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FULL TITLE: WALKING AWAY FROM TYPE 2 DIABETES: A CLUSTER RANDOMISED CONTROLLED TRIAL

RUNNING HEAD: WALKING AWAY FROM DIABETES

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COMPETING INTERESTS

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NOVELTY STATEMENT

- Walking Away from Type 2 Diabetes is an established low-resource behavioural intervention for those with a high risk of type 2 diabetes that combines pedometer use with structured education
- The longer-term effectiveness of Walking Away was previously unknown
- Using a cluster randomised controlled trial involving 808 high-risk individuals, we found modest increases in walking activity of around 400 steps/day at 12 months in those receiving Walking Away; however results were not sustained over the longer-term (36 months)
- .This study further suggests that behavioural interventions with good evidence of efficacy are difficult to replicate when translated into a primary care setting

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ABSTRACT

Aims: This study aimed to investigate whether an established behavioural intervention, Walking Away from Type 2 Diabetes, is effective at promoting and sustaining increased walking activity when delivered within primary care.

Methods: Cluster randomised controlled trial involving ten General Practices recruited from Leicestershire, UK, 2009-2010. 808 (36% female) individuals with a high risk of T2DM, identified through a validated risk score, were included. Participants in five practices were randomised to Walking Away from Type 2 Diabetes, a pragmatic 3-hour group-based structured education programme incorporating pedometer use with annual follow-on refresher sessions. The primary outcome was accelerometer assessed ambulatory activity (steps/day) at 12 months. Longer-term maintenance was assessed at 24 and 36 months. Results were analysed using generalised estimating equation models, accounting for clustering.

Results: Complete accelerometer data for the primary outcome was available for 571 (71%) participants. Increases in ambulatory activity of 411 (95% CI; 117, 704) steps/day and self-reported vigorous-intensity physical activity of 218 (6, 425) MET.min/week at 12 months were observed in the intervention group compared to control; differences between groups were not sustained at 36 months. No differences between groups were observed for markers of cardiometabolic health. Replacing missing data with multiple imputation did not affect the results.

Conclusions: A pragmatic low-resource group-based structured education programme with pedometer use resulted in modest increases in ambulatory activity compared to control conditions after 12 months when implemented within a primary care setting to those at high risk of T2DM, however results were not maintained over 36 months.

Key Words: Diabetes; Pedometer; Physical Activity; Prevention; Primary Care.

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BACKGROUND

Physical activity has consistently been shown to have a powerful therapeutic effect on glycaemic control in those with prediabetes and type 2 diabetes mellitus (T2DM) [1,2], with randomised controlled trials showing physical activity intervention slow progression to T2DM in those with impaired glucose tolerance (IGT) to similar levels as multi-faceted lifestyle interventions [2]. Observational research has also shown that moderate-intensity physical activity, such as walking, is associated with a reduced risk of T2DM and cardiovascular disease [3,4]. However, few studies have evaluated the implementation and translation of evidence-based physical activity interventions in “real-world” contexts in the prevention or management of T2DM [5,6].

In the Prediabetes Risk Education and Physical Activity Recommendation and Encouragement (PREPARE) study, we demonstrated that a 3 hour group-based structured education programme could be effectively combined with pedometer use to increase walking activity in those with impaired glucose tolerance (IGT) [7,8]. The intervention used in the PREPARE trial was subsequently developed into the Walking Away from Type 2 Diabetes programme through adapting the content for a broader range of high risk populations beyond IGT and through developing an educator training and quality assurance pathway to enable delivery within primary care. Walking Away was subsequently commissioned into routine primary care pathways within regions of the United Kingdom as a low resource prevention programme. The aim of this study was to undertake a cluster trial to investigate the extent to which the results from the PREPARE trial can be replicated at 12 months when delivered within general practices to those with a high risk of T2DM identified using an evidence-based non-invasive risk score [9], and whether results are maintained at 24 and 36 months with annual group-based follow-on support.

RESEARCH DESIGN AND METHODS

STUDY DESIGN

The study is a clustered randomised controlled trial; the full protocol has been published elsewhere [10]. Follow-up measurements were assessed at 12 months

after baseline, with maintenance assessed at 24 and 36 months. The study was coordinated from the Leicester Diabetes Centre, University Hospitals of Leicester NHS Trust.

