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Mobile Health Biometrics to Enhance Exercise and Physical Activity Adherence in Type 2 Diabetes (MOTIVATE-T2D): a Feasibility Randomised Controlled Trial

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ABSTRACT

Objectives: Assess the feasibility of a mobile health (mHealth) supported home-delivered physical activity (PA) intervention (MOTIVATE-T2D) in people with recently diagnosed type 2 diabetes (T2D).

Design: Feasibility multicentre, parallel group, Randomised Controlled Trial (RCT)

Setting: Participants were recruited from England and Canada using a decentralised design.

Participants: Adults (40-75 years) recently diagnosed with T2D (5-24 months).

Interventions: Participants were randomised 1:1 to intervention (MOTIVATE-T2D) or active control groups. Participants co-designed 6-month home-delivered, personalised, progressive PA programmes supported by virtual behavioural counselling. MOTIVATE-T2D used biofeedback from wearable technologies to support the programme. The active control group received the same intervention without wearables.

Outcomes: The primary outcomes were recruitment rate, retention and adherence to purposeful exercise. Clinical data on effectiveness were collected as exploratory outcomes at baseline, 6- and 12-months, with HbA1c and systolic blood pressure (BP) proposed as primary outcomes for a future full RCT.

Results: n=135 eligible participants expressed interest, resulting in 125 participants randomised (age 55±9yrs, 48% female, 81% white), a recruitment rate of 93%. Retention at 12-months was 82%. MOTIVATE-T2D participants were more likely to start (odds ratio [OR] 10.4, CI 3.4 to 32.1) and maintain purposeful exercise at 6 (OR 7.1, CI 3.2 to 15.7) and 12-months (OR 2.9, CI 1.2 to 7.4). Exploratory clinical outcomes showed a potential effect in favour of MOTIVATE-T2D, including proposed primary outcomes HbA1c and systolic BP (between-group mean differences: HbA1c: 6-months: -5% change from baseline, CI -10 to 2: 12-months: -2% change from baseline, CI -8 to -4; systolic BP: 6-months: -1mmHg, CI -5 to 3: 12-months: -4mmHg, CI -8 to 1).

Conclusions: Our findings support the feasibility of delivering the MOTIVATE-T2D mHealth supported PA intervention for people with recently diagnosed T2D and progression to a full RCT to examine its clinical and cost-effectiveness.

Trial Registration: ISRCTN: 14335124. ClinicalTrials.gov: NCT0465353

Key words: Type 2 diabetes, mHealth technology, physical activity, exercise, behaviour change

Strength and Limitations of the Study

- Mobile Health Biometrics to Enhance Exercise and Physical Activity Adherence in Type 2 Diabetes (MOTIVATE-T2D) is the first intervention to combine advances in biofeedback and data sharing to support a home-delivered

behavioural physical activity (PA) and exercise counselling service for people with recently diagnosed type 2 diabetes (T2D).

- Our active control intervention was matched aside from the availability of technology in MOTIVATE-T2D to assess how the addition of mHealth technology can influence PA.
- Acceptability and feasibility were established using a multidisciplinary approach drawing on quantitative, qualitative, and trial procedure data.
- The effect of the interventions on PA were evaluated using two device-derived measurements. Providing objective data on purposeful exercise of moderate-to-vigorous intensities and daily lifestyle PA which were both encouraged by the intervention and are known to be important determinants of health outcomes in T2D.
- This study was not designed or powered to definitively assess the efficacy or cost effectiveness of the MOTIVATE-T2D intervention on clinical outcomes in people with newly diagnosed T2D.

INTRODUCTION

Increasing physical activity (PA), both through purposeful exercise and unstructured lifestyle behaviours is fundamental to the initial treatment of type 2 diabetes (T2D) and recommended in international guidelines (1-3). These guidelines draw on the known benefits of regular PA on glycaemia (4), the incidence of microvascular complications, cardiovascular events, and all-cause mortality in people living with T2D (5). However, people with T2D tend to exhibit lower levels of PA compared to people who do not have diabetes (6, 7). To address this gap, diabetes care pathways are increasingly prioritising the provision of personalised PA guidance for individuals recently diagnosed with T2D (8, 9). However, given the poor adherence to existing PA interventions and strategies (10), innovative interventions which capitalise on the potential of new technologies are urgently needed to effectively support PA and health in people with T2D.

Recently, wearable technologies incorporating PA trackers have become popular to promote behaviour change in long-term conditions such as T2D (11). In particular, pedometers and accelerometers that provide biofeedback on ambulatory PA, have been used as tools for self-monitoring or alongside more complex behavioural

interventions (12). Use of PA trackers has been associated with increased PA in people with T2D (13), which can be maintained for up to 12 months (14). However, the effects of increasing PA via use of PA trackers on outcomes relevant to the clinical management of T2D are unclear. An umbrella review found little evidence that PA trackers improve HbA1c in people with T2D (15). It has been hypothesised that these findings are due to PA trackers promoting low-intensity lifestyle PA (i.e., accrual of PA through everyday activities) rather than more intense domains and/or purposeful exercise (14), crucial for improving glycaemic control (4, 16).

Accelerometers can support behaviour change by providing PA targets based on time spent in specific intensity categories (i.e., light, moderate, or vigorous). Intensity categories are delineated using threshold values derived from calibration studies which examine the association between movement acceleration and energy expenditure (17). Generic targets based on such broad and classifications of intensity are effective at encouraging general lifestyle PA, but the one-size-fits-all approach does not provide personalised formative feedback. Therefore, participants cannot utilise these targets to optimise intensity during purposeful exercise (18), which may be crucial for improving glycaemic control (4). Previous reports have also cited issues with using accelerometers to assess non-ambulatory activity (e.g cycling and resistance exercise), which may be promoted through purposeful exercise programmes (19). The latest generation smartwatches now incorporate heart rate (HR) monitors alongside accelerometers. HR monitoring has several advantages over accelerometers when targeting purposeful exercise of moderate-to-vigorous intensity. HR is the most accurate way to track the body's response to PA, providing real-time objective personalised data that accounts for age, body mass and fitness level (20). HR also reflects intensity regardless of the type of activity performed (21). The Mobile Health Biometrics to Enhance Exercise and Physical Activity Adherence in Type 2 Diabetes (MOTIVATE-T2D) intervention was designed to combine accelerometery and HR monitoring as the most effective biofeedback tools to facilitate home-based PA. Promoting both lifestyle PA and purposeful exercise of moderate-to-vigorous intensities known to influence clinical outcomes (4). Previous work suggests real-time HR biofeedback facilities purposeful exercise by helping participants work at an intensity most likely to elicit health changes, fostering self-efficacy to engage through feelings of competence (19).

Advances in mobile health (mHealth) technologies can also be used to target other barriers to home-delivered PA. One such barrier is that participants do not receive appropriate support from health providers in the time between scheduled meetings (22). MOTIVATE-T2D uses next-generation mHealth technology to share biometric data and facilitate remote communication between patients and health professionals. This aims to recreate the relationship between patients and health professionals experienced during supervised interventions, but with the advantage that communication is in the patient's own environment at convenient times. Qualitative data suggests such remote feedback may encourage adherence to a PA programme, through enhanced relatedness between patients and health professionals (19). In summary, MOTIVATE-T2D combines the latest advances in biofeedback and data sharing to optimise a home-delivered behavioural counselling service. Together the elements, provide comprehensive support to participants, enabling them to co-develop personalised PA plans which include lifestyle PA and purposeful exercise of moderate-to-vigorous intensities.

The primary aim of this study was to assess the feasibility of undertaking a subsequent definitive Randomised Controlled Trial (RCT) to assess the clinical effectiveness and cost-effectiveness of the MOTIVATE-T2D intervention in people with recently diagnosed T2D. Specific objectives of the study were to:

1. Determine the proportion and characteristics of people with recently diagnosed T2D who would be willing to take part in an RCT (i.e. recruitment rate)
2. Determine the number of participants retained at 12 months in both arms of the trial (i.e., loss to follow-up).
3. Evaluate the acceptability of the intervention and determine rates of adherence during and for 6 months after completion of the intervention.
4. Estimate precision of potential outcome measures required for sample size estimations for a future definitive RCT.
5. Pilot methods for collecting outcome measures, recruitment, randomisation, treatment, and follow-up.
6. Determine availability and completeness of economic data.

METHODS

The trial is reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) extension for pilot trials (23). Our full trial protocol can be found elsewhere (24).

Study Population and Design

The MOTIVATE-T2D feasibility trial was a multicentre (UK and Canada), parallel group, RCT in adults recently diagnosed with T2D. Participants aged 40-75 years, diagnosed with T2D within the previous 5-24 months and managing their condition through lifestyle modification alone or Metformin (stable dose for ≥3 months) were eligible. Exclusion criteria were HbA1c >86 mmol/mol, blood pressure >160/100 mmHg, glucose-lowering agents other than Metformin, unstable angina, myocardial infarction within the previous 3 months, transient ischemic attack in the previous 6 months, heart failure NYHA ≥ class II, arrythmia, healthcare professional advice against increasing level of activity, pregnancy or planning to become pregnant, <6 months postpartum or stopped breastfeeding <1 month before recruitment, not owning a smartphone or not having a data plan or access to Wi-Fi, and those who are currently meeting the recommended exercise guidelines for people with T2D (150 min of moderate intensity exercise per week).

Participants were randomised to active control or intervention (MOTIVATE-T2D) on a 1:1 basis following the completion of baseline assessments. Randomisation was stratified by centre (UK or Canada), sex (male or female) and age (40-60 or 61-75 years) and was administered using a computer-generated random allocation sequence, created and administered by the Centre for Advancing Health Outcomes. Research staff responsible for the intervention and outcomes measures and participants were aware of allocation. However, the statistician undertaking the data analysis was blinded to treatment allocation (blinded analytic assessment). The trial conforms with the principles outlined in the Declaration of Helsinki and 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). All participants provided written informed consent.

Participants were recruited from 1) general practitioner (GP) database searches (UK only); 2) flyers provided to diabetes education sessions (DESMOND and X-PERT Diabetes, UK only); 3) adverts in clinical settings (LifeLabs and GP waiting rooms, Canada only); 4) local media adverts and classifieds (Canada only); 5) third party online recruitment services (Lindus Health, UK; Trialfacts and HoneyBee Trials, Canada); 6) a consent to contact database (Research For The Future, UK only) and 7) the study website.

Interventions

Detailed descriptions of the active control and MOTIVATE-T2D interventions are published elsewhere (24). Briefly, by design, the active control and MOTIVATE-T2D interventions were matched aside from the availability of technology in MOTIVATE-T2D. Key aspects of both interventions and how they differed are presented in Table 1.

Participants in both groups co-designed their 6 month PA programmes with the aim of promoting two behaviours, namely 1) gradually increasing purposeful exercise of moderate-to-vigorous intensity, with a target of 150 minutes per week by the end of 6 months and 2) increasing daily lifestyle PA of any intensity. These aims were facilitated by an exercise specialist-led behavioural counselling service delivered virtually via phone or teleconferencing software, according to participant preference. The counselling supported participants to develop personalised PA programmes and provided regular feedback on their action plans to support them achieve their goals. MOTIVATE-T2D used biofeedback and data sharing enabled by mHealth technologies to support the development of personalised PA programmes and ongoing feedback. The mHealth technologies included a smartwatch, featuring a 3D accelerometer and optical heart rate (HR) monitor (Polar Ignite, Polar Electro), synced with an online coaching platform for the exercise specialist (Polar Flow for Coach, www.polar.com/coach) and web/smartphone app for participants (Polar Flow – Sync & Analyze).

Ongoing Management of Diabetes

Throughout the trial, all participants remained under their diabetes specialist and continued with medication management according to national guidelines (National Institute for Health and Care Excellence Guidance 28, 136 and 181) (25).

Outcome Measurements

The following feasibility outcomes were collected: percentage of people eligible for the study; total recruitment rate and rate by recruitment strategies; attrition and loss to follow-up; completeness of outcome measures at baseline, 6 and 12 months.

Acceptability of study participation and intervention were assessed via virtual (Zoom inc.) semi-structured qualitative interviews. Immediately following baseline measures 8 participants (UK N=4, Canada N=4) and 20 participants at 6 months (UK N=11, Canada N=9) were interviewed regarding study participation. At 6 months 25 participants (MOTIVATE-T2D N=14, UK N=8, Canada N=6; active control N=11, UK N=8, Canada N=3) were interviewed regarding intervention acceptability, with 21 (MOTIVATE-T2D N=12, UK N=8, Canada N=4; active control N=9, UK N=6, Canada N=3) of these participants interviewed again at 12 months.

Adherence: The intervention aimed to increase completion of purposeful exercise of moderate-to-vigorous intensities and unstructured lifestyle PA; as such, two methods for assessing these distinct factors were employed.

Table 1. Intervention components

Intervention component	Shared features	Active control	MOTIVATE-T2D
Aims	1. Progressively increase purposeful exercise of moderate-to-vigorous intensities 2. Increase daily lifestyle PA of any intensity		Supported by biofeedback and data sharing enabled by mHealth technologies: 1. Smartwatch, featuring a 3D accelerometer and optical heart rate (HR) monitor 2. Online coaching platform for the exercise specialist 3. Web/smartphone app for participants
Behavioural counselling	● Exercise specialist led, one-to-one, virtual exercise consultations (Zoom inc) ● 5 sessions: 1) prior to intervention, 2) approx. 1 week after first session, 3) 1-month, 4) 3-months, 5) 6 months		
Purposeful exercise programmes	● Individualised action plans were co-developed ● Individualised by allowing participants to choose the: 1. Mode (e.g., commuting, outdoor, indoor calisthenics, or gym-based) 2. Type (e.g., walking, cycling, resistance exercise, interval-based exercise, classes, dance, or sports) 3. Initial duration 4. Initial intensity 5. Rate of progression	● Action plan sent within a booklet containing: ○ Training calendar/diary ○ Progressive exercise guide ● Access to the trial website with exercise resources, including exercise videos	Action plan built within the coaching platform ○ Training calendar ○ Preset sessions prescribing the duration and intensity (measured through HR) of phases within each exercise session (i.e., warm-up, workout and cool-down) Smartwatch providing real-time feedback on exercise intensity through HR zones ○ During preset sessions, prescribed duration and intensity were displayed (via HR zones), with visual and haptic (vibration) alerts to coach participants Web/smartphone app: 1. Access to the action plan

			2. Track exercise and PA achievements 3. Participants rate enjoyment and provide written feedback following exercise sessions
Lifestyle PA	Advice on how to integrate physical activity into daily routines		Supported with a target on the smartwatch
On-going communication	Counselling sessions 3, 4 and 5 ○ Review progress ○ Update action plan Counselling session 5 ● Strategies for maintaining exercise and PA without support from the exercise specialist	● Updated action plans sent after counselling sessions ● Participants received SMS text messages: 1. Weekly during the first 3 months 2. Biweekly during months 4–6 ● Pre-scripted, based on self-determination theory: modelled to target relatedness, competence and autonomy ● Participants could reply and engage with their exercise specialist ○ Action plans could be updated based on discussions	● Consultations allowed mHealth data to guide discussion ● Updated action plans within the coaching platform after counselling sessions ○ Updated pre-set sessions ● Participants received SMS text messages: 1. Following each recorded exercise session during month 1 2. Weekly during months 2-3 3. Biweekly months 4-6 ● Based on data gathered by the mHealth technologies (intensity and duration of sessions and participant enjoyment and feedback) ● Participants could reply and engage with their exercise specialist ○ Action plans and pre-set sessions could be updated based on discussions

Optical HR monitoring (photoplethysmography) was used to record dose of purposeful exercise throughout the 12 month trial. A blinded Polar Verity sense (Polar Electro, Finland) was provided to active control participants for the duration of the trial. The MOTIVATE-T2D group used a Polar Verity sense paired to the fitness watch, allowing HR to be visualised in real time. HR data were used to calculate 1) frequency of exercise (number of sessions recorded); 2) adherence to prescribed exercise (% of 78 sessions achieved, based on prescribing 3 sessions per week for 26 weeks), 3) duration of exercise; 4) duration of moderate-to-vigorous intensity exercise (MVE, calculated by adding time in moderate, 50-70% HR_{max}, and time in vigorous, ≥70% HR_{max}*2, intensity exercise); 5) training drop-off (defined as the week which participants no longer completed any training sessions), and; 5) proportion of participants completing >150 minutes of MVE per week at least once during the last month of the intervention and follow-up period.

Lifestyle PA was measured in all participants using a GENEactive (Activinsights, Kimbolton, Cambridge, UK) tri-axial accelerometer for 14-days at baseline, 6 and 12 months. Data were extracted using GENEActiv PC software (V.3.0_09.02.2015) and processed in R using the open-source package GGIR V.1.2-8 (https://cran.r-project.org/web/packages/GGIR/index.html) (26) to explore accelerometer wear time, and the proportion of participants who wore the device for at least 16h on: 1) 4 days including one weekend day; 2) 3 days including at least 1 weekend day; 3) 3 days irrespective of weekend days, and; 4) 1 day. The time spent in activity intensities was established using published thresholds (27). The following metrics of PA were assessed: average weekly minutes of total PA (any intensity), and of light, moderate, vigorous and moderate-to-vigorous PA (MVPA) (MVPA), and MVPA recorded in ≥10-min bouts (MVPA10+).

Fidelity: Exercise specialists logged all contact with participants, including 1) the number of counselling sessions attended; 2) the number of SMS text messages sent by participants to exercise specialists, and 3) the number of exercise video views.

Clinical effectiveness outcomes proposed for a future trial were collected at baseline, 6 and 12 months as described previously (24). The trial used a decentralised design where outcomes were measured using remote 'home-based' solutions. HbA1c and

systolic blood pressure have been proposed as primary outcomes for a future RCT. Proposed secondary outcomes included; height; weight; waist circumference; diastolic blood pressure; mean arterial pressure; blood lipids; generic health status (5-level EQ-5D) (28); health-related quality of life (12-item short form Health Survey [SF-12]) (29); diabetes treatment satisfaction (Diabetes Treatment Satisfaction Questionnaire status version [DTSQs]) (30); healthcare utilisation using a study-specific questionnaire (primary and secondary care contacts, social care contacts and relevant medication usage); and safety outcomes (serious adverse events). Change in diabetes treatment satisfaction (DTSQ change version) (31) was assessed at 6 months only. Free-living glycemia was assessed using a FreeStyle Libre Pro flash continuous glucose monitor (CGM, Abbott Diabetes Care, Alameda, CA, USA) worn for 14-days at baseline, 6 and 12 months. Core CGM endpoints outlined in a recent position statement (32) were calculated using the web-based application Diametrics (33) if participants provided ≥70% of data over 14 consecutive days. To explore if different ways of processing CGM data influenced data availability and outcomes, CGM endpoints were calculated based on alternative wear-time criteria, including ≥80% of data over 10 consecutive days; ≥80% of data over 7 consecutive days (32).

Protocol deviation: The original protocol suggested HbA1c would be analysed by the Exeter Clinical Laboratory for UK and Canadian samples. Due to logistical challenges with shipping, Canadian HbA1c was assessed by the University of British Columbia research team, using an Afinion 2 point-of-care analyzer (Alere Technologies, Oslao, Norway). UK and Canadian assessment of blood lipids was conducted as planned by the Exeter Clinical Laboratory.

Statistical Analysis

Our planned recruitment target of 120 participants (60 per arm) allowed us to achieve the feasibility aims and objectives of this study; that is, an estimate of attrition, estimates of the standard deviation (SD) of the secondary outcomes to inform power calculations for a future definitive trial, and enough participants for qualitative interviews. For more information see our full trial protocol (23).

We report the mean and SD for both groups for all outcomes at baseline, 6 and 12 months, and the model-derived estimated marginal means (with corresponding 95%

CIs) for the within and between group effect estimates at 6 and 12 months. Effect estimates are based on intention to treat (ITT) analyses and included all participants that had a baseline or a follow-up value. Data were analysed via constrained longitudinal data analysis (cLDA) using a linear mixed model with fixed effects for timepoints (baseline, 6 and 12 months), the interaction between timepoint and intervention group, and stratified allocation factors (sex, study site, and age category), and a random effect for participant.

Given the feasibility nature of this trial, we do not report *p* values for the comparison of outcomes to baseline or between groups. Confidence intervals and minimal clinically important differences (MCID) are presented to suggest plausible evidence of effect for respective study arms (34, 35). All analyses were conducted in R (version 4.3.1.). Participant semi-structured interviews were transcribed verbatim using otter.ai software and analysed using a deductive coding and thematic analysis approach (36), using NVivo 12TM software and will be fully reported elsewhere.

Patient and Public Involvement (PPI)

Patients were involved in the oversight of trial progress and conduct via representation at periodic Trial Delivery Group and Trial Steering Group meetings. Our patient representatives also provided opinions on the protocol and patient-facing documentation (e.g., Participant Information Sheet) during the set-up of the trial.

RESULTS

Recruitment and retention of participants and acceptability of trial design

A consort diagram showing participant flow through the study is shown in Figure 1 (consort diagrams separating UK and Canada are shown in online supplementary eFigure 1-2). Between January 2021 and December 2021, *n*=596 potential participants expressed an interest in the trial, of which *n*=321 (54% of those who initially enquired) were excluded, 140 (23%) had no further contact and 10 (2%) did not wish to take part, resulting in 125 participants (93% of eligible participants) randomised (MOTIVATE-T2D 61, active control 64; UK 62, Canada 63). The actual recruitment rate of 10.4 participants per month was in line with the forecast of 10 participants per month. Enrolment success appeared to be influenced by recruitment strategy (online supplementary eTable 1). For example, GP database searches were

responsible for 94 expressions of interest and 44 participants randomised (47% of those who initially enquired), compared to third party recruitment services which were responsible for 327 expressions of interest and 38 participants randomised (12% of those who initially enquired). Demographics were also influenced by recruitment strategy (online supplementary eTable 2), with third party online recruitment services recruiting more young people in full time employment with education to higher level, but a more ethnically diverse population.

At 6 and 12 months follow-ups, 16 (13%) and 22 (18%) participants were lost to follow-up, respectively. There was evidence of imbalance in retention rate between study groups and country, with 8 (13%) MOTIVATE-T2D vs. 14 (22%) active control and 9 (14%) UK vs 13 (21%) Canadian participants lost to follow-up. Participants had a high level of satisfaction with their participation in the trial (online supplementary eTable 3).

Baseline characteristics

Baseline demographics and medication use are displayed in Table 2 and eTable 4, respectively (UK and Canada; online supplementary eTable 5-8). Baseline values for outcome measures are shown in Table 3-4. Compared with active control, MOTIVATE-T2D included a higher proportion of participants with education to further level and a lower proportion of participants who were single and living alone.

Table 2. Baseline demographic characteristics

	Total	Active control	MOTIVATE-T2D
N	125	64	61
Age, years, mean (SD)	55 (9)	54 (9)	55 (9)
Female, N (%)	60 (48)	31 (48)	29 (48)
Male, N (%)	65 (52)	33 (52)	32 (52)
Duration of T2D, months, mean (SD)	13 (6)	13 (6)	13 (6)
Ethnicity, N (%)			
White	101 (81)	52 (81)	49 (80)
African or Caribbean	5 (4)	2 (3)	3 (5)
Asian	14 (11)	8 (13)	6 (10)
Other or Mixed	5 (4)	2 (3)	3 (5)
Marital status, living arrangements, N (%)			
Married, living with spouse	90 (72)	44 (69)	46 (75)

Married, living alone	1 (1)	0 (0)	1 (2)
Married, living arrangement unknown	1 (1)	0 (0)	1 (2)
Single, living alone	15 (12)	10 (16)	5 (8)
Single, living with others	3 (2)	2 (3)	1 (2)
Single, living arrangement unknown	1 (1)	1 (2)	0 (0)
Separated, living alone	9 (7)	5 (8)	4 (7)
Separated, living with spouse/partner	1 (1)	0 (0)	1 (2)
Widowed, living with spouse/partner	1 (1)	0 (0)	1 (2)
Widowed, living alone	2 (2)	1 (2)	1 (2)
Rather not say, living with spouse/ partner	1 (1)	1 (2)	0 (0)
Educational Attainment, N (%)			
Secondary	20 (16)	15 (23)	5 (8)
Further	49 (39)	20 (31)	29 (48)
Higher	56 (45)	29 (45)	27 (44)
Employment Situation, N (%)			
Full Time	75 (60)	40 (63)	35 (57)
Part Time	11 (9)	4 (6)	7 (11)
Retired	21 (17)	11 (17)	10 (16)
Student	2 (2)	1 (2)	1 (2)
Voluntary/ unpaid work	2 (2)	1 (2)	1 (2)
Stay-at-home mother/father	1 (1)	1 (2)	0 (0)
Unable: Caring responsibility	1 (1)	0 (0)	1 (2)
Unable: Ill health/ disability	9 (7)	5 (8)	4 (7)
Unemployed	3 (2)	1 (2)	2 (3)

Table 3. Baseline and within- and between group differences at 6 and 12 months follow-up; HbA1c, anthropometrics, blood pressure, blood lipids, device-derived physical activity and continuous glucose monitoring variables

Outcome, Unit (MCID)		Baseline, Mean (SD)	Within group difference (95% CI)*		Between group difference (95% CI) *	
			6 Months	12 Months	6 Months	12 Months
HbA1c, mmol/mol (6%)	Active control	51 (11)	2 (-3 to 6)	2 (-3 to 7)	-1 (-5 to 2)	-2 (-8 to 4)
	MOTIVATE-T2D	50 (9)	-3 (7 to 1)	-1 (-5 to 4)		
					% change	
Weight, kg (5kg)	Active control	99.1 (23.6)	-2.9 (-4.4 to -1.4)	-2.7 (-4.2 to -1.2)	1.5 (-0.5 to 3.3)	1.2 (-0.9 to 3.3)
	MOTIVATE-T2D	98.0 (23.6)	-1.4 (-2.8 to 0.0)	-1.5 (-3.0 to -0.1)		
BMI, kg/m^2	Active control	34.9 (8.4	-1.1 (-1.6 to -0.6)	-1.0 (-1.5 to -0.5)	0.6 (-0.1 to 1.2)	0.4 (-0.3 to 1.1)
	MOTIVATE-T2D	33.3 (6.1)	-0.5 (-1.0 to 0.0)	-0.6 (-1.1 to -0.1)		
WC, cm	Active control	111 (17)	-5 (-6 to -3)	-4 (-6 to -2)	0 (-2 to 3)	0 (-3 to 2)
	MOTIVATE-T2D	111 (17)	-4 (-6 to -2)	-5 (-7 to -3)		
Systolic BP, mmHg (5 mmHg)	Active control	130 (15)	-1 (-5 to 2)	0 (-3 to 4)	1 (-2 to 3)	-4 (-8 to 1)
	MOTIVATE-T2D	127 (14)	-3 (-6 to 1)	-4 (-7 to 0)		
Diastolic BP, mmHg (2 mmHg)	Active control	82 (9)	-1 (-3 to 1)	-2 (-4 to 0)	0 (-2 to 3)	0 (-3 to 3)
	MOTIVATE-T2D	81 (9)	-1 (-3 to 1)	-2 (-4 to 0)		
	Active control	98 (10)	-1 (-3 to 1)	-1 (-3 to 1)	0 (-2 to 3)	-1 (-4 to 2)

