meaningful improvements in HbA1c.[8] It is hypothesised that the lack of meaningful improvement in HbA1c may be due to the fact that PA monitors promote low intensity habitual PA rather than more intense domains,[11 12] which are essential for improving glycaemic control.[14] As such, PA monitoring is a good strategy to support habitual PA goals, but to improve HbA1c this technology may need to be combined with strategies that promote activities of greater exercise intensity.

HR monitors provide objective personalised data that account for age, body mass and fitness[15] and are related to exercise intensity regardless of the type of activity being performed.[16] Recently, HR monitors have been used to promote adherence to structured home-based exercise programmes in people with type 1 diabetes and individuals with obesity and an elevated cardiovascular disease (CVD) risk.[17 18] Importantly, in both studies, >90% adherence to the prescribed exercise sessions was observed, with >85% of sessions completed at the prescribed intensity, resulting in improved aerobic capacity[17 18] and insulin sensitivity.[18] Qualitative data from an online survey in people with type 1 diabetes suggested that the availability of real-time feedback during exercise contributed to the high adherence.[17] It is hypothesised that safe practice of exercise at intensities known to influence clinical outcomes through the provision of real-time feedback fosters self-efficacy to engage in exercise, an important predictor of future exercise engagement.[19] Therefore, the combination of accelerometry and optical HR monitoring available in commercial wrist-worn smartwatches may be the most effective tool to facilitate a personalised home-based intervention, promoting both habitual PA and appropriate intensity-structured exercise that influences clinical outcomes (eg, HbA1c).

Another potentially useful aspect of mHealth technologies is that they can facilitate support from healthcare providers (HCPs), which is another significant

barrier to unsupervised exercise and PA interventions.[20] Online cloud-based portals allowing biometric data sharing between individuals and HCPs, and remote communication platforms, have been developed. Such technology could be used to facilitate communication (or 'coaching'), aiming to mimic the relationship experienced during supervised interventions. Taken together, there is accumulating evidence that mHealth technologies may increase adherence to unsupervised exercise/habitual PA programmes and improve clinical outcomes.

Study aims

The primary aim of the study is to undertake a feasibility randomised controlled trial (RCT) in adults with newly diagnosed type 2 diabetes evaluating a theoretical model where mHealth technology, allowing biometric informed feedback and coaching, is incorporated into a structured home-based exercise and PA intervention. Our overall objective is to inform an evidence-based exercise and PA intervention ready to evaluate in a future RCT.

The specific objectives are:

1. Determine the number of adults with newly diagnosed type 2 diabetes who are eligible to participate within the UK and Canada, and the proportion of these who would be willing to take part in this trial (ie, recruitment rate).
2. Define the rates of adherence to the interventions and the number of participants retained at 12 months in both arms of the trial (ie, participant drop-out).
3. Estimate precision of potential outcome measures required for sample size estimations for the definitive RCT. The main outcome measures are glycaemic control (HbA1c and flash glucose monitoring), lipid profile, blood pressure, body composition, PA and quality of life.
4. Evaluate the acceptability of the intervention.
5. Pilot methods for collecting outcome measures, recruitment, randomisation, treatment and follow-up.
6. Determine availability and completeness of economic data.

METHODS AND ANALYSIS

Trial design

A feasibility multicentre, parallel group, RCT, whereby participants will complete pre-randomisation baseline assessments before allocation to exercise counselling (active control) or exercise counselling plus mHealth (intervention). Participants will repeat PA and flash glucose monitoring in the final 14 days of the intervention and all other health measurements immediately post-intervention (6 months). All measurements will be carried out again 6 months after the intervention is completed (follow-up) (figure 2). The trial protocol adheres to Recommendations for Interventional Trials[21] and the Template for Intervention Description and Replication[22] guidelines.

Study setting and recruitment plan

Recruitment of 120 participants to the trial will take place over 12 months commencing January 2021 and will be completed in December 2021 in the UK (n=60) and from February 2021 to January 2022 in Canada (n=60). The trial will end (last data collection from the last participant) in January 2023. In the UK, participants will be recruited from (1) general practitioner (GP) database searches across 22 practices in: the North West (n=18), West Midlands (n=1), South West (n=2) and London (n=1); (2) identification of patients by clinical staff at participating GP practices in: Bristol, Birmingham, Cambridge, Devon, Dorset, Leeds, Manchester, Norfolk, Oxford, Somerset, Southampton, York and three London Boroughs. Staff will approach patients and direct patients to the trial website (www.MotivateT2D.com); (3) flyers provided to diabetes education sessions run through community clinics across the Liverpool and Knowsley areas; and (4) posters displayed in high traffic areas within the healthcare system, social media and diabetes websites. In Canada, participants will be recruited from (1) waiting room advertisements posted in: GP clinics across British Columbia and Alberta (n=10), laboratories across British Columbia (n=5) and pharmacies across the interior region of British Columbia (n=28); (2) advertisements on the Diabetes Canada social media sites; (3) third party clinical trial recruitment services (n=2); (4) local online classified ads and print media sites; and (5) partnerships with national, provincial and university-wide PA initiatives. The impact of the different recruitment strategies used in the UK and Canada will be explored to inform the design of the future RCT.

