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A randomized controlled trial of *Wearable Activity Technology And Action-Planning*
(WATAAP) to Promote Physical Activity in Colorectal and Endometrial Cancer Survivors

WATAAP Trial to Promote Physical Activity in Cancer Survivors

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Abstract

Objective: The objective of this study was to ascertain whether wearable technology, coupled with action-planning was effective in increasing physical activity (PA) in colorectal and endometrial cancer survivors at cardiovascular risk.

Methods: Sixty-eight survivors who had cardiovascular risk factors and were insufficiently active were randomized to intervention and control arms. Intervention participants were given a wearable tracker for 12-weeks, two group sessions, and a support phone-call. Participants in the control arm received print materials describing PA guidelines. Assessments at baseline and 12-weeks measured triaxial and uniaxial estimates of moderate-vigorous physical activity (MVPA), sedentary behavior, blood pressure and BMI.

Results: The intervention group significantly increased MVPA by 45-minutes/week compared to a reduction of 21-minutes/week in the control group. Group by time interactions

were significant for minutes of MVPA ($F(1,126)=5.14, p=.025$). For those with diastolic hypertension, there was a significant group by time interaction ($F(1,66)=4.89, p=.031$) with a net reduction of 9.89mmHg in the intervention group.

Conclusions: Significant improvements in MVPA were observed following the intervention. The results display promise for the use of pragmatic, low-intensity interventions using wearable technology.

Keywords: Cancer; Cardiovascular diseases; Exercise; Oncology; Wearable technology

Physical Activity (PA) reduces the risk of cardiovascular disease (CVD),¹ cancer and cancer-related death.² In cancer survivors, PA may reduce the risk of recurrence.² Sedentary behavior may be an independent risk factor for cancer occurrence and mortality.³ However, many cancer survivors fail to meet the current guidelines of >150-minutes of moderate-intensity PA per week⁴ and some are sedentary.⁵

Although survival rates are increasing, many colorectal and endometrial survivors have comorbidities and lifestyle-related risk factors for CVD⁶ including insufficient PA, sedentary behavior, poor diet, and obesity.^{2,6,7} Over 58% and 63% of colorectal and endometrial survivors respectively are overweight or obese.⁸ Further, ~50% and ~70% of colorectal and endometrial survivors respectively are insufficiently active,^{9,10} putting these survivors at risk for CVD. In a retrospective cohort study of more than 30,000 endometrial cancer patients, CVD was the leading cause of death.⁷

Most PA interventions in cancer survivors are facility-based, supervised or group-based,¹¹ despite survivors identifying barriers around cost, accessibility and intimidation.^{12,13} Many survivors express a preference for unsupervised, self-paced, low-moderate intensity

PA, specifically walking.^{14,15} Home-based interventions may mitigate barriers to exercise, complement exercise preferences and facilitate exercise adherence.^{15,16} There is a gap in knowledge concerning the effectiveness of less intensive home-based interventions that may be more cost-effective and scalable.

Wearable activity trackers (wearables) hold potential as a low-cost self-monitoring tool, with their associated applications (Apps) offering several evidence-based Behavior Change Techniques (BCTs) including goal-setting, feedback, self-monitoring and social support.^{17,18} As such, wearables could represent a cost-effective and scalable intervention. However, several evidence-based BCTs are not integrated into Apps including action-planning, coping-planning, and instruction on performance of the behavior.¹⁷ Due to these omissions and other patient barriers including dwindling motivation, wearables alone might be insufficient to produce long-term PA engagement.¹⁹ The present trial included two group sessions to include these BCTs that are largely omitted from wearables and their associated Apps.

Reviews of trials incorporating wearables support the effectiveness of trackers for increasing PA²⁰ and reducing sedentary behavior.²¹ There is evidence to support the effectiveness of wearables for increasing PA amongst adults with chronic disease,²² post-menopausal women,²³ and in breast cancer survivors.^{24,25} Research on ‘smart’ wearables in survivors has thus far been limited to predominantly breast survivors and have not involved group sessions as components of the intervention. Our trial is novel because it includes group sessions and relational support,²⁶ and the inclusion of BCTs (e.g., action planning) that are absent from wearables and their Apps. To our knowledge, our trial is the first to combine ‘smart’ wearables with group sessions, in a pragmatic, low-intensity intervention to improve PA and reduce sedentary behavior in colorectal and endometrial cancer survivors.

The primary aim of the *Wearable Activity Technology And Action-Planning* (WATAAP) trial was to ascertain whether wearable technology, in conjunction with instruction on how to perform behavior, action-planning, goal-setting and coping-planning, was effective in increasing MVPA and reducing sedentary behavior in colorectal and endometrial survivors at cardiovascular risk. A secondary aim was to assess the effectiveness of the intervention for reducing blood pressure and body mass index (BMI).