MAP, mmHg (2 mmHg)	MOTIVATE-T2D	97 (10)	-1 (-3 to 1)	-2 (-4 to 0)		
Total Chol, mmol/L (0.3 mmol/L)	Active control	5.3 (1.5)	-0.2 (-0.5 to 0.1)	0.0 (-0.3 to 0.4)	0.1 (-0.3 to 0.5)	-0.3 (-0.7 to 0.1)
	MOTIVATE-T2D	5.4 (1.3)	-0.1 (-0.5 to 0.2)	-0.3 (-0.6 to 0.0)		
HDL Chol, mmol/L (0.1 mmol/L)	Active control	1.2 (0.3)	0.0 (0.0 to 0.1)	0.0 (0.0 to 0.1)	0.0 (-0.1 to 0.1)	0.0 (-0.1 to 0.1)
	MOTIVATE-T2D	1.1 (0.3)	0.1 (0.0 to 0.1)	0.1 (0.0 to 0.1)		
LDL Chol, mmol/L (3%)	Active control	3.2 (1.3)	-6 (-15 to 4)	1 (-9 to 13)	4 (-9 to 19)	-10 (-21 to 4)
	MOTIVATE-T2D	3.3 (1.2)	-2 (-11 to 8)	-8 (-17 to 1)		
					% change [a]	
Triglycerides, mmol/L (5%)	Active control	2.0 (0.9)	-6 (-19 to 9)	0 (-15 to 16)	-1 (-18 to 21)	-4 (-21 to 18)
	MOTIVATE-T2D	2.4 (1.8)	-7 (-20 to 8)	-4 (-17 to 11)		
					% change [a]	
CGM TIR, % (3%)	Active control	81 (26)	-1 (-9 to 6)	-5 (-13 to 4)	3 (-7 to 12)	6 (-5 to 16)
	MOTIVATE-T2D	82 (26)	1 (-6 to 8)	1 (-6 to 8)		
CGM TBR, %	Active control	4 (8)	1 (0 to 3)	1 (0 to 2)	1 (0 to 4)	3 (1 to 14)
	MOTIVATE-T2D	4 (8)	1 (0 to 3)	2 (1 to 7)		
					odds ratios [b]	
CGM TAR, %	Active control	16 (26)	4 (-3 to 11)	8 (0 to 16)	-6 (-15 to 3)	-6 (-16 to 4)
	MOTIVATE-T2D	14 (27)	-2 (-8 to 5)	2 (-5 to 9)		

CGM CV, %	Active control	24 (5)	-2 (-3 to 0)	-1 (-2 to 1)	-1 (-2 to 3)	0 (-2 to 2)
	MOTIVATE-T2D	23 (6)	0 (-1 to 1)	-1 (-2 to 1)		
Mean Glucose, mmol/L	Active control	7 (3)	6 (-1 to 14)	9 (1 to 19)	-6 (-15 to 3)	-1 (-11 to 9)
	MOTIVATE-T2D	7 (3)	0 (-7 to 6)	8 (1 to 16)		
				% change[a]		
Total PA, min	Active control	1484 (574)	0 (-196 to 203)	196 (7 to 385)	-28 (-197 to 231)	-105 (-343 to 126)
	MOTIVATE-T2D	1393 (490)	-28 (-217 to 161)	91 (-84 to 259)		
MVPA, min	Active control	504 (273)	56 (-21 to 126)	56 (-14 to 126)	-21 (-112 to 77)	-21 (-112 to 70)
	MOTIVATE-T2D	427 (203)	35 (-35 to 105	35 (-28 to 98)		
MVPA10+, min	Active control	105 (168)	7 (-35 to 49)	-14 (-56 to 28)	35 (-21 to 91)	14 (-35 to 63)
	MOTIVATE-T2D	49 (77)	42 (0 to 77)	0 (-35 to 35)		

WC, waist circumference; BP, blood pressure; MAP, mean arterial pressure; Chol, cholesterol; HDL, high density lipoprotein; LDL, low density lipoprotein; CGM, continuous glucose monitor; TIR, time in range (3.9-10mmol/L); TBR, time below range (<3.9mmol/L); TAR, time above range (>10.0mmol/L); CV, coefficient of variation; PA, physical activity; MVPA, moderate-to-vigorous intensity PA; MVPA10+, MVPA accumulated in bout ≥10 minutes. All PA data is ≥4 days wear time, including ≥3 weekdays and ≥1 weekend day for ≥16h wear time. All CGM data is from 14-day wear time. * Within- and between-group differences adjusted for study site (UK or Canada), sex (male or female) and age (40-60 or 61-75 years). [a] Log-transformed, interpret effect estimates as percent change. [b] Data were analysed using mixed effects binomial regression, interpret effect estimates as odds ratios. Where possible minimal clinically important differences (MCID) have been included; HbA1c 3 mmol/mol (37, 38) which is equivalent to a 6% change from baseline in this study, weight 5% change from baseline (39) which is equivalent to 5kg in this study, systolic BP 5mmHg (40), diastolic BP 2mmHg (41), MAP 2mmHg (41), Chol 5% change from baseline (39) which is equivalent to 0.3 mmol/L, HDL Chol 0.1 mmol/L (39), LDL Chol 0.1 mmol/L (39) which is equivalent to 3% change from baseline in this study, triglycerides 5% change from baseline (39) and TIR 3% change from baseline (32).

Table 4. Baseline and within- and between-group differences at 6 and 12 months follow-up; Questionnaires

Outcome (MCID)		Baseline, Mean (SD)	Within group difference (95% CI)*		Between group difference (95% CI) *	
			6 Months	12 Months	6 Months	12 Months
EQ-5D-5L (0.03 to 0.05)	Active control	0.84 (0.17)	0.02 (-0.01 to 0.05)	-0.01 (-0.04 to 0.02)	0.02 (-0.04 to 0.03	0.01 (-0.03 to 0.05)
	MOTIVATE-T2D	0.83 (0.14)	0.01 (-0.01 to 0.04)	0.00 (-0.03 to 0.02)		
SF12						
Physical Outcome (3 to 5)	Active control	46 (9)	0 (-3 to 2)	-1 (-3 to 1)	0 (-3 to 3)	0 (-4 to 3)
	MOTIVATE-T2D	46 (10)	0 (-2 to 2)	-1 (-3 to 1)		
Mental (3 to 5)	Active control	49 (9)	2 (-1 to 5)	-1 (-4 to 3)	-2 (-6 to 2)	4 (0 to 8)
	MOTIVATE-T2D	46 (12)	0 (-2 to 3)	3 (0 to 6)		
DTSQs						
Derived Overall Score	Active control	23 (8)	4 (2 to 6)	3 (1 to 5)	1 (-2 to 4)	-1 (-4 to 2)
	MOTIVATE-T2D	21 (8)	5 (3 to 7)	2 (0 to 4)		
	Active control	3 (2)	0 (-1 to 0)	0 (-1 to 0)	0 (-1 to 0)	0 (-1 to 1)

Burden of Hyperglycaemia	MOTIVATE-T2D	2 (2)	-1 (-1 to 0)	0 (-1 to 0)		
	Active control	1 (1)	0 (0 to 0)	0 (-1 to 0)		
Burden of Hypoglycaemia	MOTIVATE-T2D	1 (1)	0 (-1 to 0)	0 (0 to 0)	0 (-1 to 0)	0 (0 to 1)
DTSQc [a]						
Derived Overall Score	Active control		9 (6)			
	MOTIVATE-T2D		0 (6)			
Burden of Hyperglycaemia	Active control		-0 (1)			
	MOTIVATE-T2D		-0 (1)			
Burden of Hypoglycaemia	Active control		-1 (1)			
	MOTIVATE-T2D		-1 (1)			

SF12, SF-12 Health Survey; DTSQs, Diabetes Treatment Satisfaction Questionnaire status version, DTSQc, Diabetes Treatment Satisfaction Questionnaire change version. The DTSQc was conducted at 6 month follow-up only and data presented are mean and SD for this time point. * Within and between-group differences adjusted for centre (UK or Canada), sex (male or female) and age (40-60 or 61-75 years). Where possible minimal clinically important differences (MCID) have been included; EQ-5D-5L between 0.03 and 0.05 (42), SF-12 physical outcome component between 3 and 5 (43), SF-12 mental component between 3 and 5 (43)

Acceptability of the MOTIVATE-T2D intervention

Qualitative interviews indicated high levels of satisfaction and acceptability of the MOTIVATE-T2D intervention in people with recently diagnosed T2D (online supplementary eTable 9). Highly valued elements of MOTIVATE-T2D included the role of the exercise specialist, where the counselling sessions and regular text messages were seen as a source of support and reassurance. The flexibility of the PA and exercise programme was also found to promote autonomy. Finally, the ability to track and monitor behaviour through the technology was viewed as an enabler. However, participants cited technical aspects of the watch and app as a challenge, highlighting the need for additional resources/training in the future.

Adherence: Participants in the MOTIVATE-T2D group exercised, measured via optical HR monitor, more regularly than active control during the 6 month intervention period and the 6 to 12 month follow-up (Table 5). The odds ratio (OR) of participants starting training (completed ≥1 training session) was more than 10 times higher for MOTIVATE-T2D compared to active control (OR 10.4, CI 3.4 to 32.1; MOTIVATE-T2D 93% started training, active control 58% started training). At 6 and 12 months the OR for participants still exercising were 7 (OR 7.1, CI 3.2 to 15.7; MOTIVATE-T2D 79% still training, active control 34% still training) and 3 (OR 2.9, CI 1.2 to 7.4; MOTIVATE-T2D 30% still training, active control 13% still training) times higher for MOTIVATE-T2D compared to active control, respectively (Figure 2a). At the end of the 6 month intervention period (weeks 24-28), 52% of MOTIVATE-T2D participants completed >150 minutes of MVE per week at least once compared to 17% in active control (Figure 2b). At the end of the 12 month follow-up period (weeks 48-52), this proportion dropped to 28% of MOTIVATE-T2D participants compared to 11% in the active control (Figure 2c).

Table 5. Device-derived exercise behaviour during the 6 month intervention period and 6 to 12 month follow-up

	0-6 Months mean (SD)	6-12 Months mean (SD)	Total mean (SD)
Number of exercise sessions (n)			

Active control	1.3±1.8	0.5±1.1	0.9±1.4
MOTIVATE-T2D	3.2±2.8	1.5±2.4	2.4±2.5
Adherence to prescribed exercise (% of 78 sessions)			
Active control	47±30	-	-
MOTIVATE-T2D	83±78	-	-
Duration (min)			
Active control	77±118	30±74	54±88
MOTIVATE-T2D	182±180	88±118	135±130
Duration MVE (min)			
Active control	78±112	31±75	54±88
MOTIVATE-T2D h	185±153	88±132	137±133

MVE, moderate to vigorous intensity exercise; when calculating MVE, vigorous intensity exercise was multiplied by two.

At 12 months, 58% of participants wore the accelerometer for 16 hours on 4 or more days, including one weekend day, and 71% wore the device for at least 16 hrs on 1 day (online supplementary eTable 10). Wear time tended to be higher in MOTIVATE-T2D compared to the active control, and in participants recruited in the UK (online supplementary eTable 12). At 6 and 12 months, within and between group (Table 3) differences in PA outcomes were highly variable but there was no evidence of compensatory reduction in lifestyle PA alongside increases in purposeful exercise in either group. There was evidence that wear time may have influenced between group differences at follow-up (online supplementary eTable 15-16).

Fidelity: Attendance at exercise counselling meetings was high (>80%) with little difference between groups (online supplementary eTable 19). Participant interaction with their counsellor by text message was higher in MOTIVATE-T2D (mean number of texts sent by participants (49±38) than active control (18±14). Active control participants interacted more with the exercise videos (total video views; MOTIVATE-T2D 101, active control 135).

Data Availability

Data on likely primary outcomes, HbA1c and systolic blood pressure, were available from 95%, 78% and 74%, and 97%, 71% and 63% of participants at baseline, 6 and 12 months, respectively (online supplementary eTable 10). Availability of data for HbA1c appeared to be influenced by country, with data available from 81% of participants in the UK and 67% of participants in Canada at 12 months. Data availability for secondary outcomes ranged from 58-74% at 12 months (online supplementary eTable 10-11). Wear time criteria influenced data availability for CGM with data availability at 12 months ranging from 58%-69% (online supplementary eTable 10). Wear time tended to be higher in MOTIVATE-T2D compared to the active control. However, wear time did not seem to influence baseline data or between-group differences (online supplementary eTable 17-18). Study site also appeared to influence data availability, with UK participants having higher availability of blood lipids and questionnaires, but worse availability of CGM (online supplementary Table e12-14).

Preliminary outcomes

Baseline and within and between group differences in exploratory clinical outcomes are shown in Table 3-4. Confidence intervals and MCIDs, displayed in Tables 3-4, suggest plausible evidence of effect in favour of MOTIVATE-T2D for our likely primary outcomes HbA1c at 6 months and systolic blood pressure at 12 months, and other secondary outcomes at 6 and 12 months, including total cholesterol, LDL cholesterol, glucose time in range and quality of life indicated by the SF-12 mental component score (Figure 3).

At 6 months, changes to glucose lowering medication were seen in 10 active control participants (1 stopped a medication, 1 started a new medication, 5 decreased dose and 3 increased dose) and 13 MOTIVATE-T2D (3 stopped a medication, 1 started a new medication, 4 decreased dose and 5 increased dose) participants. At 12 months, medication changes were seen in 12 active control (2 started a new medication, 4 decreased dose and 6 increased dose) and 12 MOTIVATE-T2D (2 started a new medication, 3 decreased dose and 7 increased dose) participants. Medication changes were more common in Canadian participants (Canada 29 (46%); UK 10 (16%)).

At 6 months, four participants (UK 2; Canada 2) experienced a serious adverse event, with none of these considered related to the study processes or interventions. No serious adverse events were reported at 12 months.

Healthcare utilisation and intervention costs

The average cost of the interventions per participant was estimated to be MOTIVATE-T2D £321.32/ $532.17 and active control £128.99/ $169.37, based on delivery of the interventions to 100 people (online supplementary eTable 20 for cost breakdown). The wider healthcare and societal utilisation for MOTIVATE-T2D and active control groups are summarised in online supplementary eTable 21.

DISCUSSION

The findings of this trial support the acceptability of the MOTIVATE-T2D intervention and indicate that it is feasible to recruit and retain newly diagnosed people with T2D in a randomised trial with a 12 month follow-up. MOTIVATE-T2D was well received by participants and intervention adherence was excellent. There was evidence of higher engagement in purposeful exercise compared to the active control group and no apparent evidence of compensatory reductions in lifestyle PA. At follow-up, compared with active control, several outcomes showed a potential direction of effect in favour of MOTIVATE-T2D, including our proposed primary outcomes of HbA1c and systolic blood pressure.

The achieved recruitment and retention rates exceeded the predetermined progression criteria for the trial, with 93% of eligible people approached being randomised (criterion: >20%) and 82% of participants retained at 12 months (criterion: >80%) (24). This recruitment rate compares well with the Early-ACTID trial, where 98% of eligible patients with newly diagnosed T2D (5- to 8-months since diagnosis) were randomised to receive usual care or lifestyle advice (14). The retention rate also compares well with studies included in a systematic review of interventions using pedometers or accelerometers to promote PA in people with T2D (N=7 randomised trials, mean 78%, range 63%-98%) (13).

The results from this trial suggest the MOTIVATE-T2D approach of using biometrics from wearable technologies to support a home-delivered, personalised behavioural counselling service was promising for the promotion, uptake and adherence to purposeful exercise in people with newly diagnosed T2D. The device-derived measurements of purposeful exercise demonstrated that MOTIVATE-T2D participants were more likely to start an exercise programme and mean weekly exercise duration was greater. Importantly, 1 in 2 MOTIVATE participants achieved the recommended 150 minutes of moderate-to-vigorous intensity exercise during the final month of the supported programme, compared to only 1 in 6 in the active control group. This was achieved despite both groups receiving similar support from an exercise specialist to co-design the personalised programme. It is difficult to compare the current data with previous trials where purposeful exercise has been performed unsupervised in people with T2D, as adherence data is rarely collected throughout interventions, and existing evidence has employed a variety of measurement methods (4, 10). However, adherence, assessed as prescribed sessions attended (MOTIVATE-T2D 78%), was comparable to data reported in a systematic review of supervised exercise interventions in people with T2D (18 trials, n=523, adherence: 87±8%) (4). A comparable intervention commissioned by health services globally, where adherence data is available, could be cardiac rehabilitation which uses a combination of supervised and unsupervised purposeful exercise to promote secondary prevention in people who have had an acute coronary event or heart failure. Adherence to MOTIVATE-T2D compares favourably to a meta-analysis (14 trials, n=8176) of cardiac rehabilitation programmes, where mean adherence (prescribed sessions attended) was 67±18.2% (44).

During the follow-up period (6 to 12 months), participants in MOTIVATE-T2D had 3 times higher odds of still completing purposeful exercise versus those in the active control. However, there was a noticeable reduction in engagement with purposeful exercise during this unsupported phase following either intervention. Again, it is difficult to compare this to previous studies because of a lack of objective data on maintenance of purposeful exercise in unsupervised trials. However, studies measuring PA have shown that maintaining behaviour change after the conclusion of an intervention is challenging (45). Data from our qualitative evaluation suggest extending the text message feedback period may be a simple and cost-effective way

of supporting participants maintain changes in behaviour. As such, future iterations of the intervention should explore the feasibility and cost implications of such a refinement. Future iterations could also look to introduce more social interactions to the intervention, as social connectedness has been shown to be an important determinant of long-term adherence (46, 47). Such interactions were difficult to incorporate into the current trial due to COVID-19 restrictions and small numbers limiting the use of online forums.

As per the study design, the active control group also completed a complex intervention containing a range of behaviour change techniques that have previously been associated with effective PA interventions, including goal setting, action planning, implementing graded tasks and self-monitoring of behaviour (48-52). However, our findings suggest the addition of biofeedback to support a complex behavioural intervention was an effective strategy to partner with behaviour change. In particular, the provision of HR monitoring to guide participants' purposeful exercise in real time and facilitate personalised feedback from exercise specialists appeared to be an important strategy within the MOTIVATE-T2D intervention. Potential mechanisms of action used throughout the MOTIVATE-T2D intervention will be explored more in a complementary paper.

Alongside measurement of purposeful exercise, lifestyle PA was assessed by accelerometer. This combined measurement strategy reflected the two step intervention approach where engagement in purposeful exercise was encouraged alongside unstructured lifestyle-based PA. It was difficult to draw conclusions from the PA data due to the small sample size and large variability. However, increased engagement in purposeful exercise did not seem to lead to a compensatory reduction in lifestyle based PA, which has previously been cited as a concern during supervised exercise interventions (53, 54). The difficulty interpreting the PA data potentially reflects the challenges of using accelerometers to assess an intervention which encourages participation in purposeful exercise alongside ambulatory PA. Both the active control and MOTIVATE-T2D interventions encouraged participants to take part in types/modes of exercise whose intensity may not have been accurately captured by the accelerometer (e.g., cycling or resistance exercise) (19, 53). Future studies could look to include cardiorespiratory fitness as an index of intervention effectiveness

alongside lifestyle-based PA and engagement in purposeful exercise. Sustained increases in cardiorespiratory fitness following The Italian Diabetes Exercise Study 2, which targeted reallocation of sedentary time with light-intensity activity and purposeful MVPA in people with T2D, was predictive of improvements in HbA1c and coronary heart disease risk, independent of changes in MVPA or sedentary time (55).

Due to the association of HbA1c and systolic blood pressure with diabetes complications and mortality (56-58), the goal for clinical management of T2D is to achieve and maintain tight control of HbA1c and systolic blood pressure (59). Therefore, HbA1c and systolic blood pressure are likely to be primary outcomes in a future RCT. Lee et al. (35) and Bell et al. (34) suggest using confidence intervals and the MCID to interpret feasibility trials. Using this approach there was evidence that a clinically important difference in HbA1c at 6 months and systolic blood pressure at 12 months between MOTIVATE-T2D and active control was plausible. Studies report a 5 mmHg reduction in systolic blood pressure as the MCID (40), and the 95% confidence intervals for systolic blood pressure in this study included 5 mmHg. Studies also suggest a difference of 3 mmol/mol would represent a clinically important difference in HbA1c (37, 38), and the -5% between-group difference at 6 months is equivalent to ~3 mmol/mol. However, the between group difference for HbA1c was not maintained at 12 months. As discussed above, future iterations of the intervention should look to improve maintenance of purposeful exercise with the aim of sustaining long term improvements in HbA1c. It is difficult to compare the between-group differences in HbA1c and systolic blood pressure to previous research as most RCTs use usual care control groups rather than the contact-matched active control group in the current study. However, a meta-analysis of unsupervised behavioural interventions suggested that they were not associated with changes in HbA1c unless combined with dietary advice (4). A similar meta-analysis of unsupervised behavioural interventions in people with T2D on systolic blood pressure suggested a small (weighted mean difference 3 mmHg, 95% CI −5 to −1) but significant effect (60). As well as the encouraging data for HbA1c and systolic blood pressure, there was evidence that a clinically important difference may be plausible for a number of secondary outcomes, including total cholesterol and LDL cholesterol at 12 months (39) and quality of life at 12 months, indicated by the SF-12 mental component score (43). The UK prospective diabetes study showed the importance of dyslipidaemia for CVD risk in people with T2D (61).

As such, potential improvements in these secondary outcomes are highly relevant for people with T2D. As discussed above, the active control group received a complex intervention and it is plausible that between-group differences would have been larger if compared to a usual care control group, increasing the likelihood of clinically important effects in the real-world.

Implications for planning a future trial

Based on HbA1c as the primary outcome, a full trial comparing MOTIVATE-T2D versus active control would require recruitment of 586 participants with recently diagnosed T2D. This estimate is based on detecting a minimum clinically important difference of 3 mmol/mol (37, 38), a standard deviation at baseline of 10 mmol/mol (as seen in this feasibility trial), and an assumed attrition rate of 20% (as seen in this feasibility trial), at 90% power and a two-tailed 5% α level.

Due to restrictions and uncertainties caused by the COVID-19 pandemic, the trial used a decentralised design. Our experience was that the decentralised design could positively impact trial feasibility, as recruitment was not limited by geographic constraints. As suggested previously (62), the decentralised design may also have provided opportunity for greater diversity in our trial population. Compared to Early-ACTID, which also recruited people with newly diagnosed T2D in the UK, the current trial recruited a more ethnically diverse population (14). Participant interviews suggested the decentralised approach was broadly acceptable, although future iterations may need to consider how participants are supported with taking blood samples. Considerations should also be made for differences between the UK and Canada in research infrastructure. During study planning, there were no services that could process capillary blood samples in Canada. This led to the approach of shipping samples to the UK for analysis. We believe this additional step may have been responsible for the reduced HbA1c and blood lipid data availability in Canada. Although data availability for outcome measures was good, the centralised Early-ACTID trial collected primary outcome data (HbA1c) from 98% of participants at 12 months. Simple refinements to the study procedures could be made to collect more complete and meaningful data. This could be achieved by providing greater financial incentives (63). Changes to survey formatting and better use of data validation filters to reduce incorrectly entered measures, which accounted for approximately 1/3 of

missing questionnaire and anthropometric data. Finally, use of next generation PA monitors that collect accelerometer data in real-time could increase compliance with wear time criteria (64).

This study has some limitations. First, the study was not designed or powered to definitively assess the efficacy of MOTIVATE-T2D in people with recently diagnosed T2D. Secondly, there was evidence of imbalances between intervention and active control groups in their demographic characteristics. Thirdly, participant and researcher blinding were not possible because of the nature of the intervention. Fourthly, it is not known if active control participants wore the blinded HR monitor for all purposeful exercise sessions. Therefore, device-derived purposeful exercise metrics may be underestimated in the active control group. Finally, the study did not employ a strict target driven approach to the regulation of glucose lowering medication which may have influenced outcomes (65). Given these limitations and the feasibility design of this trial, our findings should be considered preliminary, and encouraging trends require confirmation in a larger, adequately powered RCT.

In summary, the findings of this feasibility trial indicate the MOTIVATE-T2D intervention is feasible and acceptable with promising effects on adherence to purposeful exercise. This feasibility study will inform the funding application for a fully powered RCT to assess the clinical effectiveness and cost-effectiveness of the MOTIVATE-T2D intervention in people with recently diagnosed T2D.

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Contributors

KH, JL, RCA, CAJ, HJ, MEJ JPL, CM, RMP, JS, VSS, AMM and MC designed the protocol. RCA, CAJ, HJ, MEJ JPL, CM, JS, VSS, AMM and MC developed the original idea for the trial. KH, JL, BJRB, and SP acquired the data. KH, JL, SB, KF, JJ, MEJ,

CM, SP, RMP, CLR, JS and MC analysed the data. KH, JL and MC undertook the first draft of the manuscript. All authors were involved in critical evaluation and revision of the manuscript and have given final approval of the manuscript accepting responsibility for all aspects.

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Competing interests

The authors have no competing interests.

Patient consent for publication

Not required

Data availability statement

Data are available on reasonable request. Access to data can be arranged through the principal investigator of the study: Dr Matt Cocks to discuss data sharing, data requirements and conflicts of interest, in line with any EU and other regulations, including ethics approvals.