Eligibility criteria

Population

Eligible participants will have a recent clinical diagnosis of type 2 diabetes (within the previous 5–24 months) and will be aged between 40 and 75 years. Participants managed by lifestyle modifications alone or metformin (stable dose for ≥3 months) will be eligible.

Potentially eligible participants will be consented and screened via video call (Zoom Video Communications, 2016). This involves a medical history, details of current medications, current PA and exercise behaviour. Eligibility for blood pressure and HbA1c will be confirmed during baseline assessment. Should a participant's blood pressure or HbA1c be outside the inclusion criteria, they will be excluded at this point.

Detailed inclusion criteria

1. Clinical diagnosis of type 2 diabetes within the previous 5–24 months.
2. Aged 40–75 years.
3. Diabetes treated with diet or metformin (stable dose for 3 months or more).

Detailed exclusion criteria

1. Aged <40 or >75 years.

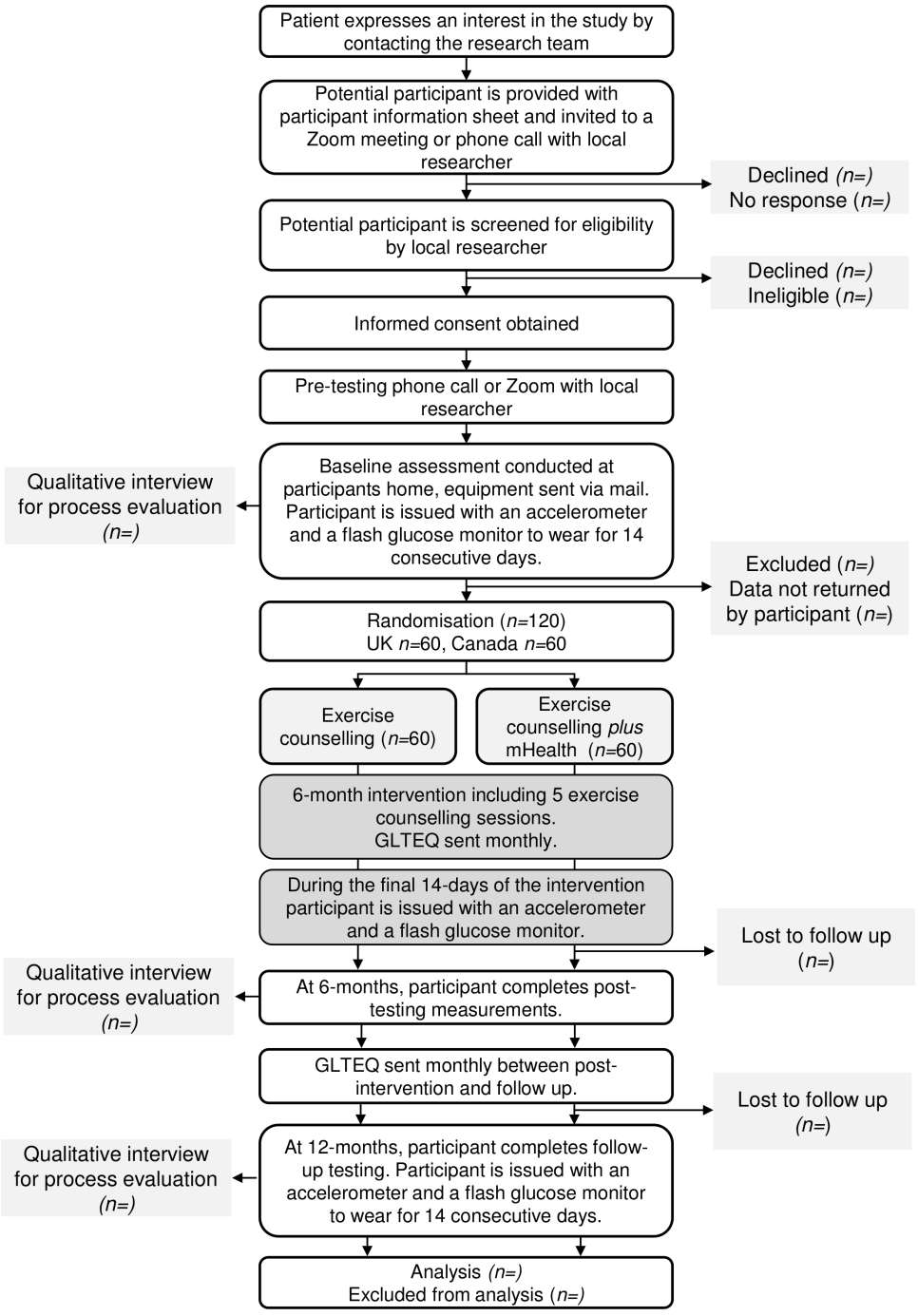

Figure 2 Trial design and participant pathway. GLTEQ, Godin Leisure Time Exercise Questionnaire; mHealth, mobile health.