PARTICIPANTS

Ten general practices were recruited from Leicestershire (UK) across urban and rural locations. Practices were recruited by dissemination at local diabetes training events, emailed invitation and presentation at practice meetings. Within practices, participants at risk of T2DM were identified using the Leicester Practice Risk Score [9]. Individuals between 18 and 74 years of age inclusive and above the 90th percentile of the calculated risk score were invited to take part [11]. All individuals with a high risk score were considered for inclusion, including those without dysglycaemia. Identified individuals were sent a letter of invitation and a patient information sheet by a member of their general practice. Individuals were excluded from invitation if they were currently taking steroids due to potential confounding endocrinological effects, had a terminal illness, or unable to take part in any walking activity.

ETHICS

NHS ethical approval was granted for this project and all participants gave informed consent. The trial was sponsored by the University Hospitals of Leicester NHS Trust who were responsible for the conduct of the research.

RANDOMISATION

Randomisation was conducted at the level of the general practice by an independent statistician employing a random number generator; a blocked design stratified for practice size was used. Practices were randomised after recruitment and baseline measures (1:1) to receive control conditions or Walking Away from T2DM. Practices were enrolled and assigned to their randomised group by a project manager. Those collecting and processing data were blinded to allocation.

PROCEDURES

Control

Control participants received a standardised booklet detailing information on T2DM risk informed by Leventhal's common sense model and how physical activity and lifestyle change can be used to prevent or delay the disease [10].

Intervention

The intervention group were offered the three hour Walking Away from T2DM group-based structured educational programme (henceforth referred to as Walking Away), described in detail previously [10]. Walking Away is based on an approach that has been shown to be effective at promoting increased ambulatory activity in those with IGT [7,8], but adapted for a broader range of high risk individuals and with a fully developed educator training and quality assurance pathway. Educators were recruited through advertisement and were registered health care professionals or had a relevant degree or occupation. Educators worked in pairs and delivered the intervention in recruited general practices, local hospitals and community settings such as church halls.

Physical activity was promoted by targeting self-efficacy, identifying barriers and promoting self-regulatory skills through pedometer use. Individuals were encouraged to increase their physical activity levels up to 3000 step/day over baseline levels depending on individual preference and ability. Goal attainment was encouraged through the use of smaller proximal objectives, such as increasing activity by 500 steps/day every fortnight. Participants set an action plan detailing where, when and how their first proximal goal will be reached and were encouraged to repeat this process for each new goal. A pedometer and step/day diary were provided free.

All participants in the intervention group were invited to attend two follow-on group-based sessions at 12 and 24 months, designed to reinforce the content of Walking Away, review progress, support the maintenance of behaviour change and discuss reasons for re-lapse. Each follow-up refresher session lasted two hours and was conducted by a single educator. Participants also received short telephone contact (around 15 minutes) between annual sessions (at 6, 18 and 30 months) to provide further support.

OUTCOMES

Physical activity

Change in total ambulatory activity (steps/day) at the individual level after 12 months was assigned *a priori* as the primary outcome, with maintenance assessed at 24 and 36 months. Ambulatory activity was measured by accelerometer (GT3X, Actigraph, FL, USA). Participants were asked to wear the accelerometer, fitted on their trunks (placed on right anterior axillary line) with a waistband, for seven consecutive days during waking hours. Data were integrated into 60 second epochs. Ambulatory activity was defined as:

1) *Total ambulatory activity (primary outcome):* The average number of all accumulated steps per day.
2) *Purposeful ambulatory activity (secondary outcome):* The average number of accumulated steps per day undertaken above an intensity threshold (≥500 counts/minute) distinguishing steps accumulated in incidental activity from those involving more purposeful walking [12].

Time spent sedentary (<100 counts/minute), in moderate- to vigorous-intensity (≥ 1952 counts/minute) and total physical activity (average counts/day) were calculated [13]. At least four valid days of data were required for inclusion, with a valid day defined as at least ten hours of accelerometer wear time (non-wear defined as 60 minutes or more of continues zero counts). Outcomes were standardised to average daily values by dividing the total accumulated data over all valid days by the number of valid days. Data were processed through a bespoke computer programme (KineSoft version 3.3.76, Kinesoft, New Brunswick, Canada; www.kinesoft.org).