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FIGURE LEGENDS

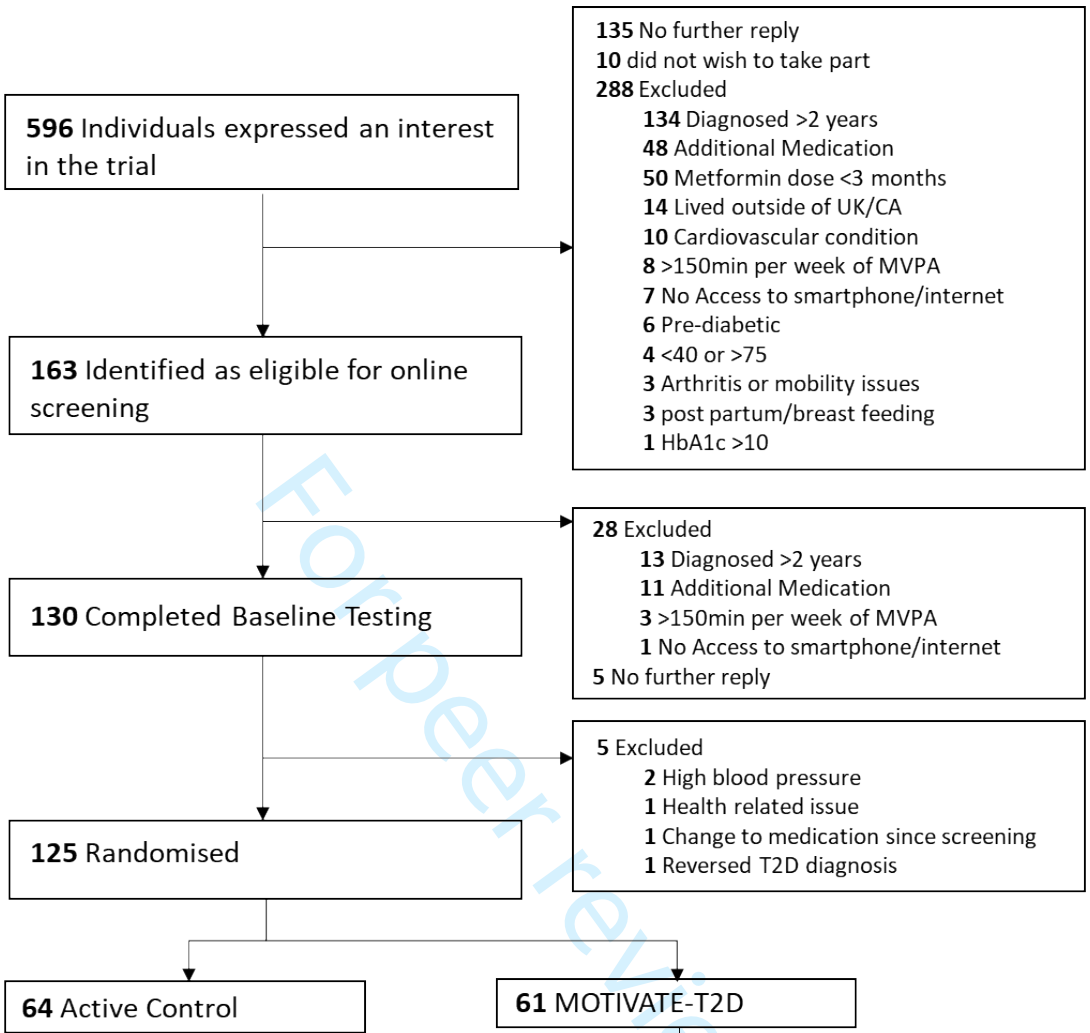
Figure 1. Consolidated Standards of Reporting Trials (CONSORT) flow chart.

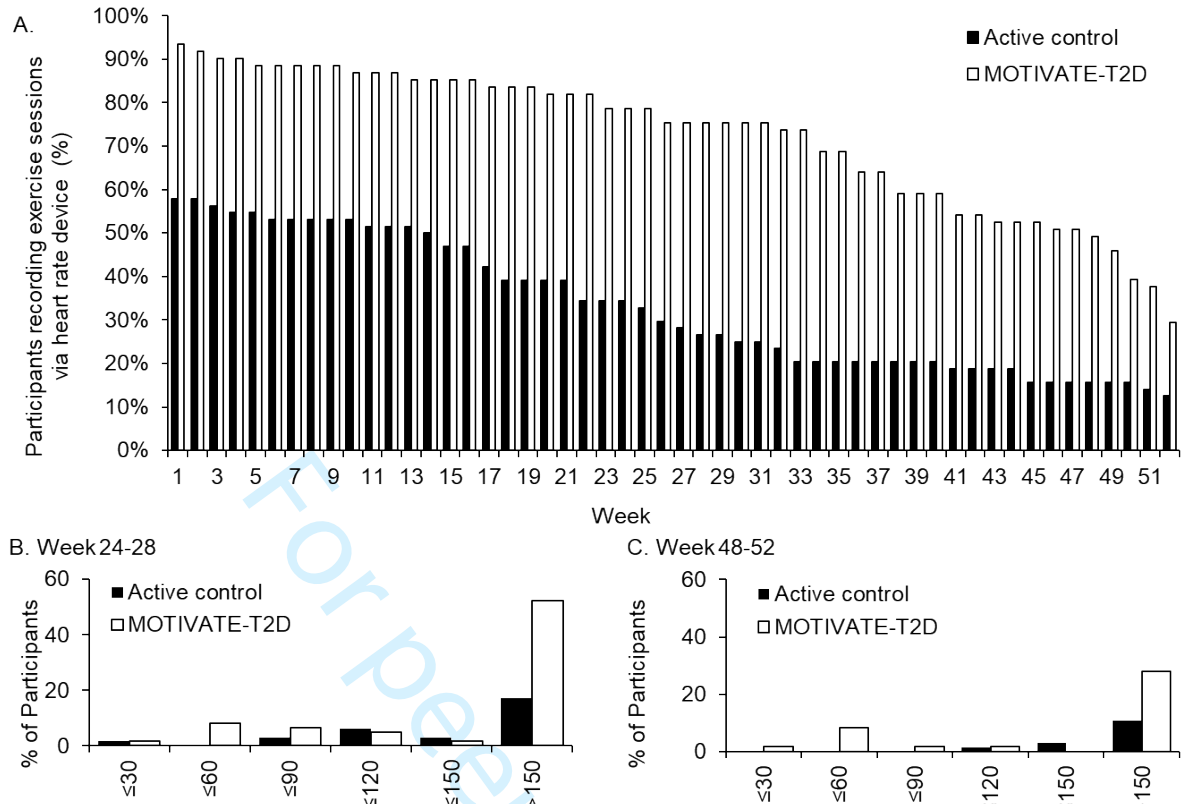
Figure 2. Exercise behaviour derived from optical heart rate monitoring

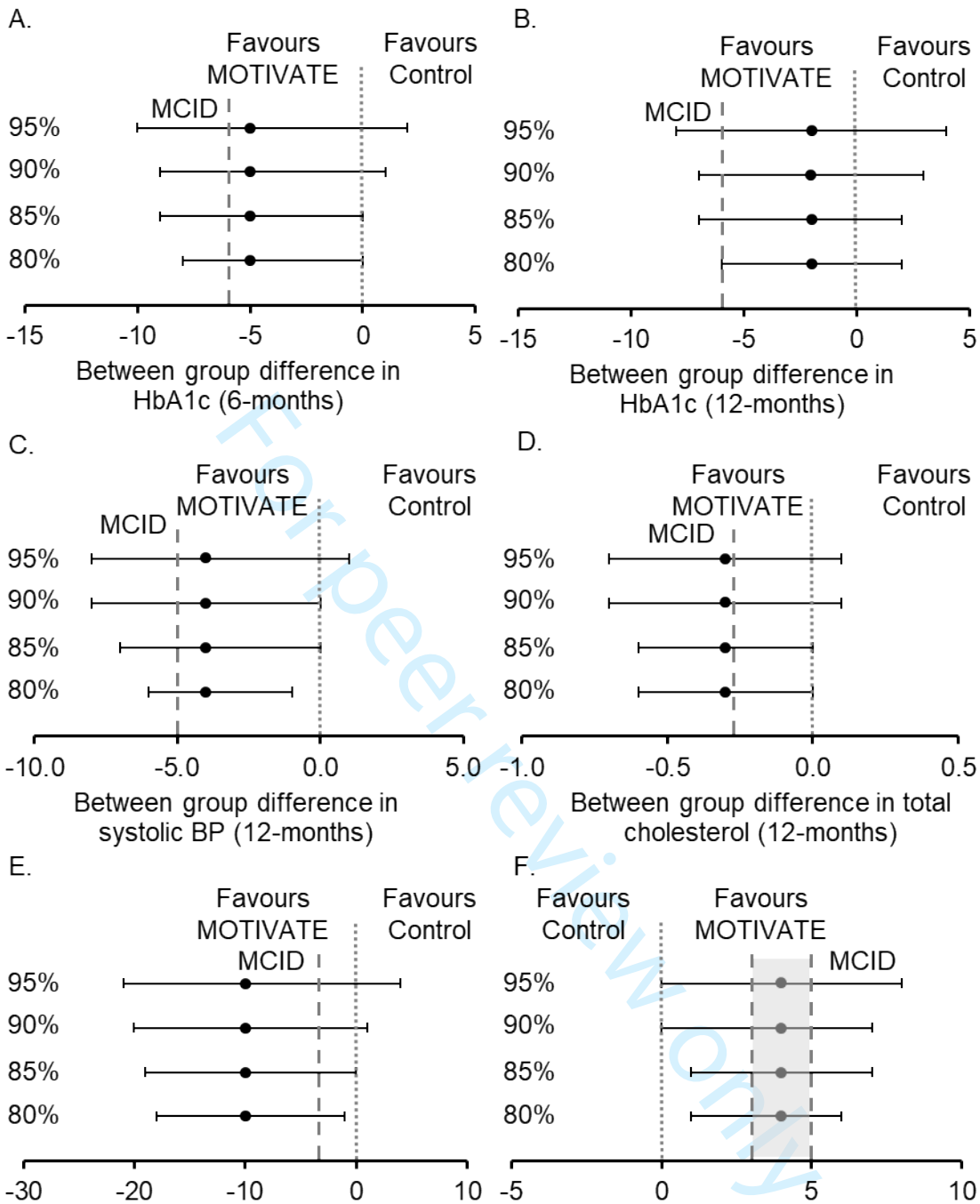
A. Training drop-off by week in MOTIVATE-T2D and active control participants. B. proportion of participants achieving MVE duration at least once during weeks 24-28. B. proportion of participants achieving MVE duration at least once during weeks 48-52. MVE, moderate to vigorous intensity exercise; when calculating MVE, vigorous intensity exercise was multiplied by two.

Figure 3. Between-group differences in outcome measures with confidence intervals

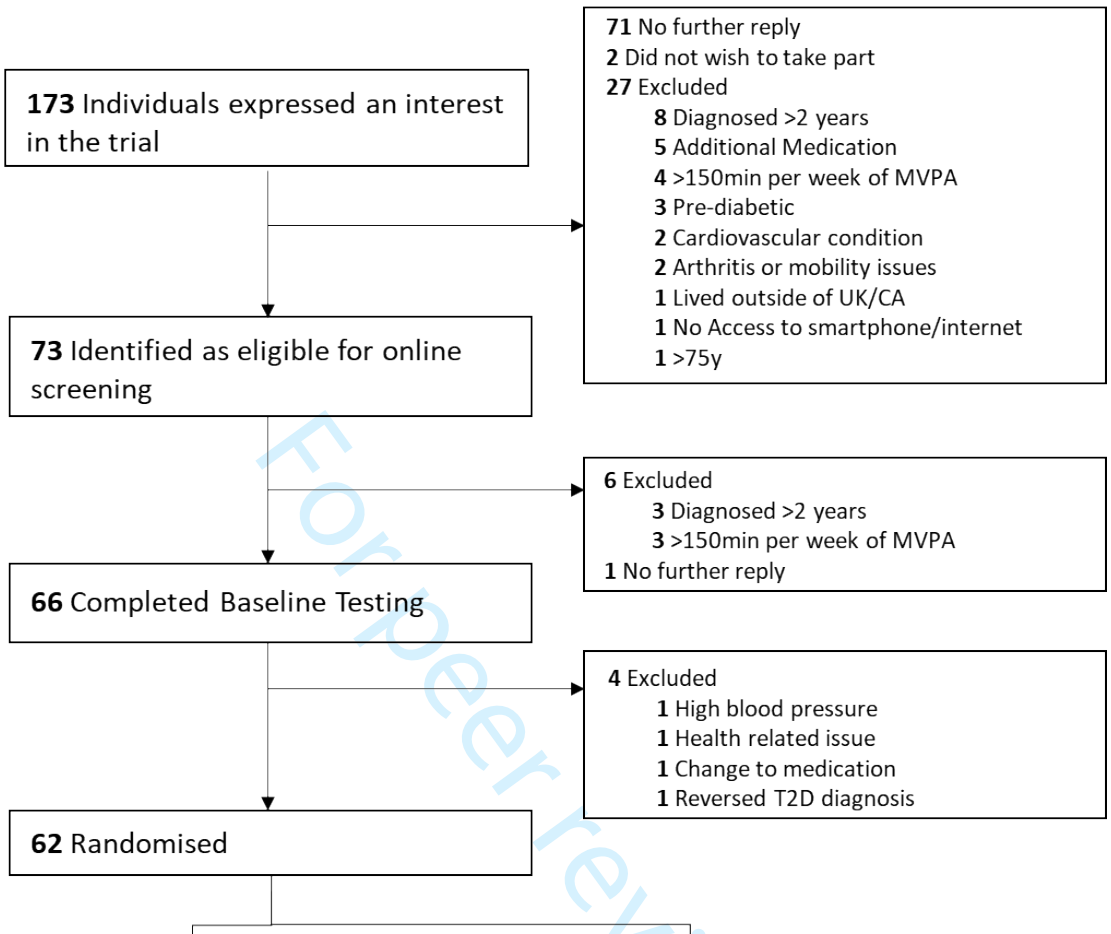
Confidence intervals presented 95%, 90%, 85% and 80%. Minimal clinically important differences (MCID), indicated by – – . A. between-group differences in HbA1c at 6 months, MCID 3 mmol/mol (37, 38) which is equivalent to a 6% change from baseline in this study. B. between-group differences in HbA1c at 12 months, MCID 3 mmol/mol (37, 38) which is equivalent to a 6% change from baseline in this study. C. between-group differences in systolic blood pressure (BP) at 12 months, MCID 5 mmHg (40). D. between-group differences in total cholesterol at 12 months, MCID 5% reduction (39). E. between-group differences in low-density-lipoprotein (LDL) cholesterol at 12 months, MCID 0.1 mmol/L (39). F. between-group differences in the 12-item short form Health Survey (SF-12) mental health component score at 12 months, MCID between 3 and 5 (43).



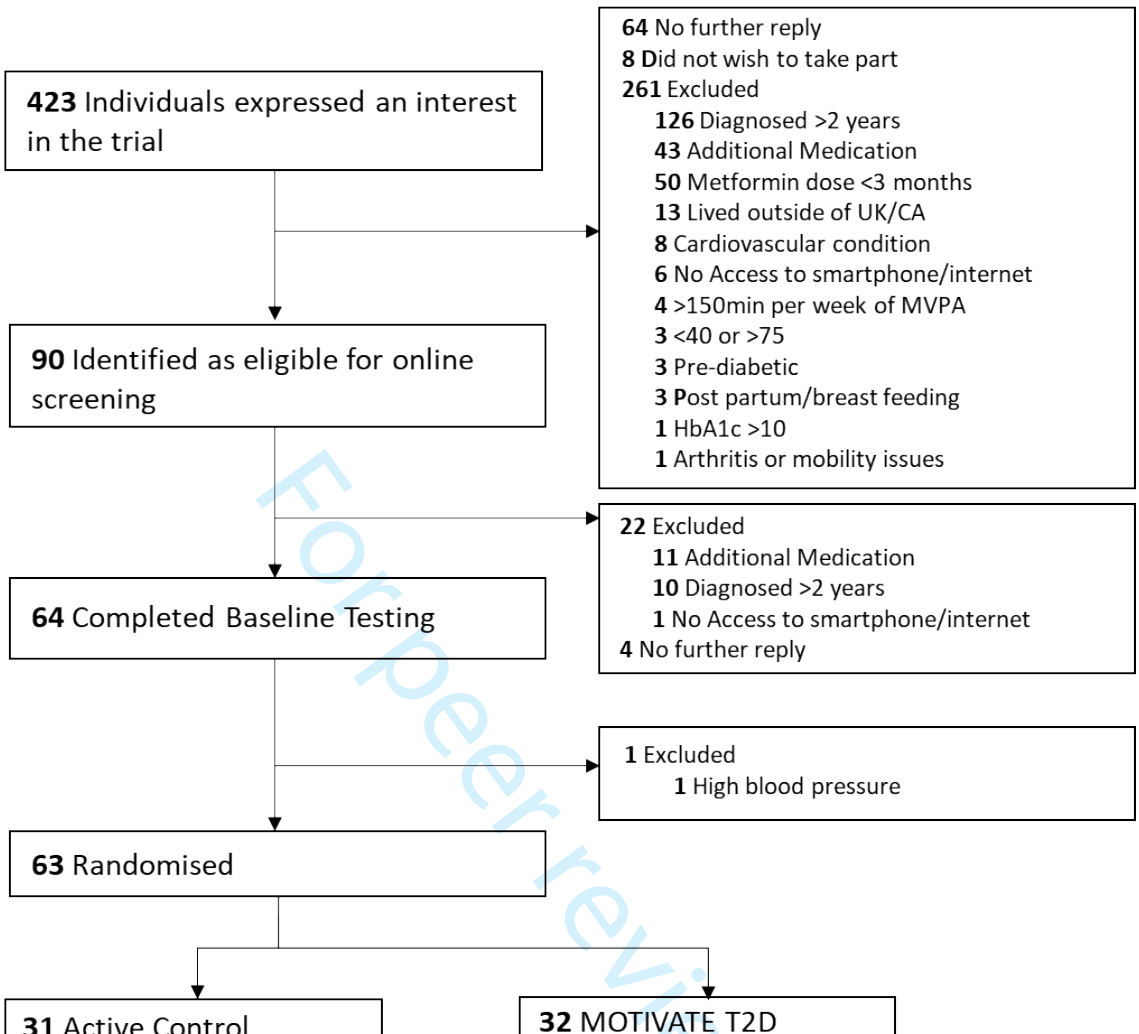




Online supplementary eFigures and eTables



eFigure 1. UK only Consolidated Standards of Reporting Trials (CONSORT) flow chart.



eFigure 2. Canada only Consolidated Standards of Reporting Trials (CONSORT) flow chart.

eTable 1. Influence of recruitment strategy on expressions of interest, participants randomised and recruitment rate

Recruitment strategy	Expressions of interest, N (% of expressions of interest n=596)	Excluded, N (% of expression of interest for strategy)	Did not reply, N (% of expression of interest for strategy)	Randomised, N (% of those randomised n=125)	Success rate, % of expression of interest for strategy randomised
GP database searches	94 (16)	13 (14)	37 (39)	44 (35)	47
Third party recruitment Services	326 (55)	239 (73)	49 (15)	38 (30)	11
Local media articles/ classifieds	83 (14)	54 (65)	18 (22)	11 (9)	13
Diabetes education sessions	10 (2)	0 (0)	0 (0)	10 (8)	100
Referral from Friend	12 (2)	2 (17)	0 (0)	10 (8)	83
Adverts in clinical settings	24 (4)	15 (63)	3 (2)	6 (5)	25
Consent to Contact Database	9 (2)	0 (0)	4 (44)	5 (4)	56
Study Website	10 (2)	7 (70)	2 (20)	1 (1)	10
Unknown	15 (3)	0 (0)	15 (100)	0 (0)	0
Advert on Diabetes Canada social media	13 (2)	0 (0)	12 (100)	1 (1)	8

eTable 2. Influence of recruitment source on participant demographics

Recruitment strategy, N= participants recruited	Male, N (%)	>60, N (%)	White, N (%)	University education, N (%)	Full time employment, N (%)
GP database searches, N=44	23 (52)	15 (34)	40 (91)	17 (17)	26 (59)
Third party recruitment Services, N=37	22 (59)	9 (24)	25 (68)	19 (51)	26 (70)
Local media articles, N=11	6 (55)	8 (73)	11 (100)	5 (45)	4 (36)
Diabetes education sessions, N=10	7 (70)	1 (10)	8 (80)	4 (40)	5 (50)
Referral from Friend, N=10	4 (40)	2 (20)	7 (70)	3 (30)	6 (60)
Adverts in clinical settings, N=6	1 (17)	1 (17)	3 (50)	5 (83)	3 (50)
Consent to Contact Database, N=5	2 (40)	1 (20)	5 (100)	2 (40)	3 (60)
Study Website, N=1	0	0	1 (100)	1 (100)	1 (100)
Advert on Diabetes Canada social media, N=1	0	0	1 (100)	0	1 (100)

eTable 3. Participant satisfaction with their involvement in the trial

The following are verbatim quotes regarding the research process:
The way it works is pretty good, the technology side of it, Zoom / Teams…it works very well so the communication side is good." (Participant 17-UK)
[If the trial were to be repeated in a clinic setting] "for me personally I would find that hard to get to because I don't drive now so this part of it being able to do in your own home I think is really good." (Participant 20-UK)
"All the instructions were clear, the feedback I had to give on my results, what I had to do with the equipment, returning and stuff, it was adequate really, more than adequate." "it was all prepaid envelope, I just took it to the main post office sealed, sent off, no problem, we have a post office very close by so that was just a little job while you're out shopping." (Participant 52-UK)
"I don't know that I had many challenges, because it was provided in such a seamless, customized format, that there really, I wouldn't say I was challenged in any way." "it's been such a pleasant experience that I'm more willing to engage as a research participant again." (Participant 02-CA)
"I'm a bit pen and paper person rather than technology but I think everything was really well, really explained so well and so easy to follow and you had that back up, that support if you needed it." "the testing booklet, that was really, really helpful and [the researcher] also gave me a link to a website that actually showed like videos of how to do the finger prick test and also how to attach the blood glucose monitor…it was very easy to follow" (Participant 02-UK)
"everything was well laid out. I really liked the detail on the instructions on what to use and how to use it and I particularly thought it was a good personal touch that the actual research instigator was the guinea pig so to speak with all the pictures so yeah it's a personal touch but also it kind of entrusts you that they've gone through it, they've had to endure it so yeah everything worked fine that side." (Participant 01-UK)
"I found that the questionnaires that I had to fill in irritating because they didn't see coherent, they weren't set out to say we're looking at this, tell us about that, they didn't ask questions which would allow me then to go on and make a sensible answer. I didn't find their terms particularly well." (Participant 27-UK)
"I'm not comfortable with needles. When I opened the box and saw that there was a needle in the middle, I started to panic, thinking that's going to hurt… I had to look at the video. I was a bit nervous, but the little needle didn't hurt at all"
"The amount of blood that they're looking for is significant from just a basically a finger prick, which is what the little device does. And it was hard to get. I never got enough blood into the vial."

eTable 4. Baseline medications

N (%)	Total	Active control	MOTIVATE-T2D
Oral hypoglycaemic agents			
Metformin	69 (55)	37 (58)	32 (52)
Antihypertensive agents	78 (62)	40 (63)	40 (62)
Renin-angiotensin agent	35 (28)	21 (33)	14 (23)
Thiazide diuretic	12 (10)	4 (6)	8 (13)
β blocker	11 (9)	5 (8)	6 (10)
Calcium-channel blocker	19 (15)	10 (16)	9 (15)
Other	1 (1)	0 (0)	1 (2)
Lipid-lowering drugs	50 (40)	25 (39)	25 (41)
Statin	49 (39)	24 (38)	25 (41)
Selective cholesterol-absorption inhibitor	1 (1)	1 (2)	0 (0)

eTable 5. Baseline demographic characteristics: UK

	Total	Active control	MOTIVATE-T2D
N	62	33	29
Age, years, mean (SD)	55 (9)	56 (9)	56 (8)
Female, N (%)	30 (48)	16 (48)	14 (48)
Male, N (%)	32 (52)	17 (52)	15 (52)
Duration of T2D, months, mean (SD)	13 (6)	12 (6)	12 (6)
Ethnicity, N (%)			
White	54 (87)	30 (91)	24 (83)
African or Caribbean	3 (5)	2 (6)	1 (3)
Asian	2 (3)	1 (3)	1 (3)
Other or mixed	3 (5)	0 (0)	3 (10)
Marital status, living arrangements, N (%)			
Married, living with spouse	41 (66)	20 (61)	21 (72)
Married, living arrangement unknown	1 (2)	0 (0)	1 (3)
Single, living alone	9 (15)	7 (21)	2 (7)
Single, living with others	2 (3)	2 (6)	0 (0)
Separated, living alone	5 (8)	2 (6)	3 (10)
Separated, living with spouse/partner	1 (2)	0 (0)	1 (3)
Widowed, living alone	2 (3)	1 (3)	1 (3)
Rather not say, living with spouse/ partner	1 (2)	1 (3)	0 (0)
Educational Attainment, N (%)			
Secondary	13 (21)	8 (24)	5 (17)
Further	24 (39)	9 (27)	15 (52)
Higher	25 (40)	16 (48)	9 (31)
Employment Situation, N (%)			
Full Time	33 (53)	16 (48)	17 (59)
Part Time	6(10)	3 (9)	3 (10)
Retired	11 (18)	7 (21)	4 (14)
Student	1 (2)	0 (0)	1 (3)
Volunteer	0 (0)	0 (0)	0 (0)
Stay at Home	1 (2)	1 (3)	0 (0)

Unable: Care	1 (2)	0 (0)	1 (3)
Unable: Health	8 (13)	5 (13)	3 (10)
Unemployed	1 (2)	1 (2)	0 (0)

eTable 6. Baseline medications: UK

N (%)	Total	Active control	MOTIVATE-T2D
Oral hypoglycaemic agents			
Metformin	26 (42)	17 (52)	9 (31)
Antihypertensive agents	50 (81)	29 (88)	21 (72)
Renin-angiotensin agent	23 (37)	16 (48)	7 (24)
Thiazide diuretic	5 (8)	2 (6)	3 (10)
β blocker	7 (11)	4 (12)	3 (10)
Calcium-channel blocker	14 (23)	7 (21)	7 (24)
Other	1 (2)	0 (0)	1 (3)
Lipid-lowering drugs	30 (48)	17 (52)	13 (45)
Statin	30 (48)	17 (52)	13 (45)
Selective cholesterol-absorption inhibitor	0 (0)	0 (0)	0 (0)

eTable 7. Baseline demographic characteristics: Canada

	Total	Active control	MOTIVATE-T2D
N	63	31	32
Age, years, mean (SD)	54 (9)	53 (8)	53 (9)
Female, N (%)	30 (48)	15 (48)	15 (47)
Male, N (%)	33 (53)	16 (52)	17 (53)
Duration of T2D, months, mean (SD)	14 (7)	14 (7)	14 (7)
Ethnicity, N (%)			
White	47 (76)	22 (71)	25 (78)
African or Caribbean	2 (3)	0 (0)	2 (6)
Asian	12 (23)	7 (23)	5 (16)
Other or mixed	2 (3)	2 (6)	0 (0)
Marital status, living arrangements, N (%)			
Married, living with spouse	49 (78)	24 (77)	25 (78)
Married, living alone	1 (2)	0 (0)	1 (3)
Single, living alone	6 (10)	3 (10)	3 (9)
Single, living with child	1 (2)	0 (0)	1 (3)
Single, living arrangement unknown	1 (2)	1 (3)	0 (0)
Separated, living alone	4 (6)	3 (10)	1 (3)
Widowed, living with spouse/partner	1 (2)	0 (0)	1 (3)
Educational Attainment, N (%)			
Secondary	6 (10)	3 (10)	3 (9)
Further	26 (41)	14 (45)	12 (38)
Higher	31 (49)	14 (45)	17 (53)
Employment Situation, N (%)			
Full Time	42 (68)	24 (73)	18 (62)
Part Time	5 (8)	1 (3)	4 (14)
Retired	10 (16)	4 (120	6 (21)
Student	1 (2)	1 (3)	0 (0)
Volunteer	2 (3)	1 (3)	1 (3)
Stay at Home	0 (0)	0 (0)	0 (0)
Unable: Care	0 (0)	0(0)	0 (0)
Unable: Health	1 (2)	0 (0)	1 (3)