2. HbA1c >86 mmol/mol (>10%).
3. Blood pressure >160/100 mm Hg.
4. Glucose-lowering agents other than metformin.
5. Insulin or GLP-1.
6. Unstable angina.
7. Myocardial infarction within the previous 3 months.
8. Transient ischaemic attack in the previous 6 months.
9. Heart failure New York Health Association (NYHA) ≥class II.
10. Arrhythmia.
11. Healthcare professional has advised against increasing level of activity.
12. Pregnancy or planning to become pregnant.
13. <6 months post partum or stopped breast feeding <1 month before recruitment.
14. Not owning a smartphone/or having no data plan or access to WiFi.
15. Currently meeting the recommended exercise guidelines (150 min of moderate intensity exercise per week).

Randomisation and blinding

Participants will be randomised to intervention (mHealth) or active control on a 1:1 basis using a computer-generated

random allocation sequence, created and administered by the Centre for Health and Evaluation and Outcome Sciences. Randomisation will be stratified by centre (UK or Canada), sex (male or female) and age (40–60 or 61–75 years). To ensure allocation concealment, researchers will request randomisation on completion of all baseline assessments. Permuted blocks of random size 4 and 6 for each stratum will be used. Due to the nature of the intervention, blinding of the participants or researchers delivering the interventions is not possible.

Outcome measures

In light of disruptions caused by the COVID-19 pandemic, outcome measures will be taken using remote 'home-based' solutions which do not require travel or in-person contact. To enable this approach, participants will be mailed all the necessary assessment resources. Videos and written guidelines explaining the assessments will be available electronically (www.motivatet2d.com), and participants will receive support from a member of the research team prior to and on the day of assessments.

Primary outcome

The primary outcomes are recruitment rate and participant drop-out. Information will be collected on (1) the number of patients approached and the reasons for not participating; and (2) the percentage of participants completing the follow-up assessment time point and reasons for drop-out, so that a full Consolidated Standards of Reporting Trials diagram can be generated. Information will be gathered on participants' age, sex, duration since diabetes diagnosis, ethnicity, postcode/zip code, marital status, living arrangements, education and employment status.

Secondary outcomes

A number of outcome measures will be piloted to obtain estimates of key trial parameters to inform future sample

Table 1 Tests/questionnaires conducted at baseline, 6 and 12 months

Measured	Measurement strategy	Outcome
Exercise adherence and habitual PA	Device-derived exercise assessment	1. Number of structured exercise sessions 2. Exercise duration 3. Exercise intensity
	14-day device-derived PA	1. Device wear time 2. Average minutes of total, light, moderate, vigorous and moderate-to-vigorous PA per day 3. Average minutes of sedentary time per day 4. Moderate-to-vigorous PA in bouts ≥10 min 5. PA volume 6. Average intensity
	Survey-reported exercise behaviour (GLTEQ)	1. Bouts of mild, moderate and strenuous exercise lasting ≥30 min 2. Weekly leisure-time exercise
Anthropometrics	Home-based measures	Height, weight, waist circumference
Blood pressure	Home-based measures	Systolic and diastolic blood pressure
Biochemistry	Fasting home-based blood collection	1. Cholesterol, HDL-C, LDL-C, non-HDL-C, triglycerides 2. HbA1c
Glycaemic control	14-day flash glucose monitoring	1. Device wear time 2. Mean glucose 3. Estimated A1c 4. Glycaemic variability (%CV and SD) 5. Time above range (L1 >10 mmol/L, L2 >13.9 mmol/L) 6. Time in range (3.9–10.0 mmol/L) 7. Time below range (L1<3.9 mmol/L, L2<3.0 mmol/L) 8. LBGI and HBGI (risk indices) 9. Episodes (hypoglycaemia and hyperglycaemia) 15 min 10. Area under the curve
Questionnaires	Qualtrics online survey	1. BREQ-2 2. SF-12 Health Survey 3. DTSQs 4. DTSQc 5. 5-level EQ-5D 6. Patient Rapport with Counsellor Questionnaire

BREQ-2, Behavioural Regulation in Exercise Questionnaire version 2; %CV, percentage coefficient of variation; DTSQc, Diabetes Treatment Satisfaction Questionnaire change version; DTSQs, Diabetes Treatment Satisfaction Questionnaire status version; EQ-5D, EuroQol-5 Dimensions questionnaire; GLTEQ, Godin Leisure Time Exercise Questionnaire; HbA1c, glycated haemoglobin; HBGI, high blood glucose index; HDL-C, high-density lipoprotein cholesterol; LBGI, low blood glucose index; LDL-C, low-density lipoprotein cholesterol; L1>10 mmol/L, level 1 hyperglycaemia; L2>13.9 mmol/L, level 2 hyperglycaemia; L1<3.9 mmol/L, level 1 hypoglycaemia; L2<3.0 mmol/L, level 2 hypoglycaemia; PA, physical activity; SF-12, 12-Item Short Form Survey.

size estimations (table 1). Unless stated below, outcomes will be assessed in all participants at baseline, post-intervention and follow-up.