Self-reported physical activity and sitting time were also measured using the short last-seven-days self-administered International Physical Activity Questionnaire (IPAQ); results were weighted my metabolic equivalents (METS) for walking (3.3 METS), moderate-intensity (4 METS), vigorous-intensity (8 METS) activities and summed to give total physical activity [14].

Other secondary outcomes

Biochemical variables

Participants were invited to attend each clinical measurement session after a 12-h fast and 24-h of avoiding vigorous-intensity exercise. Each measurement session involved an oral glucose tolerance test (OGTT) to assess fasting and 2-hour post

challenge glucose values. HbA1c and lipid profile (triglycerides, HDL- and total-cholesterol) were also assessed. Analysis was conducted in the same clinical laboratory located within Leicester Royal Infirmary, UK, using stable methodology standardised to external quality assurance reference values.

Those who had a fasting, 2-h blood glucose or HbA1c (from 2011 onwards) level in the diabetes range at any clinical measurement session were called back for a confirmatory OGTT [15,16]. Those found to have T2DM at baseline were excluded; those found to have T2DM during the study were referred to routine clinical care.

Other anthropometric, demographic lifestyle and psychological variables

Arterial blood pressure was measured in the sitting position (Omron, Healthcare, Henfield, UK); three measurements were obtained and the average of the last two measurements used. Body weight, waist circumference (midpoint between the lower costal margin and iliac crest) and height were also measured. Information on current smoking status, medication history, and ethnicity were obtained by interview. Social deprivation was determined by assigning an Index of Multiple Deprivation (IMD) score to participant postcodes.

Diet was measured using the Dietary Instrument for Nutrition Education (DINE) food frequency questionnaire which provides a unitless score for total fat, unsaturated fat, and fiber intake [17,18]. Health related quality of life [19], depression and anxiety [20], and illness perceptions (for a high risk of T2DM status) were also assessed [21].

STATISTICAL ANALYSIS

In order to detect a difference of 2000 steps/day between groups at 12 months [8], assuming a standard deviation of 4000 steps/day [10], a power of 90 %, a significance of 0.05, an average cluster size of 90 and an intracluster correlation coefficient of 0.02 [22], we required a minimum of eight clusters. In order to account for potential dropout at the cluster level and comply with guidance for minimum cluster numbers [23], 10 general practice clusters were recruited.

A statistical-analysis plan was written, finalised and agreed before data were available.

Participants were analysed in the groups to which they were assigned. Continuous outcomes were analysed using generalised estimating equation models with an exchangeable correlation structure, which adjusted for clustering. Missing data were not replaced. Outcomes were assessed at each time point along with a derived average over all three time points, thus both the cumulative and overall effect are provided.

Participants found to have developed T2DM at their 12-month measurement visit (n = 19) were withdrawn after the primary measurement was completed; these individuals had their 24 and 36-month data imputed by carrying forward their 12-month results. Similarly those diagnosed with T2DM at 24 months (n = 28) were withdrawn and had their values carried forward for the 36-month analysis. This method has been used previously [8].

Post-hoc analyses for the primary outcome were stratified by the presence or absence of any form of dysglyacemia at baseline (IGT or IFG or HbA1c ≥ 6.0%) to allow an assessment of the impact of elevated glucose (dysglycaemia) on behaviour change. Sensitivity analyses were carried out for total ambulatory activity at 12 and 36 months. The analysis was repeated when: (i) excluding those from the intervention group who did not attend the initial Walking Away education session and the two annual refresher sessions (per protocol); and (ii) intention to treat (ITT) imputing any missing values using the command MI in Stata. Sensitivity and stratified analysis was not undertaken for secondary outcomes to avoid multiple comparisons. Adjustments were not made for multiple testing. Statistical significance was set at 5%. All analyses were conducted using Stata version 13.