Unemployed	2 (3)	0 (0)	2 (7)

eTable 8. Baseline medications: Canada

N (%)	Total	Active control	MOTIVATE-T2D
Oral hypoglycaemic agents			
Metformin	43 (68)	20 (65)	23 (72)
Antihypertensive agents	28 (44)	11 (35)	17 (53)
Renin-angiotensin agent	12 (19)	5 (16)	7 (22)
Thiazide diuretic	7 (11)	2 (6)	5 (16)
β blocker	4 (6)	1 (3)	3 (9)
Calcium-channel blocker	5 (8)	3 (10)	2 (6)
Other	0 (0)	0 (0)	0 (0)
Lipid-lowering drugs	20 (32)	8 (26)	12 (38)
Statin	19 (30)	7 (23)	12 (38)
Selective cholesterol-absorption inhibitor	1 (2)	1 (3)	0 (0)

eTable 9. Participant acceptability of MOTIVATE-T2D intervention

The following are verbatim quotes of the positive experiences of MOTIVATE-T2D from participants
Support from the exercise counsellor (counselling sessions and text messages
“I think that the interactivity with someone you get to know and trust and feel a somewhat, albeit virtual connection to has been … I'll say the backbone of the program. If somebody emailed this to me, I don't think I would have taken it to heart as much as having a personal connection.”
“The motivational texts that came in once a week, and then every other week, I found to be very helpful. …it was personalized, which I really liked. And then I would respond back”
Flexibility of the physical activity program
“The goal setting process was very realistic and directed at me, I didn't feel pressured to do more than I wanted to, rather it just kind of supported what I wanted to get out of it.”
“One of the things that helped me a fair bit was the flexibility I had with the exercise because I developed some of my own exercise routines…I have a pool in the backyard, so I developed some routines there for exercising in the water.”
Tracking and monitoring behaviour
“It made me more aware…I saw the numbers and I knew if I was doing well, …then if it wasn't going in the right direction, I had to do a little bit more.”
“I think it's just part of my life now…I'm always using it, recording stuff… looking at how I'm doing… for the number of steps I make. I always have targets…so it does motivate me to make sure that I meet my goals each day.”
Technical aspects of the watch and mobile app
“It was great when K was running things for me, but a bit more instruction on how to use the watch would have been useful when I got to do things myself.”
"it's certainly easier to program, to plan your sessions through the computer as opposed to on the app. … if there was some way of making that better on the app."

eTable 10. Data availability: HbA1c, anthropometrics, blood pressure, device derived physical activity and continous glucose monitoring

All data Control/MOTIVATE-T2D	Baseline, N (%)	6-month, N (%)	12-month, N (%)
Drop-out	-	109 (87)	103 (82)
HbA1c	119 (95) 63 (98) / 56 (92)	98 (78) 48 (75) / 50 (82)	92 (74) 44 (69) / 48 (79)
Weight	125 (100)	87 (70) 42 (66) / 46 (75)	80 (64) 39 (61) / 41 (67)
Waist circumference	125 (100)	87 (70) 42 (65) / 46 (75)	77 (62) 38 (59) / 39 (64)
Systolic blood pressure	121 (97) 63 (98) / 58 (95)	89 (71) 43 (67) / 46 (75)	79 (63) 38 (59) / 41 (67)
Diastolic blood pressure	122 (98) 63 (98) / 59 (97)	89 (71) 43 (67) / 46 (75)	78 (62) 38 (59) / 40 (66)
Total Cholesterol	85 (68) 43 (67) / 41 (67)	63 (50) 33 (52) / 30 (49)	64 (51) 30 (47) / 34 (56)
HDL Cholesterol	93 (74) 48 (75) 45 (74)	76 (61) 35 (55) / 41 (67)	74 (59) 35 (55) / 39 (64)
LDL Cholesterol	81 (65) 44 (69) / 37 (61)	68 (54) 33 (52) / 35 (57)	62 (50) 28 (44) / (34 (56)
Triglycerides	83 (66) 43 (41) / 40 (66)	67 (54) 33 (52) / 34 (56)	63 (50) 29 (45) / 34 (56)
Device derived PA: Met wear time criteria			
4-day (3 WD, 1WE)	105 (84) 54 (85) / 51 (84)	61 (49) 28 (48) / 33 (54)	73 (58) 32 (50) / 41 (67)
3-day (2WD, 1WE)	105 54 (84) / 51 (84)	61 (49) 28 (44) / 33 (54)	76 (61) 34 (53) / 42 (69)
3-day (any day)	112 (90) 57 (89) / 55 (90)	65 (52) 30 (47) / 35 (57)	80 (64) 38 (59) / 42 (69)
1-day	116 (93) 60 (94) / 56 (92)	71 (57) 34 (53) / 37 (61)	89 (71) 42 (66) / 47 (77)
CGM: Met wear time criteria			
14-Day	95 (76) 46 (72) / 49 (80)	90 (72) 43 (67) / 47 (77)	72 (58) 30 (47) / 42 (69)
10-Day	105 (84) 52 (81) / 53 (87)	93 (74) 45 (70) / 48 (79)	75 (60) 30 (47) / 45 (74)
7-Day	107 (86) 54 (58) / 53 (87)	97 (78) 49 (77) / 48 (79)	86 (69) 37 (58) / 49 (80)

HDL, high density lipoprotein; LDL, low density lipoprotein; PA, physical activity; CGM, continous glucose monitor; WD, week day; WE, weekend day; All PA data is ≥16h wear time; 14-day wear time for CGM achieved if ≥70% of data available; 10- and 7-day wear time for CGM achieved if ≥80% of data available

eTable 11. Data availability: Questionnaires

All data Control/MOTIVATE-T2D	Baseline, N (%)	6-month, N (%)	12-month, N (%)
Drop-out	-	109 (87)	103 (82)
EQ-5D-5L	125 (100)	94 (75) 44 (69) / 51 (84)	88 (70) 41 (64) / 47 (77)
SF12	118 (94) 63 (98) / 55 (90)	88 (70) 41 (64) / 47 (77)	82 (66) 39 (61) / 43 (70)
DTSQs	125 (100)	94 (75) 44 (69) / 50 (82)	86 (69) 41 (64) / 45 (74)
DTSQc	-	92 (74) 43 (67) / 49 (80)	-
Healthcare usage	121 (97) 64 (100) / 57 (93)	93 (74) 44 (69) / 49 (80)	86 (69) 40 (63) / 46 (75)

VAS, visual analogue scale; SF12, SF-12 Health Survey; BREQ-2, Behavioural Regulation in Exercise Questionnaire version 2; DTSQs, Diabetes Treatment Satisfaction Questionnaire status version, DTSQc, Diabetes Treatment Satisfaction Questionnaire change version. DTSQc was only taken at 6-months post.

eTable 12. UK and Canada data availability: Device derived physical activity and continous glucose monitoring

	UK			Canada		
	Baseline, N (%)	6-month, N (%)	12-month, N (%)	Baseline, N (%)	6-month, N (%)	12-month, N (%)
Drop-out	-	55 (89)	53 (85)	-	54 (86)	50 (79)
PA: Met wear time						
4-day (3 WD, 1WE)	54 (87)	17 (27)	40 (65)	51 (82)	44 (70)	33 (52)
3-day (2WD, 1WE)	54 (87)	17 (27)	40 (65)	51 (81)	44 (70)	36 (57)
3-day (any day)	57 (92)	19 (31)	41 (66)	55 (87)	46 (73)	39 (62)
1-day	59 (95)	21 (34)	46 (74)	57 (90)	50 (79)	43 (68)
CGM: Met wear time						
14-Day	43 (69)	45 (73)	30 (48)	53 (83)	45 (71)	42 (67)
10-Day	48 (77)	48 (77)	32 (52)	58 (92)	46 (73)	43 (68)
7-Day	49 (79)	51 (82)	39 (63)	59 (94)	47 (75)	47 (75)

PA, physical activity; CGM, continous glucose monitor; WD, week day; WE, weekend day; All PA data is ≥16h wear time; 14-day wear time for CGM achieved if ≥70% of data available; 10- and 14-day wear time for CGM achieved if ≥80% of data available

eTable 13. UK and Canada data availability: HbA1c, anthropometrics, blood pressure and blood lipids

	UK			Canada		
	Baseline, N (%)	6-month, N (%)	12-month, N (%)	Baseline, N (%)	6-month, N (%)	12-month, N (%)
Drop-out	-	55 (89)	53 (85)	-	54 (86)	50 (79)
HbA1c	62 (100)	50 (81)	50 (81)	57 (90)	48 (76)	42 (67)
Weight	62 (100)	41 (66)	42 (68)	63 (100)	46 (73)	38 (60)
Waist circumference	62 (100)	42 (68)	39 (63)	63 (100)	45 (71)	38 (60)
Systolic blood pressure	60 (97)	43 (69)	40 (65)	61 (97)	46 (73)	39 (62)
Diastolic blood pressure	60 (97)	43 (69)	40 (65)	62 (98)	46 (73)	38 (60)
Total Cholesterol	43 (69)	33 (53)	37 (60)	41 (65)	30 (48)	27 (43)
HDL Cholesterol	47 (76)	36 (58)	43 (69)	46 (73)	40 (63)	31 (49)
LDL Cholesterol	42 (68)	33 (53)	36 (58)	39 (62)	35 (56)	26 (41)
Triglycerides	43 (69)	32 (52)	36 (58)	40 (63)	35 (56)	27 (43)

HDL, high density lipoprotein; LDL, low density lipoprotein

eTable 14. UK and Canada data availability: Questionnaires

	UK			Canada		
	Baseline, N (%)	6-month, N (%)	12-month, N (%)	Baseline, N (%)	6-month, N (%)	12-month, N (%)
Drop-out	-	55 (89)	53 (85)	-	54 (86)	50 (79)
EQ-5D-5L	62 (100)	48 (77)	49 (79)	63 (100)	46 (73)	39 (62)
SF12	57 (92)	45 (73)	45 (73)	61 (97)	43 (68)	37 (59)
DTSQs	62 (100)	48 (77)	49 (79)	63 (100)	46 (73)	37 (59)
DTSQc	-	46 (74)	-	-	46 (73)	-
Healthcare usage	58 (94)	48 (77)	47 (76)	63 (100)	42 (65)	37 (56)

SF12, SF-12 Health Survey; DTSQs, Diabetes Treatment Satisfaction Questionnaire status version, DTSQc, Diabetes Treatment Satisfaction Questionnaire change version

eTable 15. Baseline device derived physical activity dependent on wear time

All min	4-day (3WD, 1WE)		3-day (2WD, 1WE)		3-day (any days)		1-day	
	Active control, Mean (SD)	MOTIVATE-T2D, mean (SD)	Active control, Mean (SD)	MOTIVATE-T2D, mean (SD)	Active control, Mean (SD)	MOTIVATE-T2D, mean (SD)	Active control, Mean (SD)	MOTIVATE-T2D, mean (SD)
Total PA	1484 (574)	1393 (490)	1484 (574)	1393 (490)	1505 (581)	1392 (497)	1498 (581)	1351 (511)
Light PA	980 (406)	966 (315)	980 (406)	966 (315)	1001 (434)	959 (322)	1008 (434)	945 (329)
Moderate PA	490 (259)	420 (203)	490 (259)	420 (203)	490 (259)	406 (203)	483 (259)	399 (210)
Vigorous PA	14 (14)	7 (7)	14 (14)	7 (7)	14 (14)	7 (7)	7 (14)	7 (7)
MVPA	504 (273)	427 (203)	504 (273)	427 (203)	504 (266)	413 (210)	490 (266)	406 (210)
MVPA10+	105 (168)	49 (77)	105 (168)	49 (77)	112 (175)	49 (77)	105 (168)	49 (77)

WD, week day; WE, weekend day; PA, physical activity; MVPA, moderate-to-vigorous intensity; MVPA10+, MVPA accumulated in bout ≥10 minutes; All PA data is ≥16h wear time

eTable 16. Between group differences at 6- and 12-months follow-up for device derived physical activity dependent on wear time

	4-day (3WD, 1WE)		3-day (2WD, 1WE)		3-day (any days)		1-day	
	6-months follow-up	12-months follow-up	6-months follow-up	12-months follow-up	6-months follow-up	12-months follow-up	6-months follow-up	12-months follow-up
Total PA	-28 (-287 to 231)	-105 (-343 to 126)	-21 (-280 to 231)	-98 (-329 to 133)	35 (-210 to 287)	-42 (-238 to 182)	-35 (-273 to 196)	-49 (-259 to 168)
Light PA	-7 (-196 to 182)	-70 (-238 to 105)	-7 (-196 to 182)	-70 (-245 to 98)	28 (-161 to 210)	-35 (-224 to 126)	-21 (-196 to 154)	-35 (-189 to 119)
Moderate PA	-21 (-112 to 70)	-21 (-105 to 70)	-14 (-105 to 77)	-7 (-91 to 77)	21 (-70 to 105)	7 (-70 to 84)	-14 (-98 to 70)	0 (-70 to 77)
Vigorous PA	0 (-7 to 7)	-7 (-14 to 0)	0 (-7 to 7)	-7 (-14 to 7)	0 (-7 to 7)	0 (-7 to 7)	0 (-7 to 7)	-7 (-14 to 7)
MVPA	-21 (-112 to 77)	-21 (-112 to 70)	-14 (-112 to 84)	-7 (-91 to 84)	21 (-70 to 105)	7 (-70 to 91)	-14 (-98 to 70)	0 (-77 to 77)
MVPA10+	35 (-21 to 91)	14 (-35 to 63)	35 (-21 to 91)	21 (-28 to 70)	42 (-7 to 91)	21 (-21 to 63)	35 (-14 to 77)	28 (-14 to 70)

WD, week day; WE, weekend day; PA, physical activity; MVPA, moderate-to-vigorous intensity PA; MVPA10+, MVPA accumulated in bout ≥10 minutes;

eTable 17. Baseline continous glucose monitoring dependent on wear time

All min	14-day		10-day		7-day	
	Active control, Mean (SD)	mHealth, mean (SD)	Active control, Mean (SD)	mHealth, mean (SD)	Active control, Mean (SD)	mHealth, mean (SD)
Time in range, % (3.9-10mmol/L)	80 (27)	80 (27)	80 (26)	82 (27)	81 (25)	82 (27)
Time in tight range, % (3.9-7.8mmol/L)	62 (27)	64 (29)	62 (28)	67 (29)	63 (28)	67 (29)
Time below range, % (<3.9mmol/L)	4 (9)	4 (9)	4 (9)	4 (8)	4 (9)	4 (8)
Time below range L2, % (<3.0mmol/L)	1 (3)	1 (3)	1 (3)	1 (3)	1 (3)	1 (3)
Time above range, % (>10.0mmol/L)	16 (27)	15 (28)	16 (26)	14 (27)	15 (26)	14 (27)
Time above range L2, % (>13.9mmol/L)	6 (17)	7 (19)	5 (16)	6 (19)	5 (16)	6 (19)
Coefficient of variation, %	25 (5)	23 (5)	24 (5)	23 (5)	24 (5)	23 (5)
SD of mean glucose	1.8 (0.7)	1.7 (0.7)	1.8 (0.6)	1.7 (0.7)	1.8 (0.6)	1.7 (0.7)
Mean Glucose, mmol/L	7.6 (2.7)	7.5 (3.1)	7.5 (2.7)	7.4 (3.0)	7.5 (2.6)	7.4 (3.0)

eTable 18. Between group differences at 6- and 12-months follow-up for continous glucose monitoring dependent on wear time

All min	14-day		10-day		7-day	
	6-months follow-up	12-months follow-up	6-months follow-up	12-months follow-up	6-months follow-up	12-months follow-up
Time in range, % (3.9-10mmol/L)	3 (-7 to 12)	6 (-5 to 16)	3 (-6 to 12)	6 (-4 to 16)	3 (-6 to 11)	4 (-5 to 13)
Time in tight range, % (3.9-7.8mmol/L)	2 (-8 to 12)	5 (-5 to 16)	2 (-8 to 11)	5 (-6 to 15)	1 (-8 to 11)	4 (-6 to 14)
Time below range, odds ratio [b] (<3.9mmol/L)	1 (0 to 4)	3 (1 to 14)	1 (0 to 5)	3 (1 to 10)	1 (0 to 5)	2 (1 to 9)
Time below range L2, odds ratio [b] (<3.0mmol/L)	9 (2 to 40)	1 (0 to 3)	10 (2 to 43)	1 (0 to 2)	9 (2 to 35)	1 (0 to 2)
Time above range, % (>10.0mmol/L)	-6 (-15 to 3)	-6 (-16 to 4)	-6 (-14 to 3)	-6 (-15 to 4)	-6 (-14 to 3)	-4 (-12 to 5)
Time above range L2, odds ratio [b] (>13.9mmol/L)	1 (0 to 3)	2 (0 to 9)	1 (0 to 4)	2 (0 to 7)	1 (0 to 4)	2 (1 to 8)
Coefficient of variation, %	1 (0 to 3)	0 (-2 to 2)	2 (0 to 3)	0 (-2 to 2)	1 (0 to 3)	0 (-1 to 2)
SD of mean glucose	0 (-11 to 12)	-2 (-13 to 12)	0 (-11 to 11)	-2 (-13 to 11)	0 (-10 to 11)	0 (-10 to 12)
Mean Glucose, % change [a]	-6 (-15 to 3)	-1 (-11 to 9)	-6 (-14 to 2)	-1 (-10 to 10)	-5 (-13 to 3)	-1 (-10 to 8)

[a] Log-transformed, interpret effect estimates as percent change. [b] Data were analyzed using mixed effects binomial regression, interpret effect estimates as odds ratios

eTable 19. Attendance at exercise counselling meetings

	Active Control, N (%)	MOTIVATE-T2D, N (%)
EC1	64 (100)	61 (100)
EC2	64 (100)	59 (97)
EC3	58 (91)	56 (92)
EC4	55 (86)	55 (90)
EC5	53 (83)	54 (89)

EC, exercise counselling meeting

eTable 20. Estimated intervention delivery costs

Staff Time [a] (min)	Active Control		MOTIVATE-T2D	
	UK	Canada	UK	Canada
Exercise Counselling 1	30		30	
Exercise Counselling 2	30		50	
Exercise Counselling 3	25		25	
Exercise Counselling 4	25		25	
Exercise Counselling 5	25		25	
Exercise Counselling Total	135		155	
Watch set up	-		15	
Sending text messages	5		105	
Exercise programming	60		45	
Overall Total Counsellor Time	320		320	
Estimate Total Counsellor Cost per patient	£120.00 [b]	$137.13 [c]	£192.00 [b]	$219.41 [c]
Watch [d]	-	-	£116.33	$288.00
Postage [e]	£3.45	$22.73	£4.92	$22.73
Text messages [f]	£0.96	$1.92	£2.00	$2.00
Other resource use/ costs [g]				
Website [h]	£1.68	$2.76	£1.68	$2.76
Video calling subscription [i]	£1.19	$2.00	£1.19	$2.00
Video editing subscription [j]	£0.90	$1.48	£0.90	$1.48
Printing costs [k]	£0.75	$1.25	£0.74	$1.22
Envelopes/ Delivery box [k]	£0.06	$0.1	£1.56	$2.57
Estimated total delivery cost of the mHealth intervention	£128.99	$169.37	£321.32	$542.17

[a] Mean delivery time has been rounded up to nearest 5 minutes. [b] Staff grade equivalent to NHS Agenda for Change band 5 (staff salary at £25,023 per annum), from Curtis and Burns, Unit Costs of Health and Social Care 2020, p125. Based on. Estimated cost per hour = £36 (Curtis and Burns, 2020); Includes salary, salary on costs, overheads (management costs and non-staff costs (including travel/transport)), capital overheads, and excludes costs for qualifications. [c] Staff grade equivalent to a dietician (2020), estimated cost per hour = $41.14 (O'Reilly et al., 2022). [d] Based on using a Polar Ignite 1, Polar retailer price list, without taxes (prices relevant for 2020). [e] UK - Royal Mail, Canada - regional and national postage averages (prices relevant to 2021). [f] Based on mean of 50 texts per patient at £0.04/ $0.04 per message, via online system. [g] These costs are distributed across the first 100 participants receiving the intervention. [h] Yearly Unlimited Premium Plan accessed through Wix (Wix.com), including domain name (prices relevant for 2020). [i] Yearly access to Zoom Pro (prices relevant to 2020). [j] Yearly subscription to online video editing service (prices relevant to 2020). [k] Price is quoted per item when 100 items ordered.

eTable 21. Wider healthcare and societal utilisation at 6- and 12-month

	Active control Mean (SD)		MOTIVATE-T2D Mean (SD)	
	6-month, N=44	12-month, N=40	6-month, N=49	12-month, N=46
Secondary Care				
A&E	0.27 (0.73)	0.10 (0.30)	0.00 (0.00)	0.09 (0.35)
Inpatient	0.02 (0.15)	0.00 (0.00)	0.02 (0.14)	0.02 (0.15)
Day Hospital	0.07 (0.45)	0.03 (0.16)	0.06 (0.32)	0.04 (0.29)
Clinic	0.27 (0.54)	0.13 (0.52)	0.33 (0.90)	0.26 (0.80)
Other	0.05 (0.21)	0.03 (0.16)	0.35 (0.97)	0.38 (1.54)
Total Secondary Care	0.68	0.29	0.76	0.79
Primary Care				
GP (Home)	0.00 (0.00)	0.10 (0.44)	0.08 (0.34)	0.11 (0.48)
GP (Clinic)	0.23 (0.68)	0.15 (0.43)	0.12 (0.44)	0.35 (0.99)
GP (Phone)	0.39 (0.97)	0.35 (0.82)	0.31 (0.82)	0.24 (0.74)
Community doctor (Home)	0.00 (0.00)	0.13 (0.79)	0.00 (0.00)	0.04 (0.29)
Community doctor (Clinic)	0.00 (0.00)	0.02 (0.14)	0.00 (0.00)	0.04 (0.29)
Community doctor (phone)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.30 (2.06)
District nurse (home)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)
District nurse (clinic)	0.02 (0.15)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)
District nurse (phone)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)
Practice nurse (home)	0.00 (0.00)	0.08 (0.35)	0.00 (0.00)	0.02 (0.15)
Practice nurse (clinic)	0.16 (0.91)	0.08 (0.35)	0.04 (0.20)	0.02 (0.15)
Practice nurse (phone)	0.00 (0.00)	0.05 (0.32)	0.00 (0.00)	0.00 (0.00)
Specialist nurse (home)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)
Specialist nurse (clinic)	0.09 (0.36)	0.03 (0.16)	0.04 (0.20)	0.00 (0.00)
Specialist nurse (phone)	0.11 (0.49)	0.08 (0.27)	0.06 (0.24)	0.04 (0.21)
Physiotherapist (home)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.20 (0.93)
Physiotherapist (clinic)	0.27 (1.09)	0.00 (0.00)	0.08 (0.40)	0.15 (0.76)
Physiotherapist (phone)	0.18 (1.21)	0.00 (0.00)	0.00 (0.00)	0.04 (0.29)
Occupational therapist (clinic)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.11 (0.74)
Paramedic	0.00 (0.00)	0.05 (0.22)	0.00 (0.00)	0.00 (0.00)
Total Primary Care	1.45	1.12	0.73	1.66
Social Care				
Private home help/cleaner	0.00 (0.00)	0.00 (0.00)	0.18 (1.29)	0.13 (0.88)

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Mobile Health Biometrics to Enhance Exercise and Physical Activity Adherence in Type 2 Diabetes (MOTIVATE-T2D): a Decentralised Feasibility Randomised Controlled Trial Delivered Across the UK and Canada

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ABSTRACT

Objectives: Assess the feasibility of a mobile health (mHealth) supported home-delivered physical activity (PA) intervention (MOTIVATE-T2D) in people with recently diagnosed type 2 diabetes (T2D).

Design: Feasibility multicentre, parallel group, Randomised Controlled Trial (RCT)

Setting: Participants were recruited from England and Canada using a decentralised design.

Participants: Adults (40-75 years) recently diagnosed with T2D (5-24 months).

Interventions: Participants were randomised 1:1 to intervention (MOTIVATE-T2D) or active control groups. Participants co-designed 6-month home-delivered, personalised, progressive PA programmes supported by virtual behavioural counselling. MOTIVATE-T2D used biofeedback from wearable technologies to support the programme. The active control group received the same intervention without wearables.

Outcomes: The primary outcomes were recruitment rate, retention and adherence to purposeful exercise. Clinical data on effectiveness were collected as exploratory outcomes at baseline, 6- and 12-months, with HbA1c and systolic blood pressure (BP) proposed as primary outcomes for a future full RCT.

Results: n=135 eligible participants expressed an interest in the trial, resulting in 125 participants randomised (age 55±9yrs, 48% female, 81% white), a recruitment rate of 93%. Retention at 12-months was 82%. MOTIVATE-T2D participants were more likely to start (odds ratio [OR] 10.4, CI 3.4 to 32.1) and maintain purposeful exercise at 6 (OR 7.1, CI 3.2 to 15.7) and 12-months (OR 2.9, CI 1.2 to 7.4). Exploratory clinical outcomes showed a potential effect in favour of MOTIVATE-T2D, including proposed primary outcomes HbA1c and systolic BP (between-group mean differences: HbA1c: 6-months: -5% change from baseline, CI -10 to 2: 12-months: -2% change from baseline, CI -8 to -4; systolic BP: 6-months: -1mmHg, CI -5 to 3: 12-months: -4mmHg, CI -8 to 1).

Conclusions: Our findings support the feasibility of delivering the MOTIVATE-T2D mHealth supported PA intervention for people with recently diagnosed T2D and progression to a full RCT to examine its clinical and cost-effectiveness.

Trial Registration: ISRCTN: 14335124. ClinicalTrials.gov: NCT0465353

Key words: Type 2 diabetes, mHealth technology, physical activity, exercise, behaviour change

Strength and Limitations of the Study

- Our active control intervention was matched aside from the availability of technology in MOTIVATE-T2D to assess how the addition of mHealth technology can influence PA.

- Acceptability and feasibility were established using a multidisciplinary approach drawing on quantitative, qualitative, and trial procedure data.
- The effect of the interventions on PA were evaluated using two device-derived measurements. Providing objective data on purposeful exercise of moderate-to-vigorous intensities and daily lifestyle PA which were both encouraged by the intervention and are known to be important determinants of health outcomes in T2D.
- This study was not designed or powered to definitively assess the efficacy or cost effectiveness of the MOTIVATE-T2D intervention on clinical outcomes in people with newly diagnosed T2D.

