BMJ Open Sport & Exercise Medicine

Can 4 weeks of real-world active breaks improve glycaemic management in sedentary adults with type 1 diabetes? The EXTOD-Active randomised control trial protocol

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To cite: Jenkins JG, Cocks M, Narendran P, *et al*. Can 4 weeks of real-world active breaks improve glycaemic management in sedentary adults with type 1 diabetes? The EXTOD-Active randomised control trial protocol. *BMJ Open Sport & Exercise Medicine* 2025;**11**:e002594. doi:10.1136/bmjsem-2025-002594

► Additional supplemental material is published online only. To view, please visit the journal online (https://doi.org/10.1136/bmjsem-2025-002594).

Accepted 24 March 2025

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ABSTRACT

Sedentary behaviour is associated with an increased risk of cardiovascular disease and all-cause mortality in individuals with type 1 diabetes (T1D). Recent laboratory-based research suggests that breaking up prolonged sedentary periods improves glycaemic markers in people with T1D. However, the effects of breaking up sedentary behaviour for prolonged periods in real-world settings remain unknown. This study aims to assess the effect of 4 weeks of active breaks on time spent within the target glycaemic range (time in range (TIR), 3.9–10.0 mmol/L) in adults with T1D

Adults with T1D (n=118) who are sedentary for ≥8 hours per day will first complete a 7-day baseline assessment. Participants will then be randomised into either a control group (maintenance of habitual lifestyle) or an intervention group, where active breaks (3 min of self-paced walking every 30 min between 09:00 and 17:00, Monday through Friday) will be prescribed for 4 weeks. Activity levels (activPAL), TIR (via continuous glucose monitor), insulin dose and carbohydrate intake will be monitored throughout. The effect of active breaks on TIR will be compared between baseline and week 4, with data analysed using analysis of covariance (ANCOVA).

The trial has been approved in the UK by the West Midlands-Solihull Ethics Committee (22/WM/0221). The findings from the study will be disseminated through peer-reviewed journals and presentations at national and international scientific conferences.

Trial registration number
NCT05706298.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Sedentary behaviour increases the risk of developing a range of chronic diseases. It has been shown to have a detrimental effect on glucose management for people living with type 1 diabetes (T1D). A recent study conducted under controlled laboratory conditions demonstrated that frequent, low-intensity bouts of physical activity completed over 7 hours can acutely improve time spent in the target glycaemic range in people with T1D.

WHAT THIS STUDY ADDS

⇒ This study will be the first to assess the impact of breaking up sitting on glycaemic management, insulin dosage, carbohydrate intake and overall well-being in previously sedentary people with T1D in a free-living environment over 4 weeks.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study will provide data on the efficacy of breaking up sitting when completed in the real world. By bridging the gap between controlled laboratory findings and free-living environments, the results of this study have the potential to advance physical activity guidelines/recommendations to improve glycaemic management in people with T1D.

INTRODUCTION

Background

Type 1 diabetes (T1D) is a chronic autoimmune disease characterised by the destruction of pancreatic beta cells that necessitates the lifelong administration of exogenous insulin. Individuals with T1D frequently experience pronounced bouts of hypoglycaemia and hyperglycaemia, which are influenced by factors such as insulin administration, nutrition and physical activity levels.[1]

Prolonged exposure to hyperglycaemia and glycaemic variability (ie, poor glucose management) is associated with a significant increase in the risk of cardiovascular disease in people with T1D.[2 3] Among those factors that result in poor glucose management, sedentary behaviour can lead to prolonged bouts of hyperglycaemia due to impaired glucose clearance from the blood.[4 5] Indeed, excessive occupational sitting has been

associated with a higher risk of cardiovascular events and all-cause mortality in people with T1D, independent of leisure-time physical activity.[6]

A recent study by Campbell *et al* investigated the influence of breaking up sedentary behaviour with brief, frequent light-intensity activity (3 min bouts of self-paced walking every 30 min) on blood glucose concentrations in adults with T1D.[7] They found that when compared with 7 hours of uninterrupted sitting, breaking up sitting over a 7 hour-period increased glucose time in range (TIR, 3.9–10 mmol/L) by 13.7% and reduced glycaemic variability (coefficient of variation) by 7.8% across a 48-hour period. These improvements in glucose management are similar to those that have been found for people with T1D using a hybrid closed-loop insulin delivery system over 6 months (+11% TIR)[8] and can be considered clinically relevant; a 10% increase in TIR has been shown to reduce the risk of retinopathy and microalbuminuria by 64% and 40%, respectively.[9]