RESULTS

The flow of the participants is highlighted in Figure 1. Ten practices were recruited to the study; five randomised to intervention, five to control. Practice recruitment commenced in November 2009 and patient recruitment in January 2010. Participant recruitment was compete in January 2011 and data collection in January 2014. No clusters withdrew from the study. Overall 833 participants were recruited, of which 25 were excluded at baseline due to being diagnosed with T2DM, leaving 808 within the trial. The median number of recruited participants per practice was 83 (range 47 to 127). In total, 696 (86%) participants attended 12 month follow-up, of which 571

(71%) had valid accelerometer data across both baseline and 12-month follow-up. Missing accelerometer data was due to non-compliance with daily wear. Compared to those with available data for the primary outcome, those with missing data were more likely to be younger (61 vs. 64 years), come from more deprived areas (IMD score 17.5 vs. 13.0), have a higher BMI (33.9 vs. 32.0 kg/m2) and be less active (5910 vs. 6752 steps/day).

The baseline characteristics of the sample, stratified by intervention group are displayed in Table 1. Groups were generally well matched, but those in the intervention group had substantially higher levels of social deprivation (IMD score 18.7 vs. 9.8).

Of those randomised to the intervention, 325 (77%) attended the initial Walking Away programme, 248 (59%) attended Walking Away and at least one refresher session and 172 (41%) attended Walking Away and the two available refresher sessions. The characteristics of those that did and did not attend Walking Away are displayed in Supplemental Table S1; those that failed to attend had higher levels of BMI, waist circumference and smoking with lower levels of HDL-cholesterol; there was also a trend toward higher levels of deprivation ($p = 0.056$).

Table 2 displays the results at each time point and the average effect across all time points for the accelerometer variables. There was an increase in ambulatory activity of 411 steps/day (95% CI 117, 704) in the intervention group compared to control at 12 months. The intracluster correlation coefficient for the primary outcome was 0.004 (95% CI: 0.000 to 0.023). Over the course of the study there was a gradual decline in daily total ambulatory activity in both groups with no difference between groups by 36 months. The same pattern of results was observed for purposeful ambulatory activity. All other accelerometer outcomes were non-significant. Participants increased self-reported vigorous-intensity physical activity levels at 12 months (218 MET.min/wk; 6, 425), 24 months (325 MET.min/week; 38, 612) and overall (148 MET.min/week; 36, 261) compared to the control group; other self-reported variables were non-significant (Supplemental Table S2).

No other differences between groups were observed for any biomedical, anthropometric, illness perception, quality of life, anxiety and depression or dietary variables (Supplemental Table S3-6).

Results for the primary outcome were similar for the per-protocol analysis and when missing values were imputed (Figure 2).

When stratified by glycaemic status, increased ambulatory activity in the intervention group was only observed for those with either IGT, IFG or HbA1c ≥ 6.0% at baseline (Figure 2). In this group there was a 513 steps/day increase (175, 852) in total ambulatory activity compared to control at 12 months (Figure 2). Ambulatory activity was not different between groups in those with normal glycaemia at any time point.

DISCUSSION

This study demonstrates that a low-resource physical activity intervention for those with high risk of T2DM increases ambulatory activity by a modest 411 steps/day at 12 months compared to controls when implemented within general practice, however results were not sustained over the longer-term. When stratified by glycaemic status, changes to ambulatory activity of 562 steps/day were observed at 12 months in individuals with dysglycaemia at baseline (IGT, IFG or Hba1c ≥ 6.0%) whereas no effect was seen in those with normoglycaemia.

This trial has several strengths including the randomised design, annual follow-up over three years, the objective measurement of physical activity, and the primary care setting. Limitations include the amount of missing data in the primary outcome, although results remained unaffected by a sensitivity analysis with imputed data. In addition the method of identifying diabetes risk through a non-invasive risk score, although pragmatic, may not reflect routine clinical practice in many regions where risk is confirmed with a biochemical test, such as HbA1c. Limitations are also inherent in using a cluster design, including an increased likelihood of differences between groups at the participant level.

The results of this study are in contrast to an earlier efficacy intervention, the PREPARE trial, that demonstrated an intervention effect of around 2000 steps/day

over 12 months [8]. This finding further highlights the difficulty of translating physical activity studies into meaningful behaviour change when implemented within routine primary care or community settings which have been observed previously in the UK in high risk individuals or T2DM [24,25].