INTRODUCTION

Increasing physical activity (PA), both through purposeful exercise and unstructured lifestyle behaviours is fundamental to the initial treatment of type 2 diabetes (T2D) and recommended in international guidelines [1-3]. These guidelines draw on the known benefits of regular PA on glycaemia [4], the incidence of microvascular complications, cardiovascular events, and all-cause mortality in people living with T2D [5]. However, people with T2D tend to exhibit lower levels of PA compared to people who do not have diabetes [6 7]. To address this gap, diabetes care pathways are increasingly prioritising the provision of personalised PA guidance for individuals recently diagnosed with T2D [8 9]. However, given the poor adherence to existing PA interventions and strategies [10], innovative interventions which capitalise on the potential of new technologies are urgently needed to effectively support PA and health in people with T2D.

Recently, wearable technologies incorporating PA trackers have become popular to promote behaviour change in long-term conditions such as T2D [11]. In particular, pedometers and accelerometers that provide biofeedback on ambulatory PA, have been used as tools for self-monitoring or alongside more complex behavioural interventions [12]. Use of PA trackers has been associated with increased PA in people with T2D [13], which can be maintained for up to 12 months [14]. However, the effects of increasing PA via use of PA trackers on outcomes relevant to the clinical management of T2D are unclear. An umbrella review found little evidence that PA trackers improve HbA1c in people with T2D [15]. It has been hypothesised that these findings are due to

PA trackers promoting low-intensity lifestyle PA (i.e., accrual of PA through everyday activities) rather than more intense domains and/or purposeful exercise [14], crucial for improving glycaemic control [4 16].

Accelerometers can support behaviour change by providing PA targets based on time spent in specific intensity categories (i.e., light, moderate, or vigorous). Intensity categories are delineated using threshold values derived from calibration studies which examine the association between movement acceleration and energy expenditure [17]. Generic targets based on such broad and classifications of intensity are effective at encouraging general lifestyle PA, but the one-size-fits-all approach does not provide personalised formative feedback. Therefore, participants cannot utilise these targets to optimise intensity during purposeful exercise [18], which may be crucial for improving glycaemic control [4]. Previous reports have also cited issues with using accelerometers to assess non-ambulatory activity (e.g cycling and resistance exercise), which may be promoted through purposeful exercise programmes [19]. The latest generation smartwatches now incorporate heart rate (HR) monitors alongside accelerometers. HR monitoring has several advantages over accelerometers when targeting purposeful exercise of moderate-to-vigorous intensity. HR is the most accurate way to track the body's response to PA, providing real-time objective personalised data that accounts for age, body mass and fitness level [20]. HR also reflects intensity regardless of the type of activity performed [21]. The Mobile Health Biometrics to Enhance Exercise and Physical Activity Adherence in Type 2 Diabetes (MOTIVATE-T2D) intervention was designed to combine accelerometery and HR monitoring as the most effective biofeedback tools to facilitate home-based PA. Promoting both lifestyle PA and purposeful exercise of moderate-to-vigorous intensities known to influence clinical outcomes [4]. Previous work suggests real-time HR biofeedback facilities purposeful exercise by helping participants work at an intensity most likely to elicit health changes, fostering self-efficacy to engage through feelings of competence [19].

Advances in mobile health (mHealth) technologies can also be used to target other barriers to home-delivered PA. One such barrier is that participants do not receive appropriate support from health providers in the time between scheduled meetings [22]. MOTIVATE-T2D uses next-generation mHealth technology to share biometric data

and facilitate remote communication between patients and health professionals. This aims to recreate the relationship between patients and health professionals experienced during supervised interventions, but with the advantage that communication is in the patient's own environment at convenient times. Qualitative data suggests such remote feedback may encourage adherence to a PA programme, through enhanced relatedness between patients and health professionals [19]. In summary, MOTIVATE-T2D combines the latest advances in biofeedback and data sharing to optimise a home-delivered behavioural counselling service. Together the elements, provide comprehensive support to participants, enabling them to co-develop personalised PA plans which include lifestyle PA and purposeful exercise of moderate-to-vigorous intensities.

The primary aim of this study was to assess the feasibility of undertaking a subsequent definitive Randomised Controlled Trial (RCT) to assess the clinical effectiveness and cost-effectiveness of the MOTIVATE-T2D intervention in people with recently diagnosed T2D. Specific objectives of the study were to:

1. Determine the proportion and characteristics of people with recently diagnosed T2D who would be willing to take part in an RCT (i.e. recruitment rate)
2. Determine the number of participants retained at 12 months in both arms of the trial (i.e., loss to follow-up).
3. Evaluate the acceptability of the intervention and determine rates of adherence during and for 6 months after completion of the intervention.
4. Estimate precision of potential outcome measures required for sample size estimations for a future definitive RCT.
5. Pilot methods for collecting outcome measures, recruitment, randomisation, treatment, and follow-up.
6. Determine availability and completeness of economic data.

METHODS

The trial is reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) extension for pilot trials [23]. Our full trial protocol can be found elsewhere [24].

Study Population and Design

The MOTIVATE-T2D feasibility trial was a multicentre (UK and Canada), parallel group, RCT in adults recently diagnosed with T2D. Participants aged 40-75 years, diagnosed with T2D within the previous 5-24 months and managing their condition through lifestyle modification alone or Metformin (stable dose for ≥3 months) were eligible. Exclusion criteria were HbA1c >86 mmol/mol, blood pressure >160/100 mmHg, glucose-lowering agents other than Metformin, unstable angina, myocardial infarction within the previous 3 months, transient ischemic attack in the previous 6 months, heart failure NYHA ≥ class II, arrythmia, healthcare professional advice against increasing level of activity, pregnancy or planning to become pregnant, <6 months postpartum or stopped breastfeeding <1 month before recruitment, not owning a smartphone or not having a data plan or access to Wi-Fi, and those who are currently meeting the recommended exercise guidelines for people with T2D (150 min of moderate intensity exercise per week).

Participants were randomised to active control or intervention (MOTIVATE-T2D) on a 1:1 basis following the completion of baseline assessments. Randomisation was stratified by centre (UK or Canada), sex (male or female) and age (40-60 or 61-75 years) and was administered using a computer-generated random allocation sequence, created and administered by the Centre for Advancing Health Outcomes. Research staff responsible for the intervention and outcomes measures and participants were aware of allocation. However, the statistician undertaking the data analysis was blinded to treatment allocation (blinded analytic assessment). The trial conforms with the principles outlined in the Declaration of Helsinki and 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). All participants provided written informed consent.

Participants were recruited from 1) general practitioner (GP) database searches (UK only); 2) flyers provided to diabetes education sessions (DESMOND and X-PERT Health; both health professional led structured diabetes education and self-management programmes; UK only); 3) adverts in clinical settings (LifeLabs and GP waiting rooms, Canada only); 4) local media adverts and classifieds (Canada only); 5) third party online recruitment services (Lindus Health, UK; Trialfacts and HoneyBee

Trials, Canada); 6) a consent to contact database (Research For The Future, UK only) and 7) the study website.

Interventions

Detailed descriptions of the active control and MOTIVATE-T2D interventions are published elsewhere [24]. Briefly, by design, the active control and MOTIVATE-T2D interventions were matched aside from the availability of technology in MOTIVATE-T2D. Key aspects of both interventions and how they differed are presented in Table 1.

Participants in both groups co-designed their 6 month PA programmes with the aim of promoting two behaviours, namely 1) gradually increasing purposeful exercise of moderate-to-vigorous intensity, with a target of 150 minutes per week by the end of 6 months and 2) increasing daily lifestyle PA of any intensity. These aims were facilitated by an exercise specialist-led behavioural counselling service delivered virtually via phone or teleconferencing software, according to participant preference. The counselling supported participants to develop personalised PA programmes and provided regular feedback on their action plans to support them achieve their goals. MOTIVATE-T2D used biofeedback and data sharing enabled by mHealth technologies to support the development of personalised PA programmes and ongoing feedback. The mHealth technologies included a smartwatch, featuring a 3D accelerometer and optical heart rate (HR) monitor (Polar Ignite, Polar Electro), synced with an online coaching platform for the exercise specialist (Polar Flow for Coach, www.polar.com/coach) and web/smartphone app for participants (Polar Flow – Sync & Analyze).

Ongoing Management of Diabetes

Throughout the trial, all participants remained under their diabetes specialist and continued with medication management according to national guidelines (UK, National Institute for Health and Care Excellence (NICE) guidance on management of diabetes (NG28), hypertension (NG136) and lipid modification (NG181); Canada, Diabetes Canada 2018 Clinical Practice Guidelines[25]).

Outcome Measurements

The following feasibility outcomes were collected: percentage of people eligible for the study; total recruitment rate and rate by recruitment strategies; attrition and loss to follow-up; completeness of outcome measures at baseline, 6 and 12 months.

Acceptability of study participation and intervention were assessed via virtual (Zoom inc.) semi-structured qualitative interviews. Interviews were planned with a purposeful sampling framework, considering gender, age and country. Immediately following baseline measures 8 participants (UK N=4, Canada N=4) and 20 participants at 6 months (UK N=11, Canada N=9) were interviewed regarding study participation. At 6 months 25 participants (MOTIVATE-T2D N=14, UK N=8, Canada N=6; active control N=11, UK N=8, Canada N=3) were interviewed regarding intervention acceptability, with 21 (MOTIVATE-T2D N=12, UK N=8, Canada N=4; active control N=9, UK N=6, Canada N=3) of these participants interviewed again at 12 months.

Adherence: The intervention aimed to increase completion of purposeful exercise of moderate-to-vigorous intensities and unstructured lifestyle PA; as such, two methods for assessing these distinct factors were employed.

Table 1. Intervention components

Intervention component	Shared features	Active control	MOTIVATE-T2D
Aims	1. Progressively increase purposeful exercise of moderate-to-vigorous intensities 2. Increase daily lifestyle PA of any intensity		Supported by biofeedback and data sharing enabled by mHealth technologies: 1. Smartwatch, featuring a 3D accelerometer and optical heart rate (HR) monitor 2. Online coaching platform for the exercise specialist 3. Web/smartphone app for participants
Behavioural counselling	● Exercise specialist led, one-to-one, virtual exercise consultations (Zoom inc) ● 5 sessions: 1) prior to intervention, 2) approx. 1 week after first session, 3) 1-month, 4) 3-months, 5) 6 months		
Purposeful exercise programmes	● Individualised action plans were co-developed ● Individualised by allowing participants to choose the: 1. Mode (e.g., commuting, outdoor, indoor calisthenics, or gym-based) 2. Type (e.g., walking, cycling, resistance exercise, interval-based exercise, classes, dance, or sports) 3. Initial duration 4. Initial intensity 5. Rate of progression	● Action plan sent within a booklet containing: ○ Training calendar/diary ○ Progressive exercise guide ● Access to the trial website with exercise resources, including exercise videos	Action plan built within the coaching platform ○ Training calendar ○ Preset sessions prescribing the duration and intensity (measured through HR) of phases within each exercise session (i.e., warm-up, workout and cool-down) Smartwatch providing real-time feedback on exercise intensity through HR zones ○ During preset sessions, prescribed duration and intensity were displayed (via HR zones), with visual and haptic (vibration) alerts to coach participants Web/smartphone app: 1. Access to the action plan 2. Track exercise and PA achievements 3. Participants rate enjoyment and provide written feedback following exercise sessions

Lifestyle PA	Advice on how to integrate physical activity into daily routines		Supported with a target on the smartwatch
On-going communication	Counselling sessions 3, 4 and 5 ○ Review progress ○ Update action plan Counselling session 5 ● Strategies for maintaining exercise and PA without support from the exercise specialist	● Updated action plans sent after counselling sessions ● Participants received SMS text messages: 1. Weekly during the first 3 months 2. Biweekly during months 4–6 ● Pre-scripted, based on self-determination theory: modelled to target relatedness, competence and autonomy ● Participants could reply and engage with their exercise specialist ○ Action plans could be updated based on discussions	● Consultations allowed mHealth data to guide discussions ● Updated action plans within the coaching platform after counselling sessions ○ Updated pre-set sessions ● Participants received SMS text messages: 1. Following each recorded exercise session during month 1 2. Weekly during months 2-3 3. Biweekly, months 4-6 ● Based on data gathered by the mHealth technologies (intensity and duration of sessions and participant enjoyment and feedback) ● Participants could reply and engage with their exercise specialist ○ Action plans and pre-set sessions could be updated based on discussions

Optical HR monitoring (photoplethysmography) was used to record dose of purposeful exercise throughout the 12 month trial. A blinded Polar Verity sense (Polar Electro, Finland) was provided to active control participants for the duration of the trial. The MOTIVATE-T2D group used a Polar Verity sense paired to the fitness watch, allowing HR to be visualised in real time. HR data were used to calculate 1) frequency of exercise (number of sessions recorded); 2) adherence to prescribed exercise (% of 78 sessions achieved, based on prescribing 3 sessions per week for 26 weeks), 3) duration of exercise; 4) duration of moderate-to-vigorous intensity exercise (MVE, calculated by adding time in moderate, 50-70% HR_{max}, and time in vigorous, ≥70% HR_{max}*2, intensity exercise); 5) training drop-off (defined as the week which participants no longer completed any training sessions), and; 5) proportion of participants completing >150 minutes of MVE per week at least once during the last month of the intervention and follow-up period.

Lifestyle PA was measured in all participants using a GENEactive (Activinsights, Kimbolton, Cambridge, UK) tri-axial accelerometer for 14-days at baseline, 6 and 12 months. Data were extracted using GENEActiv PC software (V.3.0_09.02.2015) and processed in R using the open-source package GGIR V.1.2-8 (https://cran.r-project.org/web/packages/GGIR/index.html) [26] to explore accelerometer wear time, and the proportion of participants who wore the device for at least 16h on: 1) 4 days including one weekend day; 2) 3 days including at least 1 weekend day; 3) 3 days irrespective of weekend days, and; 4) 1 day. The time spent in activity intensities was established using published thresholds [27]. The following metrics of PA were assessed: average weekly minutes of total PA (any intensity), and of light, moderate, vigorous and moderate-to-vigorous PA (MVPA) (MVPA), and MVPA recorded in ≥10-min bouts (MVPA10+).

Fidelity: Exercise specialists logged all contact with participants, including 1) the number of counselling sessions attended; 2) the number of SMS text messages sent by participants to exercise specialists, and 3) the number of exercise video views.

Clinical effectiveness outcomes proposed for a future trial were collected at baseline, 6 and 12 months as described previously [24](see online supplementary eFigure 1 for a schematic outlining the study timeline). The trial used a decentralised design where

outcomes were measured using remote 'home-based' solutions. HbA1c and systolic blood pressure were collected as the proposed primary outcomes for a future RCT. A number of proposed secondary outcomes were collected included; height; weight; waist circumference; diastolic blood pressure; mean arterial pressure; blood lipids; generic health status (5-level EQ-5D) [28]; health-related quality of life (12-item short form Health Survey [SF-12]) [29]; diabetes treatment satisfaction (Diabetes Treatment Satisfaction Questionnaire status version [DTSQs]) [30]; healthcare utilisation using a study-specific questionnaire (primary and secondary care contacts, social care contacts and relevant medication usage); and safety outcomes (serious adverse events). Change in diabetes treatment satisfaction (DTSQ change version) [31] was assessed at 6 months only. Free-living glycemia was assessed using a FreeStyle Libre Pro flash continuous glucose monitor (CGM, Abbott Diabetes Care, Alameda, CA, USA) worn for 14-days at baseline, 6 and 12 months. Core CGM endpoints outlined in a recent position statement [32] were calculated using the web-based application Diametrics [33] if participants provided ≥70% of data over 14 consecutive days. To explore if different ways of processing CGM data influenced data availability and outcomes, CGM endpoints were calculated based on alternative wear-time criteria, including ≥80% of data over 10 consecutive days; ≥80% of data over 7 consecutive days [32].

Protocol deviation: The original protocol suggested HbA1c would be analysed by the Exeter Clinical Laboratory for UK and Canadian samples. Due to logistical challenges with shipping, Canadian HbA1c was assessed by the University of British Columbia research team, using an Afinion 2 point-of-care analyzer (Alere Technologies, Oslao, Norway). UK and Canadian assessment of blood lipids was conducted as planned by the Exeter Clinical Laboratory.

Statistical Analysis

Our planned recruitment target of 120 participants (60 per arm) allowed us to achieve the feasibility aims and objectives of this study; that is, an estimate of attrition, estimates of the standard deviation (SD) of the secondary outcomes to inform power calculations for a future definitive trial, and enough participants for qualitative interviews. For more information see our full trial protocol (23).

We report the mean and SD for both groups for all outcomes at baseline, 6 and 12 months, and the model-derived estimated marginal means (with corresponding 95% CIs) for the within and between group effect estimates at 6 and 12 months. Effect estimates are based on intention to treat (ITT) analyses and included all participants that had a baseline or a follow-up value. Data were analysed via constrained longitudinal data analysis (cLDA) using a linear mixed model with fixed effects for timepoints (baseline, 6 and 12 months), the interaction between timepoint and intervention group, and stratified allocation factors (sex, study site, and age category), and a random effect for participant.

Given the feasibility nature of this trial, we do not report *p* values for the comparison of outcomes to baseline or between groups. Confidence intervals and minimal clinically important differences (MCID) are presented to suggest plausible evidence of effect for respective study arms [34] [35]. All analyses were conducted in R (version 4.3.1.). Participant semi-structured interviews were conducted by BJRB, SCP and JJ, who were not otherwise involved in the intervention or study delivery. Interviews were audio recorded and transcribed verbatim using otter.ai software. Transcripts were analysed using a deductive coding and thematic analysis approach by experienced qualitative researchers (SCP, JJ and MEJ)[36], using NVivo 12TM software and will be fully reported elsewhere.

Patient and Public Involvement (PPI)

Patients were involved in the oversight of trial progress and conduct via representation at periodic Trial Delivery Group and Trial Steering Group meetings. Our patient representatives also provided opinions on the protocol and patient-facing documentation (e.g., Participant Information Sheet) during the set-up of the trial.

RESULTS

Recruitment and retention of participants and acceptability of trial design

A consort diagram showing participant flow through the study is shown in Figure 1 (consort diagrams separating UK and Canada are shown in online supplementary eFigure 2-3). Between January 2021 and December 2021, *n*=596 potential participants expressed an interest in the trial, of which *n*=321 (54% of those who initially enquired) were excluded, 140 (23%) had no further contact and 10 (2%) did

not wish to take part, resulting in 125 participants (93% of eligible participants) randomised (MOTIVATE-T2D 61, active control 64; UK 62, Canada 63). The actual recruitment rate of 10.4 participants per month was in line with the forecast of 10 participants per month. Enrolment success appeared to be influenced by recruitment strategy (online supplementary eTable 1). For example, GP database searches were responsible for 94 expressions of interest and 44 participants randomised (47% of those who initially enquired), compared to third party recruitment services which were responsible for 327 expressions of interest and 38 participants randomised (12% of those who initially enquired). Demographics were also influenced by recruitment strategy (online supplementary eTable 2), with third party online recruitment services recruiting more young people in full time employment with education to higher level, but a more ethnically diverse population.

At 6 and 12 months follow-ups, 16 (13%) and 22 (18%) participants were lost to follow-up, respectively. There was evidence of imbalance in retention rate between study groups and country, with 8 (13%) MOTIVATE-T2D vs. 14 (22%) active control and 9 (14%) UK vs 13 (21%) Canadian participants lost to follow-up. Participants had a high level of satisfaction with their participation in the trial (online supplementary eTable 3).

Baseline characteristics

Baseline demographics and medication use are displayed in Table 2 and eTable 4, respectively (UK and Canada; online supplementary eTable 5, 6, 7, 8). Baseline values for outcome measures are shown in Table 3-4. Compared with active control, MOTIVATE-T2D included a higher proportion of participants with education to further level and a lower proportion of participants who were single and living alone.

Table 2. Baseline demographic characteristics

	Total	Active control	MOTIVATE-T2D
N	125	64	61
Age, years, mean (SD)	55 (9)	54 (9)	55 (9)
Female, N (%)	60 (48)	31 (48)	29 (48)
Male, N (%)	65 (52)	33 (52)	32 (52)
Duration of T2D, months, mean (SD)	13 (6)	13 (6)	13 (6)
Ethnicity, N (%)			

White	101 (81)	52 (81)	49 (80)
African or Caribbean	5 (4)	2 (3)	3 (5)
Asian	14 (11)	8 (13)	6 (10)
Other or Mixed	5 (4)	2 (3)	3 (5)
Marital status, living arrangements, N (%)			
Married, living with spouse	90 (72)	44 (69)	46 (75)
Married, living alone	1 (1)	0 (0)	1 (2)
Married, living arrangement unknown	1 (1)	0 (0)	1 (2)
Single, living alone	15 (12)	10 (16)	5 (8)
Single, living with others	3 (2)	2 (3)	1 (2)
Single, living arrangement unknown	1 (1)	1 (2)	0 (0)
Separated, living alone	9 (7)	5 (8)	4 (7)
Separated, living with spouse/partner	1 (1)	0 (0)	1 (2)
Widowed, living with spouse/partner	1 (1)	0 (0)	1 (2)
Widowed, living alone	2 (2)	1 (2)	1 (2)
Rather not say, living with spouse/ partner	1 (1)	1 (2)	0 (0)
Educational Attainment, N (%)			
Secondary	20 (16)	15 (23)	5 (8)
Further	49 (39)	20 (31)	29 (48)
Higher	56 (45)	29 (45)	27 (44)
Employment Situation, N (%)			
Full Time	75 (60)	40 (63)	35 (57)
Part Time	11 (9)	4 (6)	7 (11)
Retired	21 (17)	11 (17)	10 (16)
Student	2 (2)	1 (2)	1 (2)
Voluntary/ unpaid work	2 (2)	1 (2)	1 (2)
Stay-at-home mother/father	1 (1)	1 (2)	0 (0)
Unable: Caring responsibility	1 (1)	0 (0)	1 (2)
Unable: Ill health/ disability	9 (7)	5 (8)	4 (7)
Unemployed	3 (2)	1 (2)	2 (3)

Table 3. Baseline and within- and between group differences at 6 and 12 months follow-up; HbA1c, anthropometrics, blood pressure, blood lipids, device-derived physical activity and continuous glucose monitoring variables

Outcome, Unit (MCID)		Baseline, Mean (SD)	Within group difference (95% CI)*		Between group difference (95% CI) *	
			6 Months	12 Months	6 Months	12 Months
HbA1c, mmol/mol (6%)	Active control	51 (11)	2 (-3 to 6)	2 (-3 to 7)	-2 (-5 to 2)	-2 (-8 to 4)
	MOTIVATE-T2D	50 (9)	-3 (7 to 1)	-1 (-5 to 4)		
				% change		
Weight, kg (5kg)	Active control	99.1 (23.6)	-2.9 (-4.4 to -1.4)	-2.7 (-4.2 to -1.2)	1.5 (-0.5 to 3.3)	1.2 (-0.9 to 3.3)
	MOTIVATE-T2D	98.0 (23.6)	-1.4 (-2.8 to 0.0)	-1.5 (-3.0 to -0.1)		
BMI, kg/m^2	Active control	34.9 (8.4	-1.1 (-1.6 to -0.6)	-1.0 (-1.5 to -0.5)	0.6 (-0.1 to 1.2)	0.4 (-0.3 to 1.1)
	MOTIVATE-T2D	33.3 (6.1)	-0.5 (-1.0 to 0.0)	-0.6 (-1.1 to -0.1)		
Systolic BP, mmHg (5 mmHg)	Active control	130 (15)	-1 (-5 to 2)	0 (-3 to 4)	1 (-5 to 3)	-4 (-8 to 1)
	MOTIVATE-T2D	127 (14)	-3 (-6 to 1)	-4 (-7 to 0)		
Diastolic BP, mmHg (2 mmHg)	Active control	82 (9)	-1 (-3 to 1)	-2 (-4 to 0)	0 (-2 to 3)	0 (-3 to 3)
	MOTIVATE-T2D	81 (9)	-1 (-3 to 1)	-2 (-4 to 0)		
MAP, mmHg (2 mmHg)	Active control	98 (10)	-1 (-3 to 1)	-1 (-3 to 1)	0 (-3 to 3)	-1 (-4 to 2)
	MOTIVATE-T2D	97 (10)	-1 (-3 to 1)	-2 (-4 to 0)		
Total Chol, mmol/L (0.3 mmol/L)	Active control	5.3 (1.5)	-0.2 (-0.5 to 0.1)	0.0 (-0.3 to 0.4)	0.1 (-0.3 to 0.5)	-0.3 (-0.7 to 0.1)
	MOTIVATE-T2D	5.4 (1.3)	-0.1 (-0.5 to 0.2)	-0.3 (-0.6 to 0.0)		
HDL Chol, mmol/L (0.1 mmol/L)	Active control	1.2 (0.3)	0.0 (0.0 to 0.1)	0.0 (0.0 to 0.1)	0.0 (-0.1 to 0.1)	0.0 (-0.1 to 0.1)
	MOTIVATE-T2D	1.1 (0.3)	0.1 (0.0 to 0.1)	0.1 (0.0 to 0.1)		

LDL Chol, mmol/L (3%)	Active control	3.2 (1.3)	-6 (-15 to 4)	1 (-9 to 13)	4 (-6 to 19)	-10 (-21 to 4)
	MOTIVATE-T2D	3.3 (1.2)	-2 (-11 to 8)	-8 (-17 to 1)		
				% change[a]		
Triglycerides, mmol/L (5%)	Active control	2.0 (0.9)	-6 (-19 to 9)	0 (-15 to 16)	-1 (-18 to 21)	-4 (-21 to 18)
	MOTIVATE-T2D	2.4 (1.8)	-7 (-20 to 8)	-4 (-17 to 11)		
				% change[a]		
CGM TIR, % (3%)	Active control	81 (26)	-1 (-9 to 6)	-5 (-13 to 4)	3 (-6 to 12)	6 (-5 to 16)
	MOTIVATE-T2D	82 (26)	1 (-6 to 8)	1 (-6 to 8)		
CGM TBR, %	Active control	4 (8)	1 (0 to 3)	1 (0 to 2)	2 (0 to 4)	3 (1 to 14)
	MOTIVATE-T2D	4 (8)	1 (0 to 3)	2 (1 to 7)		
				odds ratio[a]		
CGM TAR, %	Active control	16 (26)	4 (-3 to 11)	8 (0 to 16)	-3 (-15 to 3)	-6 (-16 to 4)
	MOTIVATE-T2D	14 (27)	-2 (-8 to 5)	2 (-5 to 9)		
CGM CV, %	Active control	24 (5)	-2 (-3 to 0)	-1 (-2 to 1)	-1 (-2 to 3)	0 (-2 to 2)
	MOTIVATE-T2D	23 (6)	0 (-1 to 1)	-1 (-2 to 1)		
Mean Glucose, mmol/L	Active control	7 (3)	6 (-1 to 14)	9 (1 to 19)	-6 (-15 to 3)	-1 (-11 to 9)
	MOTIVATE-T2D	7 (3)	0 (-7 to 6)	8 (1 to 16)		
				% change[a]		
Total PA, min	Active control	1484 (574)	0 (-196 to 203)	196 (7 to 385)	-28 (-237 to 231)	-105 (-343 to 126)
	MOTIVATE-T2D	1393 (490)	-28 (-217 to 161)	91 (-84 to 259)		
MVPA, min	Active control	504 (273)	56 (-21 to 126)	56 (-14 to 126)	-21 (-112 to 77)	-21 (-112 to 70)
	MOTIVATE-T2D	427 (203)	35 (-35 to 105	35 (-28 to 98)		
MVPA10+, min	Active control	105 (168)	7 (-35 to 49)	-14 (-56 to 28)	35 (-21 to 91)	14 (-35 to 63)
	MOTIVATE-T2D	49 (77)	42 (0 to 77)	0 (-35 to 35)		

WC, waist circumference; BP, blood pressure; MAP, mean arterial pressure; Chol, cholesterol; HDL, high density lipoprotein; LDL, low density lipoprotein; CGM, continuous glucose monitor; TIR, time in range (3.9-10mmol/L); TBR, time below range

(<3.9mmol/L); TAR, time above range (>10.0mmol/L); CV, coefficient of variation; PA, physical activity; MVPA, moderate-to-vigorous intensity PA; MVPA10+, MVPA accumulated in bout ≥10 minutes. All PA data is ≥4 days wear time, including ≥3 weekdays and ≥1 weekend day for ≥16h wear time. All CGM data is from 14-day wear time. * Within- and between-group differences adjusted for study site (UK or Canada), sex (male or female) and age (40-60 or 61-75 years). [a] Log-transformed, interpret effect estimates as percent change. [b] Data were analysed using mixed effects binomial regression, interpret effect estimates as odds ratios. Where possible minimal clinically important differences (MCID) have been included; HbA1c 3 mmol/mol [37] [38] which is equivalent to a 6% change from baseline in this study, weight 5% change from baseline [39] which is equivalent to 5kg in this study, systolic BP 5mmHg [40], diastolic BP 2mmHg [41], MAP 2mmHg [41], Chol 5% change from baseline [39] which is equivalent to 0.3 mmol/L, HDL Chol 0.1 mmol/L [39], LDL Chol 0.1 mmol/L [39] which is equivalent to 3% change from baseline in this study, triglycerides 5% change from baseline [39] and TIR 3% change from baseline [32].