While the research by Campbell *et al* provides valuable preliminary evidence for the benefits of limiting sedentary behaviour in people with T1D, further investigation beyond the laboratory setting is necessary before any definitive recommendations or guidelines can be established. Laboratory conditions often involve extreme conditions, such as prolonged periods of complete inactivity (eg, 7 hours, uninterrupted sitting with scheduled bathroom visits), which rarely represent habitual activity levels. Indeed, even highly sedentary individuals, such as office workers, report taking breaks from sitting at least once per hour.[10] Importantly, studies in people living with or at risk of T2D performed in a free-living environment have found little or no improvement in glycaemic management[11 12]—in contrast to the findings from controlled laboratory studies.[13] Therefore, it remains uncertain whether incorporating activity breaks within real-world settings, where sedentary behaviour is less severe and more consistent with habitual routines, will produce the same meaningful improvements in glycaemic management as in a laboratory setting. The proposed investigation refers to the recent work of others. It examines whether brief, frequent bouts of low-intensity exercise under free-living conditions in people with T1D improves glycaemic management over an extended period.

Study aims

Primary aim

To assess the effect of regular active breaks (3 min walking every 30 min, 09:00–17:00, Monday to Friday), conducted over a 4-week intervention period under free-living conditions, on glucose TIR.

The secondary aims of this study include investigating the impact of active breaks on additional continuous glucose monitor (CGM) derived endpoints (as outlined in the most recent consensus[14]) and daily insulin dose. These will be assessed over 7 days at baseline and compared with the last 7 days of the 4-week intervention. In addition, changes in glycated haemoglobin (HbA1c) levels, cardiometabolic risk factors (including body mass

Table 1 Primary and secondary measures and associated time points of evaluation

Objective	Outcome measures	Evaluation timepoints
Primary objective		
Time in target glycaemic range	TIR (3.9–10.0 mmol/L) measured via CGM for a 7-day period	Change from baseline to week 4 of intervention
Secondary objectives		
Additional markers of glycaemia	Mean glucose, % time in hypoglycaemia (<3.0 and 3.0–3.9 mmol/L), % time in hyperglycaemia (10.0–13.9 and >13.9 mmol/L), glycaemic variability (CV, SD), hypoglycaemia/hyperglycaemia episodes, area under the curve	Change from baseline to week 4 of intervention
Insulin dose	Insulin diary or smartpen; insulin-to-carbohydrate ratio	Change from baseline to week 4 of intervention
Cardiometabolic risk factors	Height, weight, BMI, waist circumference, HbA1c, triglycerides	Change from baseline to postintervention
Well-being	HADS, DQOL and SF-12 surveys	Change from baseline to postintervention
Exploratory objectives		
Assess adherence	% of active breaks achieved via activPAL4 monitor	Throughout the intervention
Adherence impact on TIR	Relationship between adherence (%) on TIR	Throughout the intervention
Evaluate participant experience	Qualitative interviews	Postintervention

BMI, body mass index; CGM, continuous glucose monitor; CV, coefficient of variation; DQOL, Diabetes Quality of Life Questionnaire; HADS, Hospital Anxiety Depression Scale; HbA1c, glycated haemoglobin; SF-12, Short Form-12; TIR, time in range.