This study generated some important observations that have relevance to prevention programmes implemented within routine care pathways, including the recently launched NHS Diabetes Prevention Programme (NHS DPP)[26]. Those with dysglycaemia at baseline appeared more successful in changing their behaviour at 12 months. The confirmation of a higher than normal risk status during the programmes (all individuals plotted their glucose values on a risk chart) may have helped facilitate greater motivation for behaviour change. This is consistent with Protection Motivation Theory where an association between perceived disease severity and the intention to be physically active in those with T2DM has been demonstrated [28]. Others have also noted the difficulty in promoting lifestyle changes in asymptomatic individuals when the underlying condition is not perceived as serious [29]. This suggests that diabetes prevention programmes may be more successful when dysglycaemia has been confirmed with a blood test and used to help reinforce behaviour change. Conversely, interventions that include normoglycaemic individuals may need to focus on other risk factors or strategies.

Diabetes prevention guidelines recommend the use of group-based interventions [27]. In the current study, 23% failed to attend the initial Walking Away structured education programme and tended to have worse indicators of health status compared to those that attended. In addition, only 41% attended Walking Away and all available annual follow-on maintenance sessions. These results are similar to other group-based diabetes prevention programmes implemented in real world settings. In the American DEPLOY study, participants attended 57% of available sessions and in Finland 56% of individuals reported attending all group-based sessions in the GOAL Implementation Trial [28,29]. These results suggest that strategies are needed to support up take and adherence to prevention programmes implemented within routine care pathways, particularly when delivered over multiple sessions or when targeting more deprived and higher risk populations; **strategies may need to integrate more personalised approaches tailored to individual levels of risk and motivation** including the option of one-to-one, mobile phone or

web-based support. A follow-on study is currently testing the integration of some of these strategies within Walking away [30].

In conclusion, a pragmatic low-resource group-based structured education programme with pedometer use for those with a high risk of type 2 diabetes, with previous evidence of efficacy, resulted in small increases in ambulatory activity compared to control conditions after 12 months when implemented within in a primary care setting; however results were not sustained over 36 months.

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AUTHORSHIP CONTRIBUTIONS

Authors: TY helped design the study, contributed to the development of the intervention, drafted the initial version and revised subsequent versions of the manuscript, and acts as study guarantor. MJD helped design the study, was Principle Investigator and revised the manuscript for important intellectual content. KK helped design the study and revised the manuscript for important intellectual content. LG and NA had access to data, undertook the statistical analysis and revised the manuscript for important intellectual content. JT contributed to the development of the intervention, helped train and quality assess educators and revised the manuscript for important intellectual content. CLE and JH helped manage the project, collect and analyse the physical activity data and revised the manuscript for important intellectual content.

Figure 1: Participant flow

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Figure 2: Stratified and sensitivity analysis for the primary outcome (steps/day) at 12 months (A) and 36 months (B)

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TABLE 1: BASELINE CHARACTERISTICS

	Control	Walking Away
Individual level		
Number of participants	385	423
Age (years)	63.7 ± 8.1	62.6 ± (8.2)
Male	237 ± 61.6	277 ± (65.5)
White European	350 ± 90.9	367 ± (86.8)
Current smoker	29 (7.5)	49 (11.6)
Index of Multiple Deprivation (IMD) score	9.8 (IQR 6.3-19.1)	18.7 ± (IQR 10.7-32.8)
Prescribed antihypertensives	188 (48.8)	222 (52.5)
History CVD	50 ± 13.0	62 ± 14.7
2-hour glucose (mmol/l)	6.2 ± 2.0	6.5 ± 2.1
Fasting glucose (mmol/l)	5.2 ± 0.6	5.3 ± 0.6
HbA1c (%)	5.8 ± 0.4	5.9 ± 0.4
HbA1c (mmol/mol)	40.3 4.6	40.9 ± 4.3
Total cholesterol (mmol/l)	5.1 ± 1.1	5.1 ± 1.0
HDL cholesterol (mmol/l)	1.4 ± 0.4	1.4 ± 0.3
LDL cholesterol (mmol/l)	3.1 ± 0.9	3.0 ± 0.9
Triglycerides (mmol/l)	1.5 ± 0.8	1.6 ± 1.5
Systolic blood pressure (mmHg)	142.2 ± 18.6	143.2 ± 20.2
Diastolic blood pressure (mmHg)	86.3 ± 10.0	86.9 ±10.1
Weight (kg)	92.1 ± 16.2	92.2 ± 18.5
Body Mass Index (kg/m^2)	32.4 ± 5.3	32.4 ± 5.8
Waist circumference (cm)	101.8 ± 11.5	101.7 ± 12.9
Total ambulatory activity (steps/day)	6578 ± 3148	6591 ± 3204
Purposeful ambulatory activity (steps/day)	5169 ± 3046	5126 ± 3121
Total physical activity (counts/day)	256210 ± 123484	249574 ± 122900
Moderate- to vigorous-intensity physical activity (mins/day)	27.5 ± 23.8	27.2 ±25.1
Sedentary time (mins/day)	533.0 ± 100.1	551.9 ± 98.5
Light-intensity physical activity (mins/day)	290.9 ± 80.5	285.3 ± 74.0
Impaired fasting glucose (IFG)	36 (9.3)	48 (11.3)
Impaired glucose tolerance (IGT)	79 (20.5)	104 (24.6)
HbA1c % ≥ 6.0	132 (35.4)	174 (41.9)
Any dysglycaemia (impaired fasting glucose, impaired glucose tolerance or HbA1c % ≥ 6.0)	181 (47.0)	216 (51.1)
Cluster level		
Number of practices	5	5
Practice size	11173 (IQR 10737, 11196)	11621 (IQR 6473, 13182)