Exercise adherence and habitual PA

Adherence to a long-term home-based exercise prescription is difficult to measure using one method. Three assessment measures will be piloted:

1. *Device-derived assessment of exercise sessions:* the number of planned structured exercise sessions completed along with the duration and intensity of each session will be assessed via optical HR monitoring (photoplethysmography). The mHealth group will use the Ignite fitness watch (Polar Electro, Finland) provided as part of the intervention. The active control group will be provided with a Polar Verity Sense (Polar Electro, Finland) optical HR monitor for the duration of the trial, to wear during planned structured exercise sessions. The Polar Verity Sense records HR but gives no real-time/historical feedback to participants, as such active control participants will be blinded to the HR throughout.
2. *Device-derived PA:* key metrics of PA (table 1) will be assessed using a wrist-worn triaxial accelerometer (GENEActiv, Activinsights, Kimbolton, Cambridge, UK) for 14 days (a) immediately following baseline assessments/prior to commencement of the intervention; (b) during the final 14 days of the intervention period and (c) immediately after follow-up testing. The accelerometer will be initialised and set to start and finish recording at specific dates by the research team before sending to the participant. Data will be downloaded using manufacturers' software and processed in R (R Core Team,Vienna, Austria) using the open-source GGIR software package (http://cran.r-project.org).
3. *Survey-reported exercise behaviour* will be evaluated using the Godin Leisure Time Exercise Questionnaire[23] at baseline, post-intervention, follow-up and every 4 weeks during the 12-month trial period. The questionnaire will be administered using online survey software (Qualtrics; www.qualtrics.com).

Anthropometrics and blood pressure

The degree of obesity in an individual with type 2 diabetes is an important modifiable risk factor for long-term health.[24] In addition, elevated blood pressure is linked to increased risk of CVD in type 2 diabetes.[25] As such, body mass, height, waist circumference and blood pressure will be measured by participants. Participants will be sent a tape measure (Seca 201, Germany), electronic scales (Salter, UK) and automated blood pressure monitor validated by the British and Irish Hypertension Society (UK, Salter BPA-9200-GB; Canada, Bios BD215). Participants will be asked to record their height if known; if not, participants will use the tape measure to record height. Waist circumference will be measured at the level of the umbilicus. Self-measured blood pressure is a validated approach for monitoring blood pressure, endorsed by the American Heart Association and American Medical Association.[26] Previous work suggests a strong correlation between self-measured and technician-measured height and weight[27] and waist circumference, measured at the umbilicus.[28]

Blood sampling

Elevated levels of HbA1c and blood lipids are linked to increased risk of cardiovascular complications in type 2 diabetes.[25] As such, fasting blood samples will be taken to assess HbA1c and lipid profile. Participants in both the UK and Canada will collect a 500 µL capillary blood sample from a finger prick, using a commercial blood collection kit. Blood collection kit preparation and sample analysis will be performed by the Exeter Clinical Laboratory, based at the Royal Devon and Exeter NHS Foundation Trust. In the UK, samples will be sent directly to the Exeter Clinical Laboratory for analysis, via Royal Mail. In Canada, participants will send samples to the research team at the University of British Columbia, via Canada Post. Once samples are received, they will be centrifuged and stored at –80°C before being shipped on dry ice to the Exeter Clinical Laboratory for analysis. Internal pilot data from the Exeter Clinical Laboratory demonstrate that capillary blood sampling reveals good agreement with standard venous sampling. In Canada, to ensure participants meet the inclusion criteria (HbA1c ≤86 mmol/mol), 5 µL of the sample will be used by the research team at the University of British Columbia to measure HbA1c, unless this can be confirmed by a recent (within 1 month) test conducted by a standard clinical lab. If required, the Afinion 2 point-of-care (POC) analyser (Alere Technologies, Osla, Norway) will be used for this screening. The Afinion 2 is a National Glycohemoglobin Standardization Program-certified POC device for evaluating HbA1c[29] and has shown low rates of bias and imprecision from standardised testing by the College of American Pathologists.[30]

Flash glucose monitoring

Although HbA1c is recognised as the key marker for the development of diabetes complications, it does not provide information on the magnitude and frequency of intraday and interday glucose variation, which are also important predictors of future diabetes complications.[31] As such, key metrics of glycaemic control[31] (table 1) will be assessed using a flash glucose monitor (FreeStyle Libre Pro, Abbott Diabetes Care, Alameda, California, USA) worn for 14 days (1) immediately following baseline assessments/prior to commencement of the intervention; (2) during the final 14 days of the intervention period and (3) immediately after follow-up testing.

Questionnaires

Generic health status (5-level EuroQol-5 Dimensions questionnaire[32]) health-related quality of life (12-Item Short Form Survey (SF-12) Health Survey[33]), diabetes treatment satisfaction (Diabetes Treatment Satisfaction Questionnaire status version (DTSQs)[34]) and motivation