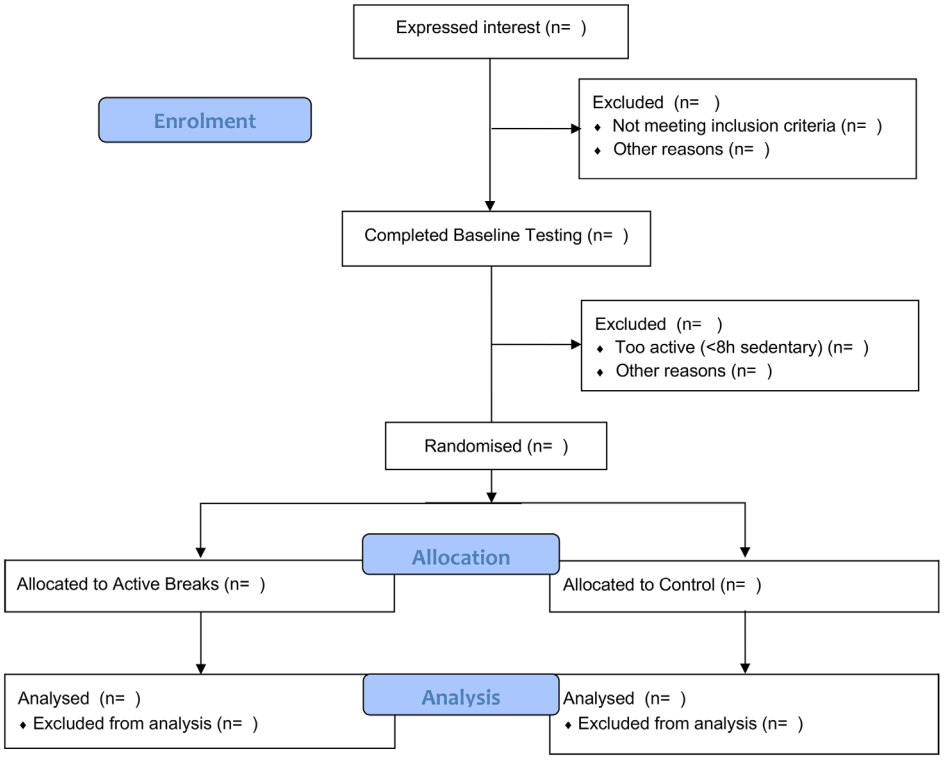

Figure 1 Consolidated Standards of Reporting Trials diagram.

index (BMI), waist circumference, and triglycerides) and well-being metrics (such as anxiety, depression and quality of life) will be assessed at baseline and postintervention. The objectives, outcome measures and specific time points of evaluation are shown in table 1.

The study also aims to explore the relationship between glucose TIR and active break adherence (%). Additionally, the study will explore participants' experiences and the acceptability of integrating active breaks into their daily routines through qualitative interviews, providing a deeper understanding of the feasibility and participant perspectives on the intervention.

METHODS AND ANALYSES

Trial design

This is an open-label randomised controlled trial in which participants will first complete 7 days of prerandomisation baseline testing before being assigned to a habitual lifestyle (control) group or an active breaks (intervention) group (figure 1). The trial will use a decentralised approach, where participants will collect data remotely without travel or in-person contact with the researchers. The trial protocol adheres to the Recommendations for Interventional Trials and the Template for Intervention Description[15] and the Replication guidelines.[16]

Study setting and recruitment plan

Recruitment of 118 adults will occur over 24 months, with the trial finishing (ie, final data collection from the last participant) in December 2026. Participants will be recruited from (1) clinical database searches, recruitment letters and text messages from participating diabetes clinics and GP practices—a full site list is available in online supplemental file 1, (2) emails sent to prospective volunteers within the 'Research for the Future' consent to approach database, (3) targeted social media advertisement, facilitated by the clinical research recruitment service Lindus Health, (4) posters displayed in high foot-traffic areas within participating diabetes clinics and GP practices and (5) websites and social media platforms of charities: Diabetes UK and Breakthrough T1D.

Eligibility criteria

Habitually sedentary adults with a clinical diagnosis of T1D (≥3 years), aged between 18 and 66 years will be sought; those using multiple daily insulin injections (MDI) or continuous subcutaneous insulin infusion (CSII), and a CGM will be eligible to participate.

Inclusion criteria

- T1D diagnosis of more than 3 years.
- >8 hours average sedentary time per day (verified over 7 days using an activPAL4 monitor).
- Using insulin therapy with MDI injections or manually controlled open-loop CSII.
- Aged 18–66 years.
- Use Abbot FreeStyle Libre CGM or Dexcom CGM (for at least 6 weeks before entering the study to avoid potential lifestyle changes due to sensor use).