Data as mean ± SD or median (IQR) for continuous variables, count (%) for categorical

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TABLE 2: PRIMARY OUTCOME AND ACCELEROMETER DERIVED SECONDARY OUTCOMES

	Number of participants		Mean change from baseline (95% CI)		Mean intervention effect (95% CI)*	P value
	Control	*Walking Away*	*Control*	*Walking Away*		
Total ambulatory activity (steps/day)						
12 months	277	294	-274 (-512, -36)	109 (-125, 344)	411 (117, 704)	0.006
24 months	272	287	-690 (-932, -447)	-486 (-747, -226)	210 (-148, 567)	0.25
36 months	274	277	-769 (-1028, -509)	-599 (-852, -347)	184 (-378, 746)	0.52
Overall	343	350			215 (-118, 548)	0.21
Purposeful ambulatory activity (steps/day)						
12 months	277	294	-287 (-515, -60)	91 (-145, 326)	392 (89, 695)	0.011
24 months	272	287	-711 (-949, -474)	-497 (-743, -230)	223 (-110, 555)	0.19
36 months	274	278	-796 (-1047, -544)	-323 (-904, 257)	473 (-389, 1335)	0.28
Overall	343	350			295 (-107, 696)	0.15
Total physical activity (1000 counts/day)						
12 months	277	294	-18.0 (-28.0, -7.9)	-8.9 (-18.7, 0.9)	6.8 (-6.6, 20.1)	0.32
24 months	272	287	-40.3 (-50.4, -30.2)	-32.3 (-43.2, -21.3)	6.1 (-7.6, 19.7)	0.38
36 months	274	278	-39.5 (-50.6, -28.4)	-9.3 (-61.8, 43.2)	27.4 (-30.9, 85.6)	0.36
Overall	343	350			9.5 (-12.2, 31.1)	0.39
Sedentary time (mins/day)						
12 months	277	294	10.6 (2.4, 18.3)	4.8 (-4.1, 13.7)	-1.9 (-9.21, 5.50)	0.15
24 months	272	287	22.1 (13.7, 30.6)	18.34 (8.7, 28.0)	0.5 (-6.6, 7.5)	0.13
36 months	274	278	22.9 (13.9, 31.9)	23.8 (12.9, 34.7)	2.0 (-13.0, 16.9)	0.15
Overall	343	350			3.3 (-3.0, 9.6)	0.13
Moderate- to vigorous-intensity physical activity (mins/day)						
12 months	277	294	-2.07 (-4.1, -0.0)	0.1 (-2.0, 2.3)	2.1 (-1.4, 5.7)	0.24
24 months	272	287	-5.9 (-8.0, -3.8)	-4.1 (-6.3, -1.9)	2.0 (-0.7, 4.8)	0.14
36 months	274	278	-6.6 (-8.9, -4.3)	-4.7 (-6.7, -2.6)	2.0 (-2.2, 6.1)	0.35
Overall	343	350			1.4 (-1.8, 4.5)	0.39

* = Intervention value minus control value adjusted for baseline value, wear time and clustering