Table 2 Details of semistructured interviews

Interview	Group sampled	Number sampled in each country (total n=)	Sampling	Date	Aim
Acceptability of virtual testing procedures	► Intervention ► Active control	4 (8)	► The first 4 participants to consent ► Stratified for age (40–60 and 61–75)	Approximately 1 week after pre-randomisation baseline testing	Learn about experiences (ease and willingness, comprehension and ability to follow instructions, length of time to complete, suggestions for improvement) with home-based baseline testing
Post-intervention feedback on the intervention	Intervention only	6–10 (12–20)	► Stratified for age (40–60, 61–75) ► Minimum of one self-identified male and female	Approximately 1 week after the intervention period is completed	Learn about experiences (barriers, facilitators, actual use of technology and coach, receptivity to the coach, perceived appropriateness and suggestions for improvement) with the intervention (technological aspects and exercise prescription and counselling)
Post-intervention feedback on acceptability of research process	► Intervention ► Active control	6–10 (12–20)	► Stratified for age (40–60, 61–75) ► Minimum of one self-identified male and female	Approximately 1 week after post-intervention testing	Learn about experiences (willingness to do the study again, refer others, perceived appropriateness, respect, dignity, confidentiality and suggestions for improvement) with recruitment, randomisation and the research process
Follow-up feedback on continuity of PA after intervention concluded	► Intervention ► Active control	► Intervention: 6–10 (12–20) ► Control: 6–10 (12–20)	► Stratified for age (40–60, 61–75) ► Minimum of one self-identified male and female	Approximately 1 week after the follow-up assessment	Learn whether, and how, participants adhered to the exercise prescription, what facilitated and hindered this behaviour and the motives behind this

PA, physical activity.

to exercise (Behavioural Regulation in Exercise Questionnaire version 2[35]) will be assessed using online versions of the surveys administered using Qualtrics. At post-intervention, only change in diabetes treatment satisfaction (DTSQ change version[36]) and participant rapport with their counsellor (10-point scale of Client Experiences of Motivational Interviewing[37]) will be assessed.

Process evaluation

A detailed process evaluation will examine the acceptability and feasibility of the intervention and evaluation methods. Semistructured interviews will be conducted at four time points (table 2):

1. Acceptability of virtual assessment procedures—following pre-randomisation baseline assessment.
2. Post-intervention feedback on the intervention—6 months post-randomisation.
3. Post-intervention feedback on acceptability of the research process—6 months post-randomisation.
4. Follow-up feedback on continuity of exercise and PA after intervention concluded—12 months post-randomisation.

All interviews will be via telephone or video call according to participant preference and will be structured using a topic guide.

Qualitative analysis

Interviews will be deductively coded and analysed using the theoretical domains framework,[38] which is an efficient means to characterise challenges and facilitators experienced in interventions as they are being refined, as well as highlight potential mediators influencing efficacy of intervention components.[39] This methodology has been used extensively in the health behavioural change sciences.[40 41] Interview audio files will be transcribed verbatim. Transcriptions will be subject to deductive thematic analysis using NVivo V.12TM software.

Analyses will be conducted in the following steps: (1) exporting the textual data from the transcriptions into NVivo; (2) reading and rereading the data independently by two experienced coders; (3) documentation of 'researcher memos' following the initial reading of the data; (4) associating preliminary themes associated with the theoretical domains framework through line-by-line coding of transcriptions; (5) grouping codes that represent familiar phenomena/themes; and (6) further defining/refining themes through subsequent review of data to gain coder consensus. Member checking[42] will be the final step in analysis, ensuring that interviewed participants have the opportunity to confirm researcher interpretation and add comments that will be incorporated into the final analysis. Consolidated criteria for Reporting Qualitative research guidelines[43] will be adhered to in reporting of these qualitative data. Our aim is to develop a comprehensive understanding of the intervention acceptability, implementation and mechanisms of impact.

Economic assessment

At baseline, post-intervention and follow-up, all participants will complete the EuroQol-5 Dimensions-5 Levels

questionnaire and a study-specific questionnaire assessing healthcare usage in the last 12 weeks (GP services, specialist care, ambulatory clinics in hospital, physiotherapy and medicines). During the interventions, researcher time per participant will also be recorded in both groups.

Interventions

Participants will be randomised to one of two arms:

1. Active control: exercise counselling.
2. Intervention arm: exercise counselling plus mHealth.

By design, the active control arm matches the provision provided to the intervention group, minus the provision of technology, as our aim is to investigate how the addition of mHealth technology can increase exercise and PA adherence and clinical outcomes.

All participants will undertake a 6-month structured exercise and PA intervention supported by an exercise specialist. Participants will co-design a personalised and progressive exercise programme. Each individual participant's exercise programme will differ (initial duration and intensity of sessions and rate of progression) but the aim will be to increase exercise intensity and duration during the first 12 weeks to meet the PA guidelines of 150–300 min of moderate-to-vigorous intensity PA per week by the end of this time period.[13 44] Participants will be given a choice of exercise types (traditional endurance, interval exercise, resistance training, exercise classes, dance or sports) and modes (gym, outdoor, home-based or commuting) depending on personal preferences and available options to increase adherence and feasibility in daily life. Participants will also be encouraged to increase their daily PA. From 12 weeks onwards, the participants will be encouraged to at least maintain the level of exercise (duration, intensity and frequency of sessions).

Active control: exercise counselling

Exercise and PA counselling

To assist participants with the transition to independent exercise and to promote long-term exercise adherence, participants will receive a behavioural exercise counselling intervention built into the 6-month exercise training programme. Participants will have five virtual counselling sessions with their exercise specialist over the 6-month intervention. The content of these meetings is based on the type 2 diabetes specific consultation guide developed by the 'Moving Medicine' initiative (http://movingmedicine.ac.uk/disease/diabetes/) and the Brief Action Planning guide and flow chart developed by the Centre for Collaboration Motivation and Innovation (https://centrecmi.ca/brief-actionplanning/#1502747767988-85883f98-7299). Details of each counselling session are outlined in table 3.