Table 4. Baseline and within- and between-group differences at 6 and 12 months follow-up; Questionnaires

Outcome (MCID)		Baseline, Mean (SD)	Within group difference (95% CI)*		Between group difference (95% CI) *	
			6 Months	12 Months	6 Months	12 Months
EQ-5D-5L (0.03 to 0.05)	Active control	0.84 (0.17)	0.02 (-0.01 to 0.05)	-0.01 (-0.04 to 0.02)	0.03 (-0.04 to 0.03	0.01 (-0.03 to 0.05)
	MOTIVATE-T2D	0.83 (0.14)	0.01 (-0.01 to 0.04)	0.00 (-0.03 to 0.02)		
SF12						
Physical Outcome (3 to 5)	Active control	46 (9)	0 (-3 to 2)	-1 (-3 to 1)	0 (-3 to 3)	0 (-4 to 3)
	MOTIVATE-T2D	46 (10)	0 (-2 to 2)	-1 (-3 to 1)		
Mental (3 to 5)	Active control	49 (9)	2 (-1 to 5)	-1 (-4 to 3)	-2 (-6 to 2)	4 (0 to 8)
	MOTIVATE-T2D	46 (12)	0 (-2 to 3)	3 (0 to 6)		
DTSQs						
Derived Overall Score	Active control	23 (8)	4 (2 to 6)	3 (1 to 5)	1 (-2 to 4)	-1 (-4 to 2)
	MOTIVATE-T2D	21 (8)	5 (3 to 7)	2 (0 to 4)		
Burden of Hyperglycaemia	Active control	3 (2)	0 (-1 to 0)	0 (-1 to 0)	0 (-1 to 0)	0 (-1 to 1)
	MOTIVATE-T2D	2 (2)	-1 (-1 to 0)	0 (-1 to 0)		
Burden of Hypoglycaemia	Active control	1 (1)	0 (0 to 0)	0 (-1 to 0)	0 (-1 to 0)	0 (0 to 1)
	MOTIVATE-T2D	1 (1)	0 (-1 to 0)	0 (0 to 0)		
DTSQc [a]						
	Active control		9 (6)			

Derived Overall Score	MOTIVATE-T2D	0 (6)
Burden of Hyperglycaemia	Active control	-0 (1)
	MOTIVATE-T2D	-0 (1)
Burden of Hypoglycaemia	Active control	-1 (1)
	MOTIVATE-T2D	-1 (1)

SF12, SF-12 Health Survey; DTSQs, Diabetes Treatment Satisfaction Questionnaire status version, DTSQc, Diabetes Treatment Satisfaction Questionnaire change version. The DTSQc was conducted at 6 month follow-up only and data presented are mean and SD for this time point. * Within and between-group differences adjusted for centre (UK or Canada), sex (male or female) and age (40-60 or 61-75 years). Where possible minimal clinically important differences (MCID) have been included; EQ-5D-5L between 0.03 and 0.05 [42], SF-12 physical outcome component between 3 and 5 [43], SF-12 mental component between 3 and 5 [43]

Acceptability of the MOTIVATE-T2D intervention

Qualitative interviews indicated high levels of satisfaction and acceptability of the MOTIVATE-T2D intervention in people with recently diagnosed T2D (online supplementary eTable 9). Highly valued elements of MOTIVATE-T2D included the role of the exercise specialist, where the counselling sessions and regular text messages were seen as a source of support and reassurance. The flexibility of the PA and exercise programme was also found to promote autonomy. Finally, the ability to track and monitor behaviour through the technology was viewed as an enabler. However, participants cited technical aspects of the watch and app as a challenge, highlighting the need for additional resources/training in the future.

Adherence: Participants in the MOTIVATE-T2D group exercised, measured via optical HR monitor, more regularly than active control during the 6 month intervention period and the 6 to 12 month follow-up (Table 5). The odds ratio (OR) of participants starting training (completed ≥1 training session) was more than 10 times higher for MOTIVATE-T2D compared to active control (OR 10.4, CI 3.4 to 32.1; MOTIVATE-T2D 93% started training, active control 58% started training). At 6 and 12 months the OR for participants still exercising were 7 (OR 7.1, CI 3.2 to 15.7; MOTIVATE-T2D 79% still training, active control 34% still training) and 3 (OR 2.9, CI 1.2 to 7.4; MOTIVATE-T2D 30% still training, active control 13% still training) times higher for MOTIVATE-T2D compared to active control, respectively (Figure 2a). At the end of the 6 month intervention period (weeks 24-28), 52% of MOTIVATE-T2D participants completed >150 minutes of MVE per week at least once compared to 17% in active control (Figure 2b). At the end of the 12 month follow-up period (weeks 48-52), this proportion dropped to 28% of MOTIVATE-T2D participants compared to 11% in the active control (Figure 2c).

Table 5. Device-derived exercise behaviour during the 6 month intervention period and 6 to 12 month follow-up

	0-6 Months mean (SD)	6-12 Months mean (SD)	Total mean (SD)
Number of exercise sessions (n)			
Active control	1.3±1.8	0.5±1.1	0.9±1.4
MOTIVATE-T2D	3.2±2.8	1.5±2.4	2.4±2.5
Adherence to prescribed exercise (% of 78 sessions)			
Active control	47±30	-	-
MOTIVATE-T2D	83±78	-	-
Duration (min)			
Active control	77±118	30±74	54±88
MOTIVATE-T2D	182±180	88±118	135±130
Duration MVE (min)			
Active control	78±112	31±75	54±88
MOTIVATE-T2D	185±153	88±132	137±133

MVE, moderate to vigorous intensity exercise; when calculating MVE, vigorous intensity exercise was multiplied by two.

At 12 months, 58% of participants wore the accelerometer for 16 hours on 4 or more days, including one weekend day, and 71% wore the device for at least 16 hrs on 1 day (online supplementary eTable 10). Wear time tended to be higher in MOTIVATE-T2D compared to the active control, and in participants recruited in the UK (online supplementary eTable 12). At 6 and 12 months, within and between group (Table 3) differences in PA outcomes were highly variable but there was no evidence of compensatory reduction in lifestyle PA alongside increases in purposeful exercise in either group. There was evidence that wear time may have influenced between group differences at follow-up (online supplementary eTable 15, 16).

Fidelity: Attendance at exercise counselling meetings was high (>80%) with little difference between groups (online supplementary eTable 19). Participant interaction with their counsellor by text message was higher in MOTIVATE-T2D (mean number

of texts sent by participants (49±38) than active control (18±14). Active control participants interacted more with the exercise videos (total video views; MOTIVATE-T2D 101, active control 135).

Data Availability

Data on likely primary outcomes, HbA1c and systolic blood pressure, were available from 95%, 78% and 74%, and 97%, 71% and 63% of participants at baseline, 6 and 12 months, respectively (online supplementary eTable 10). Availability of data for HbA1c appeared to be influenced by country, with data available from 81% of participants in the UK and 67% of participants in Canada at 12 months (online supplementary eTable 13, 14). Data availability for secondary outcomes ranged from 58-74% at 12 months (online supplementary eTable 10, 11). Wear time criteria influenced data availability for CGM with data availability at 12 months ranging from 58%-69% (online supplementary eTable 10). Wear time tended to be higher in MOTIVATE-T2D compared to the active control. However, wear time did not seem to influence baseline data or between-group differences (online supplementary eTable 17, 18). Study site also appeared to influence data availability, with UK participants having higher availability of blood lipids and questionnaires, but worse availability of CGM (online supplementary Table e12-14).

Preliminary outcomes

Baseline and within and between group differences in exploratory clinical outcomes are shown in Table 3-4. Confidence intervals and MCIDs, displayed in Tables 3-4, suggest plausible evidence of effect in favour of MOTIVATE-T2D for our likely primary outcomes HbA1c at 6 months and systolic blood pressure at 12 months, and other secondary outcomes at 6 and 12 months, including total cholesterol, LDL cholesterol, glucose time in range and quality of life indicated by the SF-12 mental component score (Figure 3).

At 6 months, changes to glucose lowering medication were seen in 10 active control participants (1 stopped a medication, 1 started a new medication, 5 decreased dose and 3 increased dose) and 13 MOTIVATE-T2D (3 stopped a medication, 1 started a new medication, 4 decreased dose and 5 increased dose) participants. At 12 months, medication changes were seen in 12 active control (2 started a new medication, 4

decreased dose and 6 increased dose) and 12 MOTIVATE-T2D (2 started a new medication, 3 decreased dose and 7 increased dose) participants. Medication changes were more common in Canadian participants (Canada 29 (46%); UK 10 (16%)).

At 6 months, four participants (UK 2; Canada 2) experienced a serious adverse event, with none of these considered related to the study processes or interventions. No serious adverse events were reported at 12 months.

Healthcare utilisation and intervention costs

The average cost of the interventions per participant was estimated to be MOTIVATE-T2D £321.32/ $532.17 and active control £128.99/ $169.37, based on delivery of the interventions to 100 people (online supplementary eTable 20 for cost breakdown). The wider healthcare and societal utilisation for MOTIVATE-T2D and active control groups are summarised in online supplementary eTable 21.

DISCUSSION

The findings of this trial support the acceptability of the MOTIVATE-T2D intervention and indicate that it is feasible to recruit and retain newly diagnosed people with T2D in a randomised trial with a 12 month follow-up. MOTIVATE-T2D was well received by participants and intervention adherence was excellent. There was evidence of higher engagement in purposeful exercise compared to the active control group and no apparent evidence of compensatory reductions in lifestyle PA. At follow-up, compared with active control, several outcomes showed a potential direction of effect in favour of MOTIVATE-T2D, including our proposed primary outcomes of HbA1c and systolic blood pressure.

The achieved recruitment and retention rates exceeded the predetermined progression criteria for the trial, with 93% of eligible people approached being randomised (criterion: >20%) and 82% of participants retained at 12 months (criterion: >80%) [24]. This recruitment rate compares well with the Early-ACTID trial, where 98% of eligible patients with newly diagnosed T2D (5- to 8-months since diagnosis) were randomised to receive usual care or lifestyle advice [14]. The retention rate also compares well with studies included in a systematic review of interventions using

pedometers or accelerometers to promote PA in people with T2D (N=7 randomised trials, mean 78%, range 63%-98%) [13].

The results from this trial suggest the MOTIVATE-T2D approach of using biometrics from wearable technologies to support a home-delivered, personalised behavioural counselling service was promising for the promotion, uptake and adherence to purposeful exercise in people with newly diagnosed T2D. The device-derived measurements of purposeful exercise demonstrated that MOTIVATE-T2D participants were more likely to start an exercise programme and mean weekly exercise duration was greater. Importantly, 1 in 2 MOTIVATE participants achieved the recommended 150 minutes of moderate-to-vigorous intensity exercise during the final month of the supported programme, compared to only 1 in 6 in the active control group. This was achieved despite both groups receiving similar support from an exercise specialist to co-design the personalised programme. It is difficult to compare the current data with previous trials where purposeful exercise has been performed unsupervised in people with T2D, as adherence data is rarely collected throughout interventions, and existing evidence has employed a variety of measurement methods [4 10]. However, adherence, assessed as prescribed sessions attended (MOTIVATE-T2D 78%), was comparable to data reported in a systematic review of supervised exercise interventions in people with T2D (18 trials, n=523, adherence: 87±8%) [4]. A comparable intervention commissioned by health services globally, where adherence data is available, could be cardiac rehabilitation which uses a combination of supervised and unsupervised purposeful exercise to promote secondary prevention in people who have had an acute coronary event or heart failure. Adherence to MOTIVATE-T2D compares favourably to a meta-analysis (14 trials, n=8176) of cardiac rehabilitation programmes, where mean adherence (prescribed sessions attended) was 67±18.2% [44].

During the follow-up period (6 to 12 months), participants in MOTIVATE-T2D had 3 times higher odds of still completing purposeful exercise versus those in the active control. However, there was a noticeable reduction in engagement with purposeful exercise during this unsupported phase following either intervention. Again, it is difficult to compare this to previous studies because of a lack of objective data on maintenance of purposeful exercise in unsupervised trials. However, studies measuring PA have shown that maintaining behaviour change after the conclusion of

an intervention is challenging [45]. Data from our qualitative evaluation suggest extending the text message feedback period may be a simple and cost-effective way of supporting participants maintain changes in behaviour. As such, future iterations of the intervention should explore the feasibility and cost implications of such a refinement. Future iterations could also look to introduce more social interactions to the intervention, as social connectedness has been shown to be an important determinant of long-term adherence [46 47]. Such interactions were difficult to incorporate into the current trial due to COVID-19 restrictions and small numbers limiting the use of online forums.

As per the study design, the active control group also completed a complex intervention containing a range of behaviour change techniques that have previously been associated with effective PA interventions, including goal setting, action planning, implementing graded tasks and self-monitoring of behaviour [48-52]. However, our findings suggest the addition of biofeedback to support a complex behavioural intervention was an effective strategy to partner with behaviour change. In particular, the provision of HR monitoring to guide participants' purposeful exercise in real time and facilitate personalised feedback from exercise specialists appeared to be an important strategy within the MOTIVATE-T2D intervention. Potential mechanisms of action used throughout the MOTIVATE-T2D intervention will be explored more in a complementary paper.

Alongside measurement of purposeful exercise, lifestyle PA was assessed by accelerometer. This combined measurement strategy reflected the two step intervention approach where engagement in purposeful exercise was encouraged alongside unstructured lifestyle-based PA. It was difficult to draw conclusions from the PA data due to the small sample size and large variability. However, increased engagement in purposeful exercise did not seem to lead to a compensatory reduction in lifestyle based PA, which has previously been cited as a concern during supervised exercise interventions [53 54]. The difficulty interpreting the PA data potentially reflects the challenges of using accelerometers to assess an intervention which encourages participation in purposeful exercise alongside ambulatory PA. Both the active control and MOTIVATE-T2D interventions encouraged participants to take part in types/modes of exercise whose intensity may not have been accurately captured by

the accelerometer (e.g., cycling or resistance exercise) [19 53]. Future studies could look to include cardiorespiratory fitness as an index of intervention effectiveness alongside lifestyle-based PA and engagement in purposeful exercise. Sustained increases in cardiorespiratory fitness following The Italian Diabetes Exercise Study 2, which targeted reallocation of sedentary time with light-intensity activity and purposeful MVPA in people with T2D, was predictive of improvements in HbA1c and coronary heart disease risk, independent of changes in MVPA or sedentary time [55].

Due to the association of HbA1c and systolic blood pressure with diabetes complications and mortality [56-58], the goal for clinical management of T2D is to achieve and maintain tight control of HbA1c and systolic blood pressure [59]. Therefore, HbA1c and systolic blood pressure are likely to be primary outcomes in a future RCT. Lee et al. [35] and Bell et al. [34] suggest using confidence intervals and the MCID to interpret feasibility trials. Using this approach there was evidence that a clinically important difference in HbA1c at 6 months and systolic blood pressure at 12 months between MOTIVATE-T2D and active control was plausible. Studies report a 5 mmHg reduction in systolic blood pressure as the MCID [40], and the 95% confidence intervals for systolic blood pressure in this study included 5 mmHg. Studies also suggest a difference of 3 mmol/mol would represent a clinically important difference in HbA1c [37 38], and the -5% between-group difference at 6 months is equivalent to ~3 mmol/mol. However, the between group difference for HbA1c was not maintained at 12 months. As discussed above, future iterations of the intervention should look to improve maintenance of purposeful exercise with the aim of sustaining long term improvements in HbA1c. It is difficult to compare the between-group differences in HbA1c and systolic blood pressure to previous research as most RCTs use usual care control groups rather than the contact-matched active control group in the current study. However, a meta-analysis of unsupervised behavioural interventions suggested that they were not associated with changes in HbA1c unless combined with dietary advice [4]. A similar meta-analysis of unsupervised behavioural interventions in people with T2D on systolic blood pressure suggested a small (weighted mean difference 3 mmHg, 95% CI −5 to −1) but significant effect [60]. As well as the encouraging data for HbA1c and systolic blood pressure, there was evidence that a clinically important difference may be plausible for a number of secondary outcomes, including total cholesterol and LDL cholesterol at 12 months [39] and quality of life at 12 months, indicated by the SF-12

mental component score [43]. The UK prospective diabetes study showed the importance of dyslipidaemia for CVD risk in people with T2D [61]. As such, potential improvements in these secondary outcomes are highly relevant for people with T2D. As discussed above, the active control group received a complex intervention and it is plausible that between-group differences would have been larger if compared to a usual care control group, increasing the likelihood of clinically important effects in the real-world.

Implications for planning a future trial

Based on HbA1c as the primary outcome, a full trial comparing MOTIVATE-T2D versus active control would require recruitment of 586 participants with recently diagnosed T2D. This estimate is based on detecting a minimum clinically important difference of 3 mmol/mol [37 38], a standard deviation at baseline of 10 mmol/mol (as seen in this feasibility trial), and an assumed attrition rate of 20% (as seen in this feasibility trial), at 90% power and a two-tailed 5% α level.

Due to restrictions and uncertainties caused by the COVID-19 pandemic, the trial used a decentralised design. Our experience was that the decentralised design could positively impact trial feasibility, as recruitment was not limited by geographic constraints. As suggested previously [62], the decentralised design may also have provided opportunity for greater diversity in our trial population. Compared to Early-ACTID, which also recruited people with newly diagnosed T2D in the UK, the current trial recruited a more ethnically diverse population [14]. Participant interviews suggested the decentralised approach was broadly acceptable, although future iterations may need to consider how participants are supported with taking blood samples. Considerations should also be made for differences between the UK and Canada in research infrastructure. During study planning, there were no services that could process capillary blood samples in Canada. This led to the approach of shipping samples to the UK for analysis. We believe this additional step may have been responsible for the reduced HbA1c and blood lipid data availability in Canada. Although data availability for outcome measures was good, the centralised Early-ACTID trial collected primary outcome data (HbA1c) from 98% of participants at 12 months. Simple refinements to the study procedures could be made to collect more complete and meaningful data. This could be achieved by providing greater financial

incentives [63]. Changes to survey formatting and better use of data validation filters to reduce incorrectly entered measures, which accounted for approximately 1/3 of missing questionnaire and anthropometric data. Finally, use of next generation PA monitors that collect accelerometer data in real-time could increase compliance with wear time criteria [64].

This study has some limitations. First, the study was not designed or powered to definitively assess the efficacy of MOTIVATE-T2D in people with recently diagnosed T2D. Secondly, there was evidence of imbalances between intervention and active control groups in their demographic characteristics. Thirdly, participant and researcher blinding were not possible because of the nature of the intervention. Fourthly, it is not known if active control participants wore the blinded HR monitor for all purposeful exercise sessions. Therefore, device-derived purposeful exercise metrics may be underestimated in the active control group. Finally, the study did not employ a strict target driven approach to the regulation of glucose lowering medication which may have influenced outcomes [65]. Given these limitations and the feasibility design of this trial, our findings should be considered preliminary, and encouraging trends require confirmation in a larger, adequately powered RCT.

In summary, the findings of this feasibility trial indicate the MOTIVATE-T2D intervention is feasible and acceptable with promising effects on adherence to purposeful exercise. This feasibility study will inform the funding application for a fully powered RCT to assess the clinical effectiveness and cost-effectiveness of the MOTIVATE-T2D intervention in people with recently diagnosed T2D.

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Contributors

KH, JL, RCA, CAJ, HJ, MEJ JPL, CM, RMP, JS, VSS, AMM and MC designed the protocol. RCA, CAJ, HJ, MEJ JPL, CM, JS, VSS, AMM and MC developed the original idea for the trial. KH, JL, BJRB, and SP acquired the data. KH, JL, SB, KF, JJ, MEJ, CM, SP, RMP, CLR, JS and MC analysed the data. KH, JL and MC undertook the first draft of the manuscript. All authors were involved in critical evaluation and revision of the manuscript and have given final approval of the manuscript accepting responsibility for all aspects. MC acted as guarantor.

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Competing interests

The authors have no competing interests.

Patient consent for publication

Not required

Data availability statement

Data are available on reasonable request. Access to data can be arranged through the principal investigator of the study: Dr Matt Cocks to discuss data sharing, data requirements and conflicts of interest, in line with any EU and other regulations, including ethics approvals.

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FIGURE LEGENDS

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) flow chart.

Figure 2. Exercise behaviour derived from optical heart rate monitoring
A. Training drop-off by week in MOTIVATE-T2D and active control participants. B. proportion of participants achieving MVE duration at least once during weeks 24-28. B. proportion of participants achieving MVE duration at least once during weeks 48-52. MVE, moderate to vigorous intensity exercise; when calculating MVE, vigorous intensity exercise was multiplied by two.

Figure 3. Between-group differences in outcome measures with confidence intervals
Confidence intervals presented 95%, 90%, 85% and 80%. Minimal clinically important differences (MCID), indicated by – – . A. between-group differences in HbA1c at 6 months, MCID 3 mmol/mol [37 38] which is equivalent to a 6% change from baseline in this study. B. between-group differences in HbA1c at 12 months, MCID 3 mmol/mol [37 38] which is equivalent to a 6% change from baseline in this study. C. between-group differences in systolic blood pressure (BP) at 12 months, MCID 5 mmHg [40]. D. between-group differences in total cholesterol at 12 months, MCID 5% reduction [39]. E. between-group differences in low-density-lipoprotein (LDL) cholesterol at 12 months, MCID 0.1 mmol/L [39]. F. between-group differences in the 12-item short form Health Survey (SF-12) mental health component score at 12 months, MCID between 3 and 5 [43].

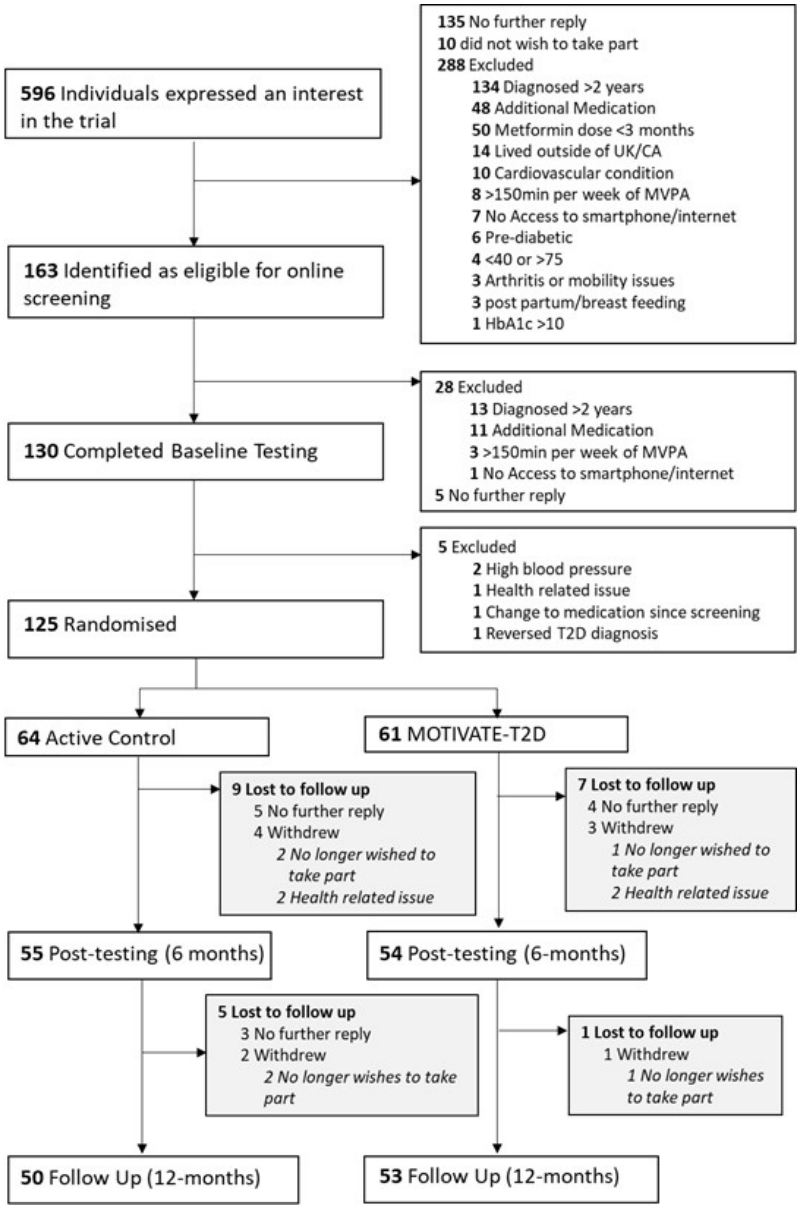

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) flow chart.