Exclusion criteria

- Engaging in regular structured, purposeful exercise (eg, running, cycling, gym or sports).
- Pregnancy or planning to become pregnant.
- <6 months post partum or stopped breastfeeding <1 month before recruitment.
- Existing cerebrovascular or cardiovascular disease.
- Significant history of hyperglycaemia (HbA1c >85 mmol/mol).
- History of severe hypoglycaemia requiring third-party assistance within the last 3 months.
- Using a hybrid closed-loop insulin delivery system.

Study timeline

A research team member will assess potential participants' eligibility during an initial phone/video call. Medical history, details of current medications and an estimate of the total time spent sitting (including transportation) during an average working day will be noted. Those who self-report sitting for, on average <8 hours per day at this point will be excluded. Those who meet the study's eligibility criteria and remain interested in joining the study will be invited to provide informed consent using the eSignature software DropBox Sign—online supplemental file 2.

To facilitate the decentralised trial design, participants will be mailed all necessary testing equipment at least 3 days before the agreed baseline testing date. Participants will then receive a phone/video call from a research team member to discuss the testing protocols, in addition to receiving detailed written instructions and links to online tutorial videos. The baseline testing will include the self-measurement of anthropometrics, a finger-prick blood sample and a set of online questionnaires. Participants will then wear an activPAL4 inclinometer device (PAL Technologies, Glasgow, UK) for 7 days, and these data will be used to determine habitual sedentary time. The participant's CGM will record interstitial glucose throughout the 7 days, and data-sharing platforms will be used to log daily carbohydrate intake and insulin administration.

Following baseline testing and subsequent data analysis, if participants still meet the (in)activity inclusion criteria (mean daily sedentary time >8 hours per day), they will be randomised to either the control (habitual lifestyle) or intervention (active breaks) group using a computer-generated random allocation sequence (Sealed Envelope, London, UK).

All participants will undertake their assigned free-living intervention within 14 days following baseline testing (figure 2). The 4-week periods for each group will be identical, except those in the intervention group will incorporate active breaks into their daily routine. All the necessary equipment for the 4-week testing period will be sent to participants at least 3 days before the proposed start date. Participants will receive a phone/video call from a research team member on the day before beginning the intervention to discuss the requirements of their allocated group. The participant's own CGM will record interstitial glucose throughout the 4 weeks, and the same data-sharing platforms as those used during baseline testing will be used to log their daily carbohydrate intake and insulin administration. Given the 14-day recording capacity of the activPAL4 monitor, a second activity monitor will be sent to participants after day 10 of the intervention to be worn for the final 14 days to ensure uninterrupted data collection.

Within 7 days of completing the 4-week intervention, all participants will undergo postintervention assessments, following the same procedures as those used in baseline testing. This will again include the self-measurement of anthropometrics, a finger-prick blood sample and a set of online questionnaires. A postintervention call will be arranged to help facilitate this.

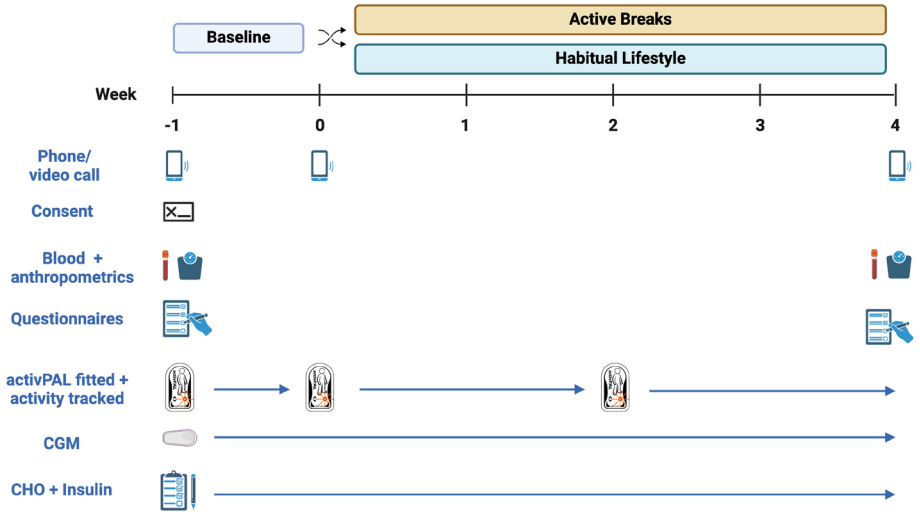

Figure 2 Study flow diagram. CGM, continuous glucose monitoring; CHO, carbohydrate intake.