Exercise prescription delivery

After exercise counselling session 2, participants will be sent a copy of their personalised exercise programme (booklet) which includes calendar and progressive exercise guides. Exercise videos will also be available on the trial website (www.motivateT2D.com). The exercise programme will be updated after exercise counselling sessions 3 and 4.

Ongoing communication with exercise specialist

Text messages will be sent weekly during the first 3 months and biweekly during months 4–6. The messages will be pre-scripted, based on self-determination theory and modelled[45] to target relatedness, competence and autonomy. Participants will not be required to reply but will have the option to, should they want to comment or ask a question.

Intervention arm: exercise counselling plus mHealth

Exercise and PA counselling

The counselling used within the intervention will follow the same format as active control, with additions on how to use the mHealth technology and HR to guide exercise intensity. Consultations 3, 4 and 5 will also be modified to allow participant feedback on exercise sessions (see below) and data recorded in the smartphone app and online coaching platform to guide discussions.

Exercise prescription delivery

The intervention arm includes three mHealth elements: (1) an online coaching platform for the exercise specialist

Table 3 Details of the counselling intervention

	Date	Details
Consultation 1	Prior to intervention	Initial meeting to assess current beliefs/concerns, explore the benefits of exercise and agree on a SMART (specific, measurable, achievable, relevant and time-bound) plan
Consultation 2	Prior to intervention	Development of the personal exercise programme and education on exercise intensity
Consultation 3	Month 1	Patient feedback and refinement of the exercise programme with the aim of progressing the programme
Consultation 4	Month 3	Patient feedback and refinement of the exercise programme with the aim of progressing the programme, or maintaining if the government guidelines are being met
Consultation 5	Month 6	Patient feedback and review of progress. Discussion on strategies for maintaining exercise and PA

PA, physical activity.

(Polar Flow for Coach, www.polar.com/coach); (2) a smartphone app for the participant (Polar Flow—Sync & Analyze) and (3) a wrist-worn fitness watch (Polar Ignite, Polar Electro). These three elements will be synchronised allowing data transfer between platforms.

Online platform for coach: within this platform, the exercise specialist will build the co-designed exercise programme, specifying the agreed number of sessions per week and modality of exercise. The exercise specialist will input the individual exercise sessions, prescribing the duration and intensity (measured through HR) of each phase within the session, that is, warm up, workout and cool down. These detailed exercise sessions will then be available as preset sessions on the participant's fitness watch. Throughout the intervention, the online platform will also provide the exercise specialist with access to the participants' training and PA data including: daily PA, HR traces from exercise sessions, Rating of Perceived Exertion (RPE, CR-10 scale[46]) following exercise sessions and written comments on exercise sessions.

Smartphone app for participant: participants will use the app to access their training programme and to track exercise and PA achievements. All data recorded by the fitness watch will be available within the app, and participants will be able to provide feedback on each exercise session including sessions, RPE (CR-10 scale[46]) and a written comment on each exercise session.

Fitness watch: the Polar Ignite fitness watch features a triaxial accelerometer and optical HR monitor. Progress towards a personalised PA target will be displayed throughout the day on the watch screen. Participants will be able to access preset exercise sessions, designed by their exercise specialist, on the device. The prescribed duration and intensity, via HR zones, will be displayed in real time on the watch throughout the exercise session. The watch will also provide live visual and haptic (vibration) alerts, coaching participants to execute the session as prescribed. Should participants not wish to use preset exercise sessions, the monitor screen will still provide live visual feedback on exercise time and intensity (current HR). All data recorded on the watch will be synchronised with both the smartphone app and the online platform.

Exercise videos will also be available to participants on the trial website (www.motivateT2D.com). Videos will be formatted to fit with the preset exercise sessions prescribed to participants.

Ongoing communication with exercise specialist

During the first month, participants will be asked to provide RPE and written comments following all exercise sessions, using the app. The comment will relate to the appropriateness of the session duration and intensity and their enjoyment of the session and exercise type. After each recorded exercise session, the exercise specialist will then use the feedback provided to send a personalised text message in response to the session. Based on this feedback, the exercise specialist will update the training programme and preset exercise sessions as appropriate, using the online platform. The aim of this initial period is to refine the exercise sessions to ensure participants have a programme that fits with their current fitness, lifestyle and exercise goals.

Following exercise counselling 3 (1 month), participants will receive weekly text messages from their exercise specialist. The exercise specialist will continue to use the data recorded in the online platform to provide personalised messages on exercise sessions and daily PA goals. Participants will not be asked to leave feedback after each exercise session during this period, but if feedback is provided, it will be used to guide the messages. During months 4–6, the frequency of the text messages will reduce to biweekly.

Exercise specialists

The role of exercise specialist will be assumed by a postdoctoral research fellow in the UK (PhD in exercise physiology) and a PhD student in Canada (MSc in exercise physiology). The same exercise specialist will provide support to both arms of the trial. To promote the fidelity of intervention delivery and to ensure the behavioural change, techniques are administered as intended, a comprehensive counsellor training workshop will be delivered to the two exercise specialists by an expert in health behaviour change counselling from the Diabetes Prevention Research Group at the University of British Columbia.