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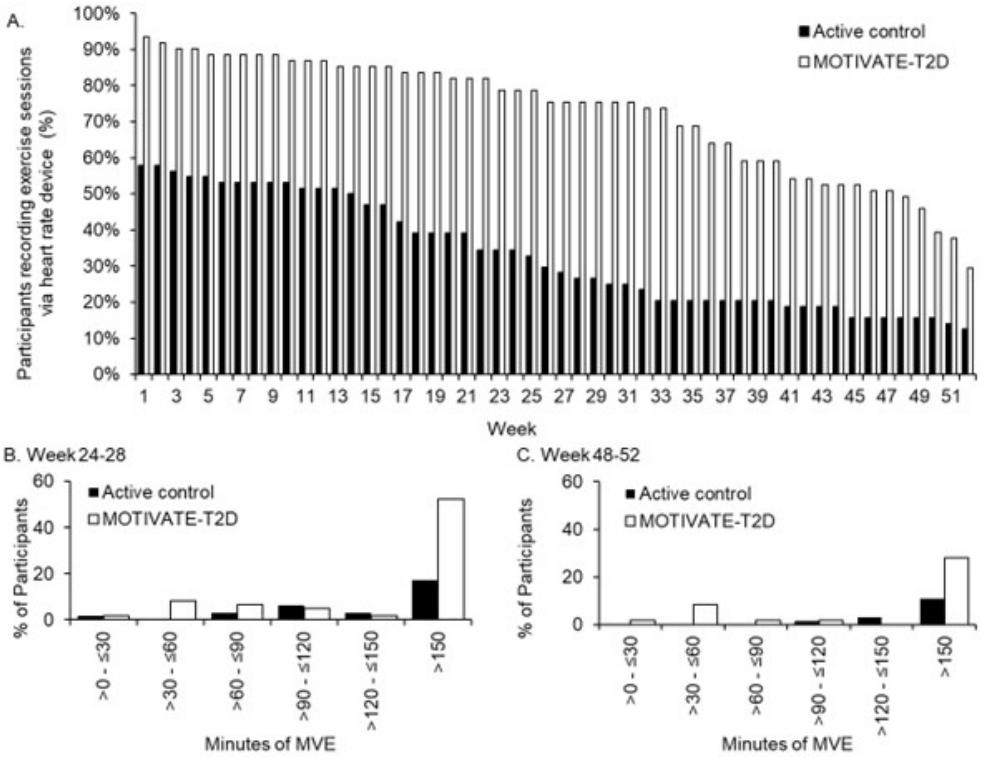

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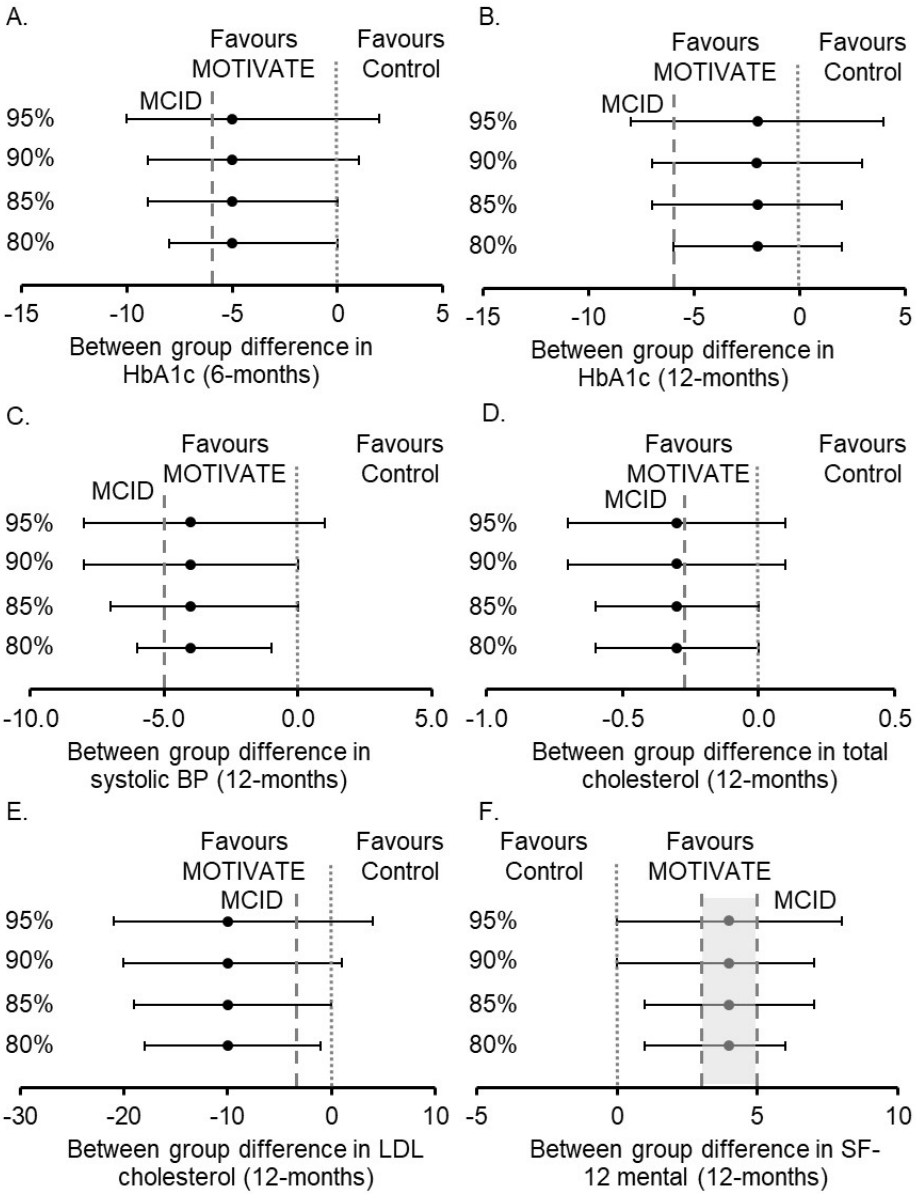

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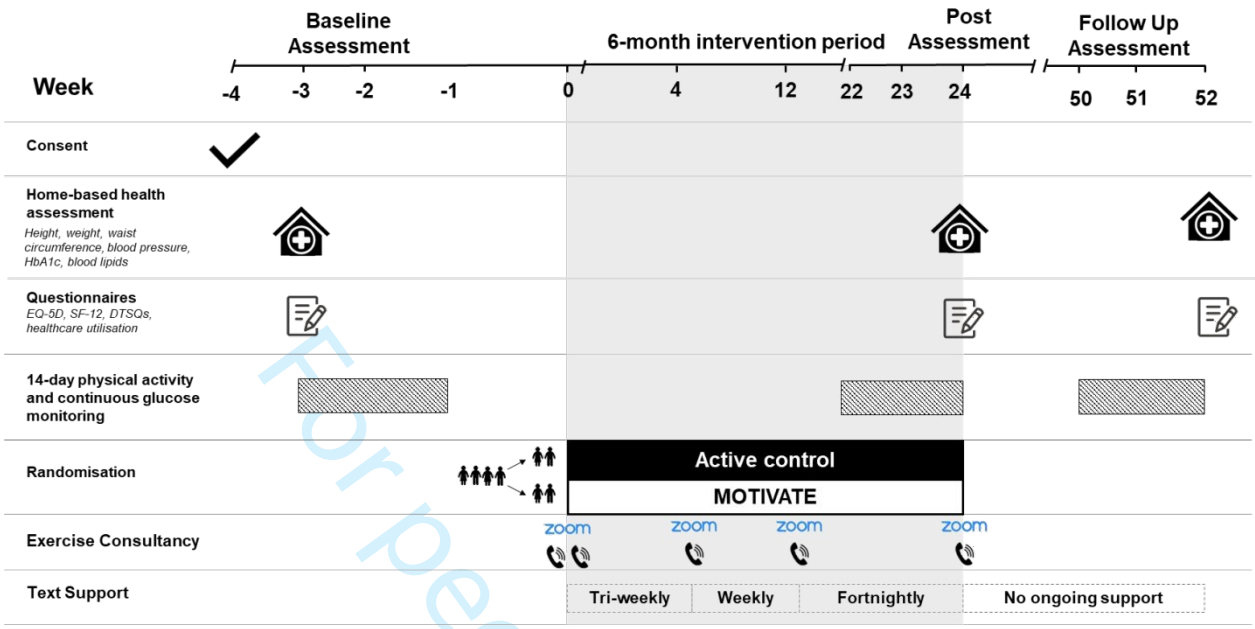
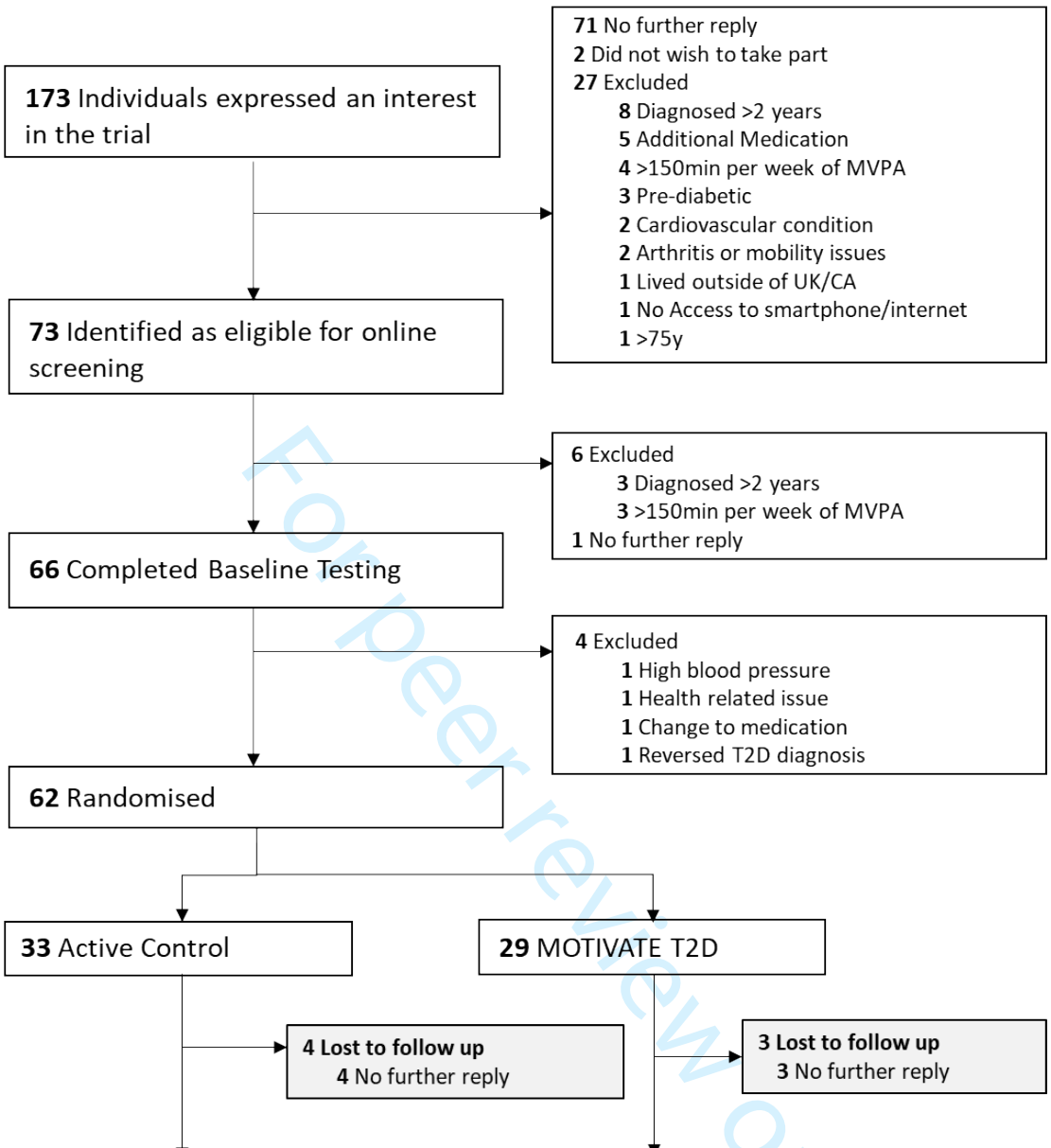
148x190mm (150 x 150 DPI)

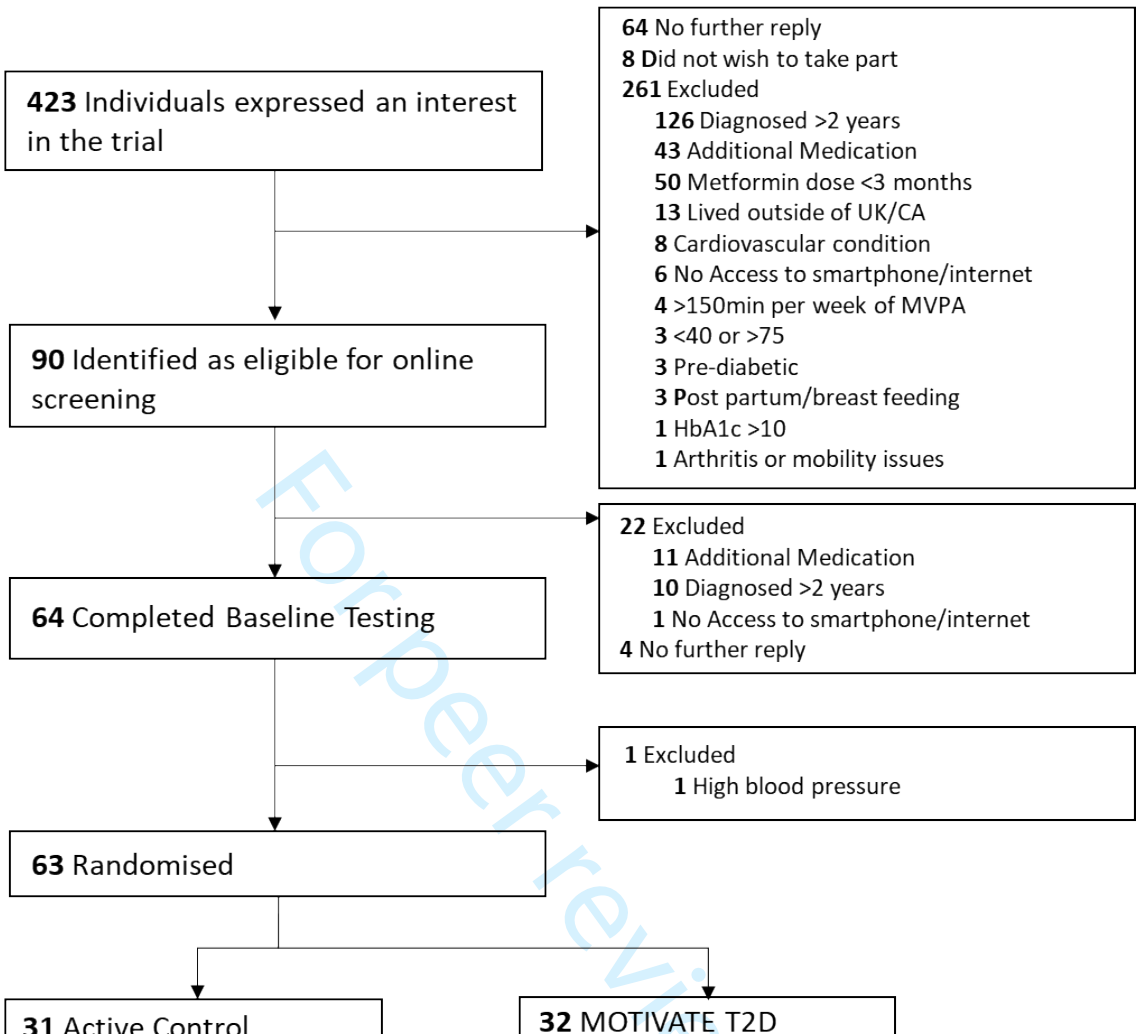
Online supplementary eFigures and eTables



eFigure 1. Schematic of the study timeline.



eFigure 2. UK only Consolidated Standards of Reporting Trials (CONSORT) flow chart.



eFigure 3. Canada only Consolidated Standards of Reporting Trials (CONSORT) flow chart.

eTable 1. Influence of recruitment strategy on expressions of interest, participants randomised and recruitment rate

Recruitment strategy	Expressions of interest, N (% of expressions of interest n=596)	Excluded, N (% of expression of interest for strategy)	Did not reply, N (% of expression of interest for strategy)	Randomised, N (% of those randomised n=125)	Success rate, % of expression of interest for strategy randomised
GP database searches	94 (16)	13 (14)	37 (39)	44 (35)	47
Third party recruitment Services	326 (55)	239 (73)	49 (15)	38 (30)	11
Local media articles/ classifieds	83 (14)	54 (65)	18 (22)	11 (9)	13
Diabetes education sessions	10 (2)	0 (0)	0 (0)	10 (8)	100
Referral from Friend	12 (2)	2 (17)	0 (0)	10 (8)	83
Adverts in clinical settings	24 (4)	15 (63)	3 (2)	6 (5)	25
Consent to Contact Database	9 (2)	0 (0)	4 (44)	5 (4)	56
Study Website	10 (2)	7 (70)	2 (20)	1 (1)	10
Unknown	15 (3)	0 (0)	15 (100)	0 (0)	0
Advert on Diabetes Canada social media	13 (2)	0 (0)	12 (100)	1 (1)	8

eTable 2. Influence of recruitment source on participant demographics

Recruitment strategy, N= participants recruited	Male, N (%)	>60, N (%)	White, N (%)	University education, N (%)	Full time employment, N (%)
GP database searches, N=44	23 (52)	15 (34)	40 (91)	17 (17)	26 (59)
Third party recruitment Services, N=37	22 (59)	9 (24)	25 (68)	19 (51)	26 (70)
Local media articles, N=11	6 (55)	8 (73)	11 (100)	5 (45)	4 (36)
Diabetes education sessions, N=10	7 (70)	1 (10)	8 (80)	4 (40)	5 (50)
Referral from Friend, N=10	4 (40)	2 (20)	7 (70)	3 (30)	6 (60)
Adverts in clinical settings, N=6	1 (17)	1 (17)	3 (50)	5 (83)	3 (50)
Consent to Contact Database, N=5	2 (40)	1 (20)	5 (100)	2 (40)	3 (60)
Study Website, N=1	0	0	1 (100)	1 (100)	1 (100)
Advert on Diabetes Canada social media, N=1	0	0	1 (100)	0	1 (100)

eTable 3. Participant satisfaction with their involvement in the trial

The following are verbatim quotes regarding the research process:
The way it works is pretty good, the technology side of it, Zoom / Teams…it works very well so the communication side is good." (Participant 17-UK)
[If the trial were to be repeated in a clinic setting] "for me personally I would find that hard to get to because I don't drive now so this part of it being able to do in your own home I think is really good." (Participant 20-UK)
"All the instructions were clear, the feedback I had to give on my results, what I had to do with the equipment, returning and stuff, it was adequate really, more than adequate." "it was all prepaid envelope, I just took it to the main post office sealed, sent off, no problem, we have a post office very close by so that was just a little job while you're out shopping." (Participant 52-UK)
"I don't know that I had many challenges, because it was provided in such a seamless, customized format, that there really, I wouldn't say I was challenged in any way." "it's been such a pleasant experience that I'm more willing to engage as a research participant again." (Participant 02-CA)
"I'm a bit pen and paper person rather than technology but I think everything was really well, really explained so well and so easy to follow and you had that back up, that support if you needed it." "the testing booklet, that was really, really helpful and [the researcher] also gave me a link to a website that actually showed like videos of how to do the finger prick test and also how to attach the blood glucose monitor…it was very easy to follow" (Participant 02-UK)
"everything was well laid out. I really liked the detail on the instructions on what to use and how to use it and I particularly thought it was a good personal touch that the actual research instigator was the guinea pig so to speak with all the pictures so yeah it's a personal touch but also it kind of entrusts you that they've gone through it, they've had to endure it so yeah everything worked fine that side." (Participant 01-UK)
"I found that the questionnaires that I had to fill in irritating because they didn't see coherent, they weren't set out to say we're looking at this, tell us about that, they didn't ask questions which would allow me then to go on and make a sensible answer. I didn't find their terms particularly well." (Participant 27-UK)
"I'm not comfortable with needles. When I opened the box and saw that there was a needle in the middle, I started to panic, thinking that's going to hurt… I had to look at the video. I was a bit nervous, but the little needle didn't hurt at all"
"The amount of blood that they're looking for is significant from just a basically a finger prick, which is what the little device does. And it was hard to get. I never got enough blood into the vial."

eTable 4. Baseline medications

N (%)	Total	Active control	MOTIVATE-T2D
Oral hypoglycaemic agents			
Metformin	69 (55)	37 (58)	32 (52)
Antihypertensive agents	78 (62)	40 (63)	40 (62)
Renin-angiotensin agent	35 (28)	21 (33)	14 (23)
Thiazide diuretic	12 (10)	4 (6)	8 (13)
β blocker	11 (9)	5 (8)	6 (10)
Calcium-channel blocker	19 (15)	10 (16)	9 (15)
Other	1 (1)	0 (0)	1 (2)
Lipid-lowering drugs	50 (40)	25 (39)	25 (41)
Statin	49 (39)	24 (38)	25 (41)
Selective cholesterol-absorption inhibitor	1 (1)	1 (2)	0 (0)

eTable 5. Baseline demographic characteristics: UK

	Total	Active control	MOTIVATE-T2D
N	62	33	29
Age, years, mean (SD)	55 (9)	56 (9)	56 (8)
Female, N (%)	30 (48)	16 (48)	14 (48)
Male, N (%)	32 (52)	17 (52)	15 (52)
Duration of T2D, months, mean (SD)	13 (6)	12 (6)	12 (6)
Ethnicity, N (%)			
White	54 (87)	30 (91)	24 (83)
African or Caribbean	3 (5)	2 (6)	1 (3)
Asian	2 (3)	1 (3)	1 (3)
Other or mixed	3 (5)	0 (0)	3 (10)
Marital status, living arrangements, N (%)			
Married, living with spouse	41 (66)	20 (61)	21 (72)
Married, living arrangement unknown	1 (2)	0 (0)	1 (3)
Single, living alone	9 (15)	7 (21)	2 (7)
Single, living with others	2 (3)	2 (6)	0 (0)
Separated, living alone	5 (8)	2 (6)	3 (10)
Separated, living with spouse/partner	1 (2)	0 (0)	1 (3)
Widowed, living alone	2 (3)	1 (3)	1 (3)
Rather not say, living with spouse/ partner	1 (2)	1 (3)	0 (0)
Educational Attainment, N (%)			
Secondary	13 (21)	8 (24)	5 (17)
Further	24 (39)	9 (27)	15 (52)
Higher	25 (40)	16 (48)	9 (31)
Employment Situation, N (%)			
Full Time	33 (53)	16 (48)	17 (59)
Part Time	6(10)	3 (9)	3 (10)
Retired	11 (18)	7 (21)	4 (14)
Student	1 (2)	0 (0)	1 (3)
Volunteer	0 (0)	0 (0)	0 (0)
Stay at Home	1 (2)	1 (3)	0 (0)

Unable: Care	1 (2)	0 (0)	1 (3)
Unable: Health	8 (13)	5 (13)	3 (10)
Unemployed	1 (2)	1 (2)	0 (0)

eTable 6. Baseline medications: UK

N (%)	Total	Active control	MOTIVATE-T2D
Oral hypoglycaemic agents			
Metformin	26 (42)	17 (52)	9 (31)
Antihypertensive agents	50 (81)	29 (88)	21 (72)
Renin-angiotensin agent	23 (37)	16 (48)	7 (24)
Thiazide diuretic	5 (8)	2 (6)	3 (10)
β blocker	7 (11)	4 (12)	3 (10)
Calcium-channel blocker	14 (23)	7 (21)	7 (24)
Other	1 (2)	0 (0)	1 (3)
Lipid-lowering drugs	30 (48)	17 (52)	13 (45)
Statin	30 (48)	17 (52)	13 (45)
Selective cholesterol-absorption inhibitor	0 (0)	0 (0)	0 (0)

eTable 7. Baseline demographic characteristics: Canada

	Total	Active control	MOTIVATE-T2D
N	63	31	32
Age, years, mean (SD)	54 (9)	53 (8)	53 (9)
Female, N (%)	30 (48)	15 (48)	15 (47)
Male, N (%)	33 (53)	16 (52)	17 (53)
Duration of T2D, months, mean (SD)	14 (7)	14 (7)	14 (7)
Ethnicity, N (%)			
White	47 (76)	22 (71)	25 (78)
African or Caribbean	2 (3)	0 (0)	2 (6)
Asian	12 (23)	7 (23)	5 (16)
Other or mixed	2 (3)	2 (6)	0 (0)
Marital status, living arrangements, N (%)			
Married, living with spouse	49 (78)	24 (77)	25 (78)
Married, living alone	1 (2)	0 (0)	1 (3)
Single, living alone	6 (10)	3 (10)	3 (9)
Single, living with child	1 (2)	0 (0)	1 (3)
Single, living arrangement unknown	1 (2)	1 (3)	0 (0)
Separated, living alone	4 (6)	3 (10)	1 (3)
Widowed, living with spouse/partner	1 (2)	0 (0)	1 (3)
Educational Attainment, N (%)			
Secondary	6 (10)	3 (10)	3 (9)
Further	26 (41)	14 (45)	12 (38)
Higher	31 (49)	14 (45)	17 (53)
Employment Situation, N (%)			
Full Time	42 (68)	24 (73)	18 (62)
Part Time	5 (8)	1 (3)	4 (14)
Retired	10 (16)	4 (120	6 (21)
Student	1 (2)	1 (3)	0 (0)
Volunteer	2 (3)	1 (3)	1 (3)
Stay at Home	0 (0)	0 (0)	0 (0)
Unable: Care	0 (0)	0(0)	0 (0)
Unable: Health	1 (2)	0 (0)	1 (3)