Outcome measures

Anthropometric measures

Participants will be sent a measuring tape (Seca, Germany) and electronic scales (Salter, UK); waist circumference will be measured in triplicate at the level of the umbilicus with an average reading of the three measurements recorded. Each participant will then weigh themselves using the electronic scales, and, should participants not know their height, the measuring tape will be used to assess height. Participants will be asked to record the anthropometric measures fasted in the morning on the first day of baseline testing and within 7 days of finishing the intervention.

Blood sampling

Participants will be asked to collect 2×100 µL capillary blood samples using a finger prick commercial blood collection kit (MonitorMyHealth.org.uk), fasted on the morning of the first day of baseline testing and within 7 days of finishing the intervention. Blood collection kit preparation and sample analysis (for HbA1c and triglyceride concentrations) will be undertaken by the Exeter Clinical Laboratory, based at the Royal Devon and Exeter National Health Service (NHS) Foundation Trust. The samples will be sent directly to the Exeter Clinical Laboratory for analysis via Royal Mail.

Waist circumference, HbA1c and triglycerides will be used to calculate the Insulin Sensitivity Score using the equation[17]:

$$\begin{aligned}\text{LogeIS} = {} & 4.64725 - 0.02032\ (\text{Waist, cm}) - \\ & 0.0977\ (\text{HbA1c, \%}) - 0.00235 \\ & (\text{triglyceride, mg.dl}^{-1})\end{aligned}$$

Questionnaires

Participants will be sent an online link (Google Forms) to a series of questionnaires, including (1) the International Physical Activity Questionnaire–Short Form (SF),[18] (2) the Hospital Anxiety and Depression Scale (HADS),[19] (3) the Diabetes Quality of Life questionnaire (DQOL)[20] and (4) the SF-12 Health Survey (SF-12).[21] A study-specific questionnaire (based on current NHS guidance) will be completed to record their age, sex, ethnicity and diabetes history (duration of diabetes, insulin therapy and insulin-to-carbohydrate ratio). Each will be asked to complete the questionnaires during the 7-day baseline testing period and again within 7 days of completing the intervention.

Physical activity monitoring

Participants must wear an activPAL4 inclinometer device that measures posture (ie, sitting/lying and upright transitions) and the transitions from one posture to another.[22] The device will be preinitialised to record for either 7 days (baseline) or 14 days (intervention) before it is returned to the research team using a prepaid envelope. Due to the 14-day recording capacity of the activPAL4, a second device will be provided to participants on day 10 of the 4-week intervention to ensure uninterrupted data collection for the final 14 days. The research team will download and assess data stored on the devices using activPAL proprietary software (PALanalysis).

Interstitial glucose via CGM

Participants will continue to use their own Abbot FreeStyle Libre (2 or 3) (Abbott Diabetes Care, UK) or Dexcom (G6 or G7) (Dexcom, San Diego, California, USA) CGM devices for the duration of the study. Where possible, an intervention period will be timed to begin when a new CGM sensor is inserted and initialised. The research team will have access to participants' glucose reports using their respective devices' online data-sharing platforms (LibreView or Dexcom Clarity). This will enable the research team to view and download current and historical glucose data using proprietary software. In addition to the data collected during the baseline and intervention periods, researchers will have access to historical data (4 weeks before the baseline assessment) to ensure the baseline results are representative of typical recordings and have not been influenced by study participation.

Insulin administration and carbohydrate intake

The same data collection platforms (LibreView or Dexcom Clarity) will record and download the participants' daily carbohydrate intake and insulin administration. If preferred, participants will be supplied with a physical carbohydrate and insulin diary that will be returned to the researcher alongside the activity monitors in a prepaid envelope.

Randomisation and blinding

Randomisation will be stratified by TIR (<70% of TIR vs ≥70% of TIR) and minimised by sex, insulin therapy (MDI vs CSII) and CGM device brand (Abbott FreeStyle Libre vs Dexcom). Researchers will request randomisation on completion of completing all baseline measures to ensure allocation concealment. Due to the nature of the intervention, blinding the participants or researchers who are delivering the interventions is impossible. However, the trial statistician and investigators will remain blinded to group allocation until after prespecified statistical analyses and interpretation are agreed on.