Ongoing management of diabetes

Management of diabetes, lipids and blood pressure will not be provided by the study team. In the UK, if alterations to medications are needed, GPs will be encouraged (via a GP letter) to do so according to the targets suggested by The National Institute for Health and Care Excellence (NICE) guidance on management of diabetes (NG28) and hypertension (NG136) and lipid modification (CG181). In Canada, family physicians who care for patients with type 2 diabetes are informed by the Diabetes Canada Clinical Practice Guidelines.[44] Participants will be asked to inform the exercise specialist of any changes to their medications throughout the trial.

Study withdrawal

If a participant wishes to withdraw from the trial, the importance of providing outcome measures will be explained. Data collected up to withdrawal will be included. If the participant explicitly states their wish not to contribute further data to the study, an End of Study Case Report Form will be completed documenting the reason for withdrawal.

Serious adverse event reporting and monitoring

All adverse events will be reported and assignment of the severity/grading (mild, moderate, severe, life-threatening, death) made by the investigator responsible for the care of the participant. The assignment of causality will be made by an independent clinician in the UK and Canada. All non-serious adverse events (SAEs),

whether expected or not, will be recorded and updated at each visit. All new SAEs will be reported from the point of consent until follow-up. Investigators will report SAEs to the sponsor within 24 hours of the local site becoming aware of the event. All adverse events will be followed until satisfactory resolution.

Data management

Data will be collected and stored in accordance with the Data Protection Act 1998/General Data Protection Regulation 2018 in the UK and in accordance with British Columbia's Freedom of Information and Protection of Privacy Act 2015 in Canada.

All data will be entered electronically. Outcomes and questionnaire data collected by participants will be reported using online survey software (Qualtrics; www.qualtrics.com). Blood reports will be sent via email to the UK and Canadian sites. The administrative database (ie, participant information) and trial data will be managed by the research teams at the UK and Canadian sites. Random checks will be performed on the entered data against online records. All errors will be logged and corrected. All data will be stored on password-protected and encrypted computers. Participant files will be maintained in storage for a period of 15 years after completion of the trial, with access granted to the local research team only.

Our intended policy is that the research team should have exclusive use of the data for a period of 12 months or until the data are published. Data will be shared with named collaborators during this time. Following this time period, data will be made publicly available through the Liverpool John Moores University (LJMU) Data Repository, published under a permissive reuse license.

Statistical analysis plan

The proportion of eligible participants who consent will be presented by centre and overall, along with the proportions in each intervention group completing each follow-up assessment and the reasons for withdrawal. Exploratory analyses on the predefined secondary outcomes will include a constrained baseline longitudinal analyses via linear mixed model with fixed effects of time point, stratified allocation factors, and the interaction between time point and group, and random effects for participants. Effect estimates with 95% CI for between-group differences, and changes within group over time, will be reported. Interview data will be analysed as outlined above, which will allow the research team to discuss emerging themes and refine the intervention protocol and trial design (eg, inclusion and exclusion criteria and approach to participants) to maximise recruitment. The data collected within the trial will aid the Trial Steering Committee (TSC) in evaluating the study progression criteria (table 4), to inform a decision on whether a full RCT is warranted and feasible.

Sample size calculation

We aim to provide precise estimates of outcome variability that will aid in the planning of a definitive RCT.[47 48] A sample size of 60 per arm provides acceptably precise estimates of the variability in changes in outcome variables. For example, for outcomes measured as a proportion, for example, drop-out rate, the 95% CI (modified Wald method) for a drop-out rate of, for example, 20% would be 12%–32%.[47] A sample size of 60 per arm would also provide acceptably precise estimates of the variability in change in our primary outcome(s) and is higher than

Table 4 Summary of progression criteria

Progression criteria	Measures used	Assessment of whether criteria have been met
Feasibility to recruit participants to participate in the trial, with appropriate retention rates to 12-month follow-up	► % of participants recruited, and retained at each follow-up ► Regression models will identify predictors of loss to follow-up	► If >20% of new patients recruited=proceed; if <5%=full-scale trial unlikely to be feasible. If 5%–20%, the Trial Steering Committee (TSC) will consider proceeding. ► If >80% retained at 12 months=proceed, if <60%=full-scale trial unlikely to be feasible. If 60%–80%, the TSC will consider the feasibility of proceeding.
The intervention is acceptable to participants	► % of participants reporting acceptability on patient questionnaire ► Qualitative interviews	The TSC will consider the quantitative and qualitative data to judge acceptability.
Recruitment, randomisation and outcome measures are acceptable to >50% of recruited participants	► % of participants reporting acceptability on the patient questionnaire ► Qualitative interviews	► >50% report 'agree' or 'strongly agree' on the acceptability of recruitment and randomisation processes. ► The TSC will apply discretion in judging this criterion and how it could be improved in a full-scale trial.

the median value for feasibility studies (36 participants per arm) reported in an audit of pilot and feasibility trials registered in the UK clinical research network.[49]