Unemployed	2 (3)	0 (0)	2 (7)

eTable 8. Baseline medications: Canada

N (%)	Total	Active control	MOTIVATE-T2D
Oral hypoglycaemic agents			
Metformin	43 (68)	20 (65)	23 (72)
Antihypertensive agents	28 (44)	11 (35)	17 (53)
Renin-angiotensin agent	12 (19)	5 (16)	7 (22)
Thiazide diuretic	7 (11)	2 (6)	5 (16)
β blocker	4 (6)	1 (3)	3 (9)
Calcium-channel blocker	5 (8)	3 (10)	2 (6)
Other	0 (0)	0 (0)	0 (0)
Lipid-lowering drugs	20 (32)	8 (26)	12 (38)
Statin	19 (30)	7 (23)	12 (38)
Selective cholesterol-absorption inhibitor	1 (2)	1 (3)	0 (0)

eTable 9. Participant acceptability of MOTIVATE-T2D intervention

The following are verbatim quotes of the positive experiences of MOTIVATE-T2D from participants
Support from the exercise counsellor (counselling sessions and text messages
“I think that the interactivity with someone you get to know and trust and feel a somewhat, albeit virtual connection to has been … I'll say the backbone of the program. If somebody emailed this to me, I don't think I would have taken it to heart as much as having a personal connection.”
“The motivational texts that came in once a week, and then every other week, I found to be very helpful. …it was personalized, which I really liked. And then I would respond back”
Flexibility of the physical activity program
“The goal setting process was very realistic and directed at me, I didn't feel pressured to do more than I wanted to, rather it just kind of supported what I wanted to get out of it.”
“One of the things that helped me a fair bit was the flexibility I had with the exercise because I developed some of my own exercise routines…I have a pool in the backyard, so I developed some routines there for exercising in the water.”
Tracking and monitoring behaviour
“It made me more aware…I saw the numbers and I knew if I was doing well, …then if it wasn't going in the right direction, I had to do a little bit more.”
“I think it's just part of my life now…I'm always using it, recording stuff… looking at how I'm doing… for the number of steps I make. I always have targets…so it does motivate me to make sure that I meet my goals each day.”
Technical aspects of the watch and mobile app
“It was great when K was running things for me, but a bit more instruction on how to use the watch would have been useful when I got to do things myself.”
"it's certainly easier to program, to plan your sessions through the computer as opposed to on the app. … if there was some way of making that better on the app."

eTable 10. Data availability: HbA1c, anthropometrics, blood pressure, device derived physical activity and continous glucose monitoring

All data Control/MOTIVATE-T2D	Baseline, N (%)	6-month, N (%)	12-month, N (%)
Drop-out	-	109 (87)	103 (82)
HbA1c	119 (95) 63 (98) / 56 (92)	98 (78) 48 (75) / 50 (82)	92 (74) 44 (69) / 48 (79)
Weight	125 (100)	87 (70) 42 (66) / 46 (75)	80 (64) 39 (61) / 41 (67)
Waist circumference	125 (100)	87 (70) 42 (65) / 46 (75)	77 (62) 38 (59) / 39 (64)
Systolic blood pressure	121 (97) 63 (98) / 58 (95)	89 (71) 43 (67) / 46 (75)	79 (63) 38 (59) / 41 (67)
Diastolic blood pressure	122 (98) 63 (98) / 59 (97)	89 (71) 43 (67) / 46 (75)	78 (62) 38 (59) / 40 (66)
Total Cholesterol	85 (68) 43 (67) / 41 (67)	63 (50) 33 (52) / 30 (49)	64 (51) 30 (47) / 34 (56)
HDL Cholesterol	93 (74) 48 (75) 45 (74)	76 (61) 35 (55) / 41 (67)	74 (59) 35 (55) / 39 (64)
LDL Cholesterol	81 (65) 44 (69) / 37 (61)	68 (54) 33 (52) / 35 (57)	62 (50) 28 (44) / (34 (56)
Triglycerides	83 (66) 43 (41) / 40 (66)	67 (54) 33 (52) / 34 (56)	63 (50) 29 (45) / 34 (56)
Device derived PA: Met wear time criteria			
4-day (3 WD, 1WE)	105 (84) 54 (85) / 51 (84)	61 (49) 28 (48) / 33 (54)	73 (58) 32 (50) / 41 (67)
3-day (2WD, 1WE)	105 54 (84) / 51 (84)	61 (49) 28 (44) / 33 (54)	76 (61) 34 (53) / 42 (69)
3-day (any day)	112 (90) 57 (89) / 55 (90)	65 (52) 30 (47) / 35 (57)	80 (64) 38 (59) / 42 (69)
1-day	116 (93) 60 (94) / 56 (92)	71 (57) 34 (53) / 37 (61)	89 (71) 42 (66) / 47 (77)
CGM: Met wear time criteria			
14-Day	95 (76) 46 (72) / 49 (80)	90 (72) 43 (67) / 47 (77)	72 (58) 30 (47) / 42 (69)
10-Day	105 (84) 52 (81) / 53 (87)	93 (74) 45 (70) / 48 (79)	75 (60) 30 (47) / 45 (74)
7-Day	107 (86) 54 (58) / 53 (87)	97 (78) 49 (77) / 48 (79)	86 (69) 37 (58) / 49 (80)

HDL, high density lipoprotein; LDL, low density lipoprotein; PA, physical activity; CGM, continous glucose monitor; WD, week day; WE, weekend day; All PA data is ≥16h wear time; 14-day wear time for CGM achieved if ≥70% of data available; 10- and 7-day wear time for CGM achieved if ≥80% of data available

eTable 11. Data availability: Questionnaires

All data Control/MOTIVATE-T2D	Baseline, N (%)	6-month, N (%)	12-month, N (%)
Drop-out	-	109 (87)	103 (82)
EQ-5D-5L	125 (100)	94 (75) 44 (69) / 51 (84)	88 (70) 41 (64) / 47 (77)
SF12	118 (94) 63 (98) / 55 (90)	88 (70) 41 (64) / 47 (77)	82 (66) 39 (61) / 43 (70)
DTSQs	125 (100)	94 (75) 44 (69) / 50 (82)	86 (69) 41 (64) / 45 (74)
DTSQc	-	92 (74) 43 (67) / 49 (80)	-
Healthcare usage	121 (97) 64 (100) / 57 (93)	93 (74) 44 (69) / 49 (80)	86 (69) 40 (63) / 46 (75)

VAS, visual analogue scale; SF12, SF-12 Health Survey; BREQ-2, Behavioural Regulation in Exercise Questionnaire version 2; DTSQs, Diabetes Treatment Satisfaction Questionnaire status version, DTSQc, Diabetes Treatment Satisfaction Questionnaire change version. DTSQc was only taken at 6-months post.

eTable 12. UK and Canada data availability: Device derived physical activity and continous glucose monitoring

	UK			Canada		
	Baseline, N (%)	6-month, N (%)	12-month, N (%)	Baseline, N (%)	6-month, N (%)	12-month, N (%)
Drop-out	-	55 (89)	53 (85)	-	54 (86)	50 (79)
PA: Met wear time						
4-day (3 WD, 1WE)	54 (87)	17 (27)	40 (65)	51 (82)	44 (70)	33 (52)
3-day (2WD, 1WE)	54 (87)	17 (27)	40 (65)	51 (81)	44 (70)	36 (57)
3-day (any day)	57 (92)	19 (31)	41 (66)	55 (87)	46 (73)	39 (62)
1-day	59 (95)	21 (34)	46 (74)	57 (90)	50 (79)	43 (68)
CGM: Met wear time						
14-Day	43 (69)	45 (73)	30 (48)	53 (83)	45 (71)	42 (67)
10-Day	48 (77)	48 (77)	32 (52)	58 (92)	46 (73)	43 (68)
7-Day	49 (79)	51 (82)	39 (63)	59 (94)	47 (75)	47 (75)

PA, physical activity; CGM, continous glucose monitor; WD, week day; WE, weekend day; All PA data is ≥16h wear time; 14-day wear time for CGM achieved if ≥70% of data available; 10- and 14-day wear time for CGM achieved if ≥80% of data available

eTable 13. UK and Canada data availability: HbA1c, anthropometrics, blood pressure and blood lipids

	UK			Canada		
	Baseline, N (%)	6-month, N (%)	12-month, N (%)	Baseline, N (%)	6-month, N (%)	12-month, N (%)
Drop-out	-	55 (89)	53 (85)	-	54 (86)	50 (79)
HbA1c	62 (100)	50 (81)	50 (81)	57 (90)	48 (76)	42 (67)
Weight	62 (100)	41 (66)	42 (68)	63 (100)	46 (73)	38 (60)
Waist circumference	62 (100)	42 (68)	39 (63)	63 (100)	45 (71)	38 (60)
Systolic blood pressure	60 (97)	43 (69)	40 (65)	61 (97)	46 (73)	39 (62)
Diastolic blood pressure	60 (97)	43 (69)	40 (65)	62 (98)	46 (73)	38 (60)
Total Cholesterol	43 (69)	33 (53)	37 (60)	41 (65)	30 (48)	27 (43)
HDL Cholesterol	47 (76)	36 (58)	43 (69)	46 (73)	40 (63)	31 (49)
LDL Cholesterol	42 (68)	33 (53)	36 (58)	39 (62)	35 (56)	26 (41)
Triglycerides	43 (69)	32 (52)	36 (58)	40 (63)	35 (56)	27 (43)

HDL, high density lipoprotein; LDL, low density lipoprotein

eTable 14. UK and Canada data availability: Questionnaires

	UK			Canada		
	Baseline, N (%)	6-month, N (%)	12-month, N (%)	Baseline, N (%)	6-month, N (%)	12-month, N (%)
Drop-out	-	55 (89)	53 (85)	-	54 (86)	50 (79)
EQ-5D-5L	62 (100)	48 (77)	49 (79)	63 (100)	46 (73)	39 (62)
SF12	57 (92)	45 (73)	45 (73)	61 (97)	43 (68)	37 (59)
DTSQs	62 (100)	48 (77)	49 (79)	63 (100)	46 (73)	37 (59)
DTSQc	-	46 (74)	-	-	46 (73)	-
Healthcare usage	58 (94)	48 (77)	47 (76)	63 (100)	42 (65)	37 (56)

SF12, SF-12 Health Survey; DTSQs, Diabetes Treatment Satisfaction Questionnaire status version, DTSQc, Diabetes Treatment Satisfaction Questionnaire change version

eTable 15. Baseline device derived physical activity dependent on wear time

All min	4-day (3WD, 1WE)		3-day (2WD, 1WE)		3-day (any days)		1-day	
	Active control, Mean (SD)	MOTIVATE-T2D, mean (SD)	Active control, Mean (SD)	MOTIVATE-T2D, mean (SD)	Active control, Mean (SD)	MOTIVATE-T2D, mean (SD)	Active control, Mean (SD)	MOTIVATE-T2D, mean (SD)
Total PA	1484 (574)	1393 (490)	1484 (574)	1393 (490)	1505 (581)	1392 (497)	1498 (581)	1351 (511)
Light PA	980 (406)	966 (315)	980 (406)	966 (315)	1001 (434)	959 (322)	1008 (434)	945 (329)
Moderate PA	490 (259)	420 (203)	490 (259)	420 (203)	490 (259)	406 (203)	483 (259)	399 (210)
Vigorous PA	14 (14)	7 (7)	14 (14)	7 (7)	14 (14)	7 (7)	7 (14)	7 (7)
MVPA	504 (273)	427 (203)	504 (273)	427 (203)	504 (266)	413 (210)	490 (266)	406 (210)
MVPA10+	105 (168)	49 (77)	105 (168)	49 (77)	112 (175)	49 (77)	105 (168)	49 (77)

WD, week day; WE, weekend day; PA, physical activity; MVPA, moderate-to-vigorous intensity; MVPA10+, MVPA accumulated in bout ≥10 minutes; All PA data is ≥16h wear time

eTable 16. Between group differences at 6- and 12-months follow-up for device derived physical activity dependent on wear time

	4-day (3WD, 1WE)		3-day (2WD, 1WE)		3-day (any days)		1-day	
	6-months follow-up	12-months follow-up	6-months follow-up	12-months follow-up	6-months follow-up	12-months follow-up	6-months follow-up	12-months follow-up
Total PA	-28 (-287 to 231)	-105 (-343 to 126)	-21 (-280 to 231)	-98 (-329 to 133)	35 (-210 to 287)	-42 (-238 to 182)	-35 (-273 to 196)	-49 (-259 to 168)
Light PA	-7 (-196 to 182)	-70 (-238 to 105)	-7 (-196 to 182)	-70 (-245 to 98)	28 (-161 to 210)	-35 (-224 to 126)	-21 (-196 to 154)	-35 (-189 to 119)
Moderate PA	-21 (-112 to 70)	-21 (-105 to 70)	-14 (-105 to 77)	-7 (-91 to 77)	21 (-70 to 105)	7 (-70 to 84)	-14 (-98 to 70)	0 (-70 to 77)
Vigorous PA	0 (-7 to 7)	-7 (-14 to 0)	0 (-7 to 7)	-7 (-14 to 7)	0 (-7 to 7)	0 (-7 to 7)	0 (-7 to 7)	-7 (-14 to 7)
MVPA	-21 (-112 to 77)	-21 (-112 to 70)	-14 (-112 to 84)	-7 (-91 to 84)	21 (-70 to 105)	7 (-70 to 91)	-14 (-98 to 70)	0 (-77 to 77)
MVPA10+	35 (-21 to 91)	14 (-35 to 63)	35 (-21 to 91)	21 (-28 to 70)	42 (-7 to 91)	21 (-21 to 63)	35 (-14 to 77)	28 (-14 to 70)

WD, week day; WE, weekend day; PA, physical activity; MVPA, moderate-to-vigorous intensity PA; MVPA10+, MVPA accumulated in bout ≥10 minutes;

eTable 17. Baseline continous glucose monitoring dependent on wear time

All min	14-day		10-day		7-day	
	Active control, Mean (SD)	mHealth, mean (SD)	Active control, Mean (SD)	mHealth, mean (SD)	Active control, Mean (SD)	mHealth, mean (SD)
Time in range, % (3.9-10mmol/L)	80 (27)	80 (27)	80 (26)	82 (27)	81 (25)	82 (27)
Time in tight range, % (3.9-7.8mmol/L)	62 (27)	64 (29)	62 (28)	67 (29)	63 (28)	67 (29)
Time below range, % (<3.9mmol/L)	4 (9)	4 (9)	4 (9)	4 (8)	4 (9)	4 (8)
Time below range L2, % (<3.0mmol/L)	1 (3)	1 (3)	1 (3)	1 (3)	1 (3)	1 (3)
Time above range, % (>10.0mmol/L)	16 (27)	15 (28)	16 (26)	14 (27)	15 (26)	14 (27)
Time above range L2, % (>13.9mmol/L)	6 (17)	7 (19)	5 (16)	6 (19)	5 (16)	6 (19)
Coefficient of variation, %	25 (5)	23 (5)	24 (5)	23 (5)	24 (5)	23 (5)
SD of mean glucose	1.8 (0.7)	1.7 (0.7)	1.8 (0.6)	1.7 (0.7)	1.8 (0.6)	1.7 (0.7)
Mean Glucose, mmol/L	7.6 (2.7)	7.5 (3.1)	7.5 (2.7)	7.4 (3.0)	7.5 (2.6)	7.4 (3.0)

eTable 18. Between group differences at 6- and 12-months follow-up for continous glucose monitoring dependent on wear time

All min	14-day		10-day		7-day	
	6-months follow-up	12-months follow-up	6-months follow-up	12-months follow-up	6-months follow-up	12-months follow-up
Time in range, % (3.9-10mmol/L)	3 (-7 to 12)	6 (-5 to 16)	3 (-6 to 12)	6 (-4 to 16)	3 (-6 to 11)	4 (-5 to 13)
Time in tight range, % (3.9-7.8mmol/L)	2 (-8 to 12)	5 (-5 to 16)	2 (-8 to 11)	5 (-6 to 15)	1 (-8 to 11)	4 (-6 to 14)
Time below range, odds ratio [b] (<3.9mmol/L)	1 (0 to 4)	3 (1 to 14)	1 (0 to 5)	3 (1 to 10)	1 (0 to 5)	2 (1 to 9)
Time below range L2, odds ratio [b] (<3.0mmol/L)	9 (2 to 40)	1 (0 to 3)	10 (2 to 43)	1 (0 to 2)	9 (2 to 35)	1 (0 to 2)
Time above range, % (>10.0mmol/L)	-6 (-15 to 3)	-6 (-16 to 4)	-6 (-14 to 3)	-6 (-15 to 4)	-6 (-14 to 3)	-4 (-12 to 5)
Time above range L2, odds ratio [b] (>13.9mmol/L)	1 (0 to 3)	2 (0 to 9)	1 (0 to 4)	2 (0 to 7)	1 (0 to 4)	2 (1 to 8)
Coefficient of variation, %	1 (0 to 3)	0 (-2 to 2)	2 (0 to 3)	0 (-2 to 2)	1 (0 to 3)	0 (-1 to 2)
SD of mean glucose	0 (-11 to 12)	-2 (-13 to 12)	0 (-11 to 11)	-2 (-13 to 11)	0 (-10 to 11)	0 (-10 to 12)
Mean Glucose, % change [a]	-6 (-15 to 3)	-1 (-11 to 9)	-6 (-14 to 2)	-1 (-10 to 10)	-5 (-13 to 3)	-1 (-10 to 8)

[a] Log-transformed, interpret effect estimates as percent change. [b] Data were analyzed using mixed effects binomial regression, interpret effect estimates as odds ratios

eTable 19. Attendance at exercise counselling meetings

	Active Control, N (%)	MOTIVATE-T2D, N (%)
EC1	64 (100)	61 (100)
EC2	64 (100)	59 (97)
EC3	58 (91)	56 (92)
EC4	55 (86)	55 (90)
EC5	53 (83)	54 (89)

EC, exercise counselling meeting

eTable 20. Estimated intervention delivery costs

Staff Time [a] (min)	Active Control		MOTIVATE-T2D	
	UK	Canada	UK	Canada
Exercise Counselling 1	30		30	
Exercise Counselling 2	30		50	
Exercise Counselling 3	25		25	
Exercise Counselling 4	25		25	
Exercise Counselling 5	25		25	
Exercise Counselling Total	135		155	
Watch set up	-		15	
Sending text messages	5		105	
Exercise programming	60		45	
Overall Total Counsellor Time	320		320	
Estimate Total Counsellor Cost per patient	£120.00 [b]	$137.13 [c]	£192.00 [b]	$219.41 [c]
Watch [d]	-	-	£116.33	$288.00
Postage [e]	£3.45	$22.73	£4.92	$22.73
Text messages [f]	£0.96	$1.92	£2.00	$2.00
Other resource use/ costs [g]				
Website [h]	£1.68	$2.76	£1.68	$2.76
Video calling subscription [i]	£1.19	$2.00	£1.19	$2.00
Video editing subscription [j]	£0.90	$1.48	£0.90	$1.48
Printing costs [k]	£0.75	$1.25	£0.74	$1.22
Envelopes/ Delivery box [k]	£0.06	$0.1	£1.56	$2.57
Estimated total delivery cost of the mHealth intervention	£128.99	$169.37	£321.32	$542.17

[a] Mean delivery time has been rounded up to nearest 5 minutes. [b] Staff grade equivalent to NHS Agenda for Change band 5 (staff salary at £25,023 per annum), from Curtis and Burns, Unit Costs of Health and Social Care 2020, p125. Based on. Estimated cost per hour = £36 (Curtis and Burns, 2020); Includes salary, salary on costs, overheads (management costs and non-staff costs (including travel/transport)), capital overheads, and excludes costs for qualifications. [c] Staff grade equivalent to a dietician (2020), estimated cost per hour = $41.14 (O'Reilly et al., 2022). [d] Based on using a Polar Ignite 1, Polar retailer price list, without taxes (prices relevant for 2020). [e] UK - Royal Mail, Canada - regional and national postage averages (prices relevant to 2021). [f] Based on mean of 50 texts per patient at £0.04/ $0.04 per message, via online system. [g] These costs are distributed across the first 100 participants receiving the intervention. [h] Yearly Unlimited Premium Plan accessed through Wix (Wix.com), including domain name (prices relevant for 2020). [i] Yearly access to Zoom Pro (prices relevant to 2020). [j] Yearly subscription to online video editing service (prices relevant to 2020). [k] Price is quoted per item when 100 items ordered.

eTable 21. Wider healthcare and societal utilisation at 6- and 12-month

	Active control Mean (SD)		MOTIVATE-T2D Mean (SD)	
	6-month, N=44	12-month, N=40	6-month, N=49	12-month, N=46
Secondary Care				
A&E	0.27 (0.73)	0.10 (0.30)	0.00 (0.00)	0.09 (0.35)
Inpatient	0.02 (0.15)	0.00 (0.00)	0.02 (0.14)	0.02 (0.15)
Day Hospital	0.07 (0.45)	0.03 (0.16)	0.06 (0.32)	0.04 (0.29)
Clinic	0.27 (0.54)	0.13 (0.52)	0.33 (0.90)	0.26 (0.80)
Other	0.05 (0.21)	0.03 (0.16)	0.35 (0.97)	0.38 (1.54)
Total Secondary Care	0.68	0.29	0.76	0.79
Primary Care				
GP (Home)	0.00 (0.00)	0.10 (0.44)	0.08 (0.34)	0.11 (0.48)
GP (Clinic)	0.23 (0.68)	0.15 (0.43)	0.12 (0.44)	0.35 (0.99)
GP (Phone)	0.39 (0.97)	0.35 (0.82)	0.31 (0.82)	0.24 (0.74)
Community doctor (Home)	0.00 (0.00)	0.13 (0.79)	0.00 (0.00)	0.04 (0.29)
Community doctor (Clinic)	0.00 (0.00)	0.02 (0.14)	0.00 (0.00)	0.04 (0.29)
Community doctor (phone)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.30 (2.06)
District nurse (home)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)
District nurse (clinic)	0.02 (0.15)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)
District nurse (phone)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)
Practice nurse (home)	0.00 (0.00)	0.08 (0.35)	0.00 (0.00)	0.02 (0.15)
Practice nurse (clinic)	0.16 (0.91)	0.08 (0.35)	0.04 (0.20)	0.02 (0.15)
Practice nurse (phone)	0.00 (0.00)	0.05 (0.32)	0.00 (0.00)	0.00 (0.00)
Specialist nurse (home)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)
Specialist nurse (clinic)	0.09 (0.36)	0.03 (0.16)	0.04 (0.20)	0.00 (0.00)
Specialist nurse (phone)	0.11 (0.49)	0.08 (0.27)	0.06 (0.24)	0.04 (0.21)
Physiotherapist (home)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.20 (0.93)
Physiotherapist (clinic)	0.27 (1.09)	0.00 (0.00)	0.08 (0.40)	0.15 (0.76)
Physiotherapist (phone)	0.18 (1.21)	0.00 (0.00)	0.00 (0.00)	0.04 (0.29)
Occupational therapist (clinic)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.11 (0.74)
Paramedic	0.00 (0.00)	0.05 (0.22)	0.00 (0.00)	0.00 (0.00)
Total Primary Care	1.45	1.12	0.73	1.66
Social Care				
Private home help/cleaner	0.00 (0.00)	0.00 (0.00)	0.18 (1.29)	0.13 (0.88)

LIVERPOOL JOHN MOORES UNIVERSITY CONSENT FORM

Title of Project: **Mobile Health Biometrics to Enhance Exercise and Physical Activity Adherence in Type 2 Diabetes (MOTIVATE T2D)**

IRAS number:
REC reference:

Participant ID: **……..**

Chief investigator: Dr Matt Cocks (LJMU)

UK Investigators: Katie Hesketh (LJMU), Dr Robert Andrews (Medical Doctor, University of Exeter), Prof Helen Jones (LJMU), Dr Tori Sprung (LJMU), Prof Ceu Mateus (University of Lancaster)

Collaborators from The University of British Columbia (UBC), Canada: Prof Ali McManus, Dr Jonathan Little, Dr Mary Jung, Dr Charlotte Jones (Medical Doctor), Prof Joel Singer

	Please add initials to boxes once you have read and understood the corresponding item.	
1.	I confirm that I have read and understand the patient information sheet (Date: …… Version: .....) describing the above study and have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and that this will not affect my legal rights.	
3.	I agree for a copy of this completed consent form to be retained at Liverpool John Moores University (where it will be kept securely) to allow confirmation that my consent for the trial has been given.	
4.	I understand that any personal information collected during the study will be pseudonymised and remain confidential	
5.	I understand that the study team does not own the data downloaded to the Polar Flow website, and that therefore the study team does not have control over it. I have been provided with the Polar privacy policy and can confirm that I am happy to use the Polar application (Polar Flow– Sync & Analyze) and website (Polar Flow) for the study duration.	
6.	I agree to allow my General Practitioner and any other relevant medical practitioner to be informed of my involvement in the study.	
7.	I agree to the anonymised data collected from me being used in future ethically approved research.	
8.	I give permission for the research team to use an audio/ video recorder during semi-structured interviews. I understand these recordings will be transferred to a computer file, encrypted and saved using pseudonyms immediately after the testing visit. Once data has been saved, it will be immediately deleted from the recording device.	

LIVERPOOL JOHN MOORES UNIVERSITY CONSENT FORM

9.	I agree for the research team to use pseudonymised quotes from my semi-structured interviews for research purposes only.	
10.	I give permission for my counselling sessions with my exercise specialist to be audio/ video recorded. I understand these recordings will be transferred to a computer file, encrypted and saved using pseudonyms immediately after the testing visit. Once data has been saved, it will be immediately deleted from the recording device.	
11.	I agree to my blood samples being sent to Royal Devon and Exeter NHS Foundation Trust for analysis and storage, as described in the participant information sheet.	
12.	I agree to gift samples and data, collected during this study, to the Peninsula Research Bank Research Bank and understand that they may be used in future research. I understand that these studies will be approved by a steering committee and my samples will not be used for any of the following: Sold for profit, used in animal research, shared with non-research organisations such as the police. My samples may be provided anonymously to researchers from the UK and abroad including academic organisations and commercial companies.	
13.	I agree for my pseudonymised data and audio/ video recordings to be transferred to the research team at The University of British Columbia. The audio/ video files shared with The University of British Columbia are likely to include personal data.	
14.	I understand that the sponsor of the study and regulatory bodies have access to my data.	
15	I agree to being contacted with details of future research and my details to be stored on a computer database for this purpose	
16.	I agree to take part in this study.	

You should keep a signed copy of this form for your records. A signed copy will also be stored by the research team.

Name of Participant	Date	Signature
Name of person taking consent	Date	Signature

a place of mind
THE UNIVERSITY OF BRITISH COLUMBIA

Study Title: Mobile Health Biometrics to Enhance Exercise and Physical Activity Adherence in Type 2 Diabetes (Motivate T2D)

My signature on this consent form means:

1. I have read and understood the information in this consent form.
2. I have had sufficient time to consider the information provided and to ask for advice if necessary.
3. I understand that I am not waiving any of my legal rights as a result of signing this consent form.
4. I have been able to ask questions and have had satisfactory responses to my questions.
5. I understand that all of the information collected will be kept confidential and that the results will only be used for scientific purposes.
6. I understand that participation in this study is entirely voluntary and I am completely free at any time to refuse to participate or to withdraw from this study at any time, and that this will not change the quality of care that I receive.
7. I will receive a signed and dated copy of the consent form by email.

Signatures

I consent to participate in this study

_____	_____	_____
Name of Participant	Signature	Date

_____

Participant Contact telephone

_____	_____	_____
Consent obtained by Signature	Study Role	Date