Interventions

Control group: habitual lifestyle

Participants assigned to the control group will maintain their usual lifestyle for 4 weeks.

Intervention group: active breaks

Participants assigned to the intervention group will be electronically prompted via a phone notification to undertake 3 min bouts of self-paced walking every 30 min (16 bouts, equalling 48 min of walking daily) from 09:00 to 17:00, Monday to Friday throughout the intervention.[7 13] Should participants miss a bout of walking at

30 min, they will be asked to complete 6 min of walking when they receive the next electronic prompt at 60 min.[23] Participants will be required to download a smartphone app (StandUp! The Work Break Timer V.1.4.1), which enables automatic alert notifications to be sent every 30 min from 09:00 to 17:00, Monday to Friday to the participant's phone with the message 'Time to stand up and move for 3 min'. This will, in turn, be synced to a Polar Ignite 2 fitness watch (Polar, Warwick, England) to allow the notification to be sent to the watch. The fitness watch will also be paired with a Polar mobile app, which participants will be asked to download and log in to using preregistered account details (Polar Flow—Sync and Analyse). This approach will enable the research team to monitor adherence to the intervention remotely in real-time. If participants miss three consecutive active breaks, defined by sedentary periods exceeding 90 min, the researcher will issue a reminder prompt with a phone call or text message.

Acceptability of the intervention

On completion of the study, 8–12 participants from the intervention group will be invited to participate in semistructured interviews, seeking their views and experiences of the intervention.[24] Interviews will be conducted via an online/phone meeting. The interview guide will contain open-ended questions focusing on the participant's experiences living with T1D, their typical daily activity/sedentary patterns and their experiences incorporating active breaks into their daily schedule. A spread of age, gender/sex and adherence to the active breaks in participant interviews will be used to achieve representative acceptability of the intervention. Interviews will be audio-recorded and transcribed verbatim before undergoing inductive thematic analysis.[25]

Study withdrawal

Participants will have the right to withdraw from the study at any time, with no obligation to provide a reason. If provided, reasons for withdrawal will be retained, but personal data will be deleted. In addition, participants may be withdrawn from the study by the research team at any time should there be significant safety concerns. Withdrawal from the study will not necessarily exclude a participant's data from analysis.

Data analysis

Sample size

A power calculation has shown that 49 participants in each condition (n=98 in total) will be required to detect a 10% difference in TIR, previously shown to be associated with a clinically relevant effect on microvascular complications[14]; calculations are based on a power of 90% and an α probability of 0.05, assuming an SD for TIR of 15.1% (unpublished group data). To account for a potential drop-out of ~20%, 118 participants will be recruited.

Physical activity data

All activity data will be retrospectively analysed and assessed in 24-hour time blocks. Total daily activity (ie, number of steps, sit-to-stand transitions and time spent walking or sitting) and sedentary behaviour (sitting bouts >30 min, sitting bouts >60 min, time spent in sitting bouts >30 min, time spent in sitting bouts >60 min) will be calculated as the sum of all values from 09:00 to 17:00 per day Monday to Friday. A day will be considered valid if >10 hours of wear time were recorded during waking hours and <95% of that time was spent in any one behaviour (ie, sedentary, standing or walking), with a minimum of 500 steps recorded during that day.[26] A minimum of 4 valid days of activity data will be required during the baseline and the final week of the intervention for the data collected during these periods to be included in the final analysis.

Adherence (active breaks)

If participants fail to complete a 3 min bout of walking within 30 min, they will be asked to complete a 6 min bout of walking when they receive the next electronic prompt. Therefore, participants will be considered to have completed an active break if a block of <60 min of sedentary time was recorded from 09:00 to 17:00 using the activPAL4 device. Adherence to the active breaks group will require a minimum of 8 hourly active breaks per day, Monday–Friday. Across the 4-week intervention period, participants randomly assigned to the active breaks group will be prompted to complete a minimum of 180 active breaks (ie, 8×20).