Trial oversight

Management structure

The trial will be overseen by a TSC and operated on a day-to-day basis by a Trial Delivery Group (TDG). Local Delivery Groups in the UK and Canada (UK: KH, HJ, VSS and MC; Canada: JLo and AMM) will produce monthly recruitment reports, to allow the TSC and TDG to regularly review the trial across sites. The TSC will comprise of experienced medical experts and trialists. The TSC will also encompass the role of the Data Monitoring Committee. Meetings will be held at regular intervals dependent on need, but no less than once a year. The responsibilities of the TDG will include:

1. Report to the TSC.
2. Maintain the Trial Master File.
3. Confirm all approvals are in place before the start of the trial at a site.
4. Provide study materials.
5. Data management centre.
6. Give collaborators regular information about the progress of the study.
7. Respond to any questions (eg, from collaborators) about the trial.
8. Ensure data security and quality and observe data protection laws.
9. Safety reporting.
10. Ensure trial is conducted in accordance with Good Clinical Practice (GCP).
11. Statistical analysis.
12. Publication of trial results.

The role of the TSC is to provide overall supervision of the trial. In particular, the TSC will concentrate on the progress of the trial, adherence to the protocol, participant safety and consideration of new information. The TSC must be in agreement with the final protocol and, throughout the trial, will take responsibility for:

1. Major decisions such as need to change the protocol for any reason.
2. Monitoring and supervising the progress of the trial.
3. Reviewing relevant information from other sources.
4. Informing and advising the TDG on all aspects of the trial.

Patient and public involvement

Patients are involved in the oversight of trial progress and conduct via representation at periodical TDG and TSC meetings. Our patient representatives also provided opinions on the protocol and patient-facing documentation (eg, Participant Information Sheet) during the set-up of the trial.

ETHICS AND DISSEMINATION

This study is being conducted in accordance with GCP, as defined by The International Council for Harmonisation (ICH). The trial protocol has received favourable opinion from the South East Scotland Research Ethics Committee 01 (20/SS/0101; protocol number 19LJMU-SPONSOR0094) in the UK and Clinical Research Ethics Board of the University of British Columbia (H20-1936) in Canada. Appropriate participant information sheets (online supplemental file 1 (UK) and online supplemental file 2 (Canada)) and consent forms (online supplemental file 3 (UK) and online supplemental file 4 (Canada)) describing in detail the trial interventions, trial procedures and risks were approved by the ethical committees. Aside from providing a participant information sheet to all potential participants, the investigator will explain the study and answer any questions posed. A contact point where further information about the trial may be obtained will be provided. After being given adequate time to consider the information, the participant will be asked to sign the informed consent document using the eSignature solution HELLOSIGN (UK) or REDCap (Canada), in line with Health Research Authority (HRA) advice.[50] A copy of the informed consent document will be sent to the participants for their records, with the original retained in the investigator site file. The participant may withdraw from the trial at any time by revoking their informed consent. The rights and welfare of the participants will be protected by emphasising to them that the quality of medical care will not be adversely affected if they decline participation.

The results will be analysed together and published as soon as possible. The Uniform Requirements for Manuscripts Submitted to Biomedical Journals (http://wwwicmje.org/) will be respected. The ISRCTN allocated to this trial would be attached to any publications resulting from this trial.

Dissemination plan (publications, data deposition and curation)

It is our intention to present our research findings to all our research participants in a written lay summary and hold an open feedback session where the results will be presented in a lay-friendly manner. We plan to present the scientific findings as oral communications and abstracts at regional, national and international scientific meetings related to type 2 diabetes. We also intend to publish our findings in peer-reviewed journals.

Author affiliations
[1]Research Institute for Sport and Exercise Science, Liverpool John Moores University, Liverpool, UK
[2]School of Health and Exercise Sciences, University of British Columbia, Kelowna, British Columbia, Canada
[3]Exeter Medical School, University of Exeter, Exeter, UK
[4]Department of Diabetes, Taunton and Somerset NHS Foundation Trust, Taunton, UK
[5]Faculty of Medicine, University of British Columbia, Kelowna, British Columbia, Canada
[6]Division of Health Research, Lancaster University, Lancaster, UK
[7]Sport and Health Sciences, University of Exeter, Exeter, UK
[8]School of Population and Public Health, University of British Columbia, Vancouver, British Columbia, Canada
[9]Department of Musculoskeletal Biology II, University of Liverpool, Liverpool, UK

Twitter Katie Hesketh @kathskth and Victoria S Sprung @torisprung

Contributors KH, JLo, HJ, VSS, RA, CM, RP, MEJ, JLi, CAJ, AMM and MC initiated the study design. HJ, VSS, RA, CM, MEJ, JLi, JS, CAJ, AMM and MC are grant holders. JS provided statistical expertise in clinical trial design and is conducting the primary statistical analysis. All authors contributed to refinement of the protocol and approved the final manuscript.

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ORCID iDs
Katie Hesketh http://orcid.org/0000-0003-3409-3906
Helen Jones http://orcid.org/0000-0001-8282-1459
Mary E Jung http://orcid.org/0000-0002-2360-0952
Victoria S Sprung http://orcid.org/0000-0002-2666-4986

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