Intervention adherence will be determined using an 80% threshold, consistent with medication and exercise adherence literature.[27–29] Adherence will be expressed as a percentage of the total number of active breaks completed over the 4 weeks (eg, 180 active breaks completed=100% adherence or 144 active breaks completed=80% adherence). Additionally, the total number and percentage of non-adherent participants and drop-outs will be reported, and reasons for non-adherence will be documented where provided.

Statistical analysis

Results will be reported as mean±SD. The primary outcome of TIR will be analysed using an analysis of covariance (ANCOVA) to compare changes in TIR from baseline to the final week of the intervention period between the habitual lifestyle and active breaks group. The model will include a group (habitual lifestyle vs active breaks) adjusted for baseline TIR. Potential covariates, such as age, sex, insulin therapy and CGM device brand, will also be included in the model to examine the effect of the intervention on TIR while controlling for these factors. Significance will be set at $p<0.05$, and effect size (adjusted mean difference in time in the range between control and active breaks) will be reported to assess the magnitude of the intervention effect. Assumptions of ANCOVA (eg, normality, homogeneity of variances) will be checked.

The secondary outcomes of this study, including CGM-derived endpoints, daily insulin dose, changes in HbA1c levels, cardiometabolic risk factors (eg, BMI, waist

circumference, triglycerides) and well-being metrics (eg, anxiety, depression, quality of life), will also be analysed using ANCOVA to compare mean values from the final 7 days of the intervention with baseline values between the active breaks and habitual lifestyle groups, adjusting for baseline values. To account for the potential inflation of type I error due to multiple comparisons, a correction for multiple testing (such as Bonferroni or false discovery rate adjustment) will be applied to control for the family-wise error rate or false discovery rate, as appropriate. Significance will be set at $p<0.05$, with adjusted p values reported for all comparisons to control for multiple testing.

Exploratory outcome analyses

A linear regression model will be conducted to examine the effect of active break adherence on glucose TIR while controlling for potential covariates such as age, sex, insulin therapy and CGM device brand. Model assumptions, including homoscedasticity, normality of residuals and multicollinearity, will be checked to ensure validity. We will also explore using categories of adherence if the association is non-linear. A complete case analysis will be reported for comparison.

Qualitative data

Qualitative data from the semistructured interview transcripts will be analysed using thematic analysis, guided by Braun and Clarke's approach. NVivo software (V.15) will facilitate the coding process, allowing for the systematic identification and organisation of text segments into initial codes, which will then be combined to define overarching themes. Strategies such as researcher triangulation and member checking will be employed to enhance the rigour and credibility of the analysis.

Dissemination

The findings will be published in clinical and physiological journals and presented at National and International conferences.

Serious adverse events reporting

Patients will be asked if an adverse event (AE) has occurred during meetings held postintervention. Should an AE be reported, the study's lead clinicians, RA and PN, will assess the event and the end outcome using a serious AEs (SAE) report form. The research team will then report the event to the sponsor.

SAE is defined as any AE at any stage in the research participation of the study that:

- Results in death.
- Is life-threatening.
- Requires hospitalisation or prolongation of existing hospitalisation.
- Results in persistent or significant disability or incapacity.
- Is a congenital anomaly/birth defect.

'Life-threatening' refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

Potential AEs include:

- Hypoglycaemia that could be dealt with by self.
- Hyperglycaemia that could be dealt with by self.
- Cough and colds.
- Influenza.
- Muscle aches and pains.
- Muscle strains.
- Indigestion.
- Constipation.
- COVID-19.

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Contributors MC, KH and RA conceived the study. PN and RA provided clinical expertise. SNS, SJEL and CR helped with implementation. BMS provided statistical expertise in clinical trial design and statistical analysis. JGJ will coordinate the project and collect the data. All authors contributed to refining the study protocol and approved the final manuscript. The trial will be sponsored by Liverpool John Moores University, which will oversee but not have authority over study design, data collection, analysis, interpretation and dissemination. KH is the guarantor.

Funding This study is funded by Diabetes UK (BDA number 23/0006624).

Disclaimer The funding agency does not have any role in the study design, data collection, analysis, interpretation and dissemination.

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval The trial protocol has received a favourable opinion from the West Midlands-Solihull Ethics Committee (22/WM/0221) in the UK.

Provenance and peer review Not commissioned; externally peer reviewed.

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