Methods

The trial was a two-arm, multicenter randomized controlled trial (RCT), conducted in Perth, Western Australia. The study was approved by the St. John of God Human Research Ethics Committee (Reference #1102), and registered (ANZCTR2617000131358). Written informed consent was obtained from participants prior to enrolment.

Participants

Participants included stage 1 or 2 colorectal or endometrial cancer survivors who had completed active cancer treatment within the five-years prior to recruitment and were deemed insufficiently physically active and at CVD risk. The full eligibility criteria have been previously published.²⁷

Recruitment

Eligible survivors were identified from oncologists' medical records and were mailed a participant information sheet and invitation letter. Individuals who expressed interest were screened by telephone to ensure eligibility prior to recruitment from July-2017, with assessments in December-2017 and March-2018.

Randomization

Following baseline assessments, an independent statistician who was blinded to the assessments and intervention, randomized participants using consecutive randomization codes (STATA v14) with a 1:1 allocation in blocks of 4.

Design

Intervention arm

The 12-week intervention consisted of three components, which have previously been described.²⁷

1. The Fitbit Alta™ is a wrist-worn tracker that is cost-effective, with demonstrated acceptability for use by cancer survivors.²⁸ The tracker records daily steps, MVPA accrued in bouts of ≥10-minutes ('Active minutes'), distance, and provides automated prompts encouraging participants to accumulate ≥250 steps/hour. Participants received and set-up their Fitbit during group session-1 using their phone, tablet or computer. Fitbit engagement data were collected daily via the Fitbit Dashboard following participants' acceptance of a friend request with a study investigator.
2. Participants attended two-hour group sessions (~11 per group) facilitated by behavior change specialist SJH and CMS in weeks 1 and 4. Session 1 involved Fitbit set-up and presentation on PA messaging, instruction on performance of the behavior, goal-setting, confidence building, action-planning, coping-planning and self-monitoring of active and sedentary behavior. Emphasis was given to reducing bouts of sedentary behavior and responding to the automatic prompts to take steps, in addition to

encouraging planned bouts of MVPA. Participants were assisted to complete action-planning and goal-setting activities. Session-2 focused on reviewing goals, forming 'if-then' plans to overcome barriers, based on our previous research.^{12,13} Home-based strength exercises were demonstrated with an opportunity for practice and participants were encouraged to log strength training manually on the Fitbit app.

3. Participants received a 20-minute phone-call during week-8 to provide support and feedback regarding PA progress, review goals, action plans and coping-planning strategies.

Control arm

This group received print materials containing PA guidelines (also given to the intervention group) but were not specifically encouraged to increase their PA. Printed materials included examples of home-based aerobic and strength-training, and worksheets to self-monitor and self-regulate PA engagement.

Assessments

Data collection was performed during 30-minute assessments at baseline (T1), and 12-weeks (T2). Assessments post-randomization were conducted at St. John of God Subiaco Hospital by hospital staff blinded to group allocation, who measured height (only at T1), weight, and blood pressure. Participants were given an Actigraph Link GT9X accelerometer, waistband, log, and postage materials. Participants were instructed to wear the accelerometer on the day following their assessment and continue wear for seven consecutive days before posting the accelerometer back to the research team.

Outcome measures

Physical activity

Minutes/week of MVPA were ascertained from the Actigraph GT9X accelerometer (Actigraph, Pensacola, FL). Minutes/day of MVPA accrued in bouts of at least 10-minutes (referred to as MV10) were also determined from the Actigraph. Participants wore the accelerometer on their right hip for all waking hours across seven consecutive days at each assessment time point. Wear time had to exceed ten hours per day and contain no excessive counts ($>20,000$) to be considered valid, with non-wear time defined as at least 60-consecutive minutes of zero counts.²⁹ Data were processed using 60-second epochs. Daily accelerometer logs were completed by participants to allow for cross-checking of data.

Two thresholds were applied to the data to define PA.

- i. Sasaki cut-points were our primary outcome measure since they utilise triaxial data based on three planes of movement (vertical, antero-posterior and medio-lateral).³⁰ The Sasaki equation has been validated³⁰ and demonstrated better accuracy and precision in assessing MVPA among free-living older adults.³¹ Sasaki vector magnitude cut-points were: sedentary ($<674\text{vmu}$), moderate ($2690\text{--}6165\text{vmu}$), vigorous (6167+vmu), and MVPA (2690+vmu). Bouts of sedentary time for a minimum of 20-consecutive minutes were analysed due to corresponding clinical changes in cardio-metabolic biomarkers.⁵
- ii. Freedson cut-points³² rely on uniaxial data (vertical plane) and are the most commonly reported in the field, therefore allowing comparison of our findings to other studies.³³ Freedson cut-points were: sedentary ($<100\text{cpm}$), moderate ($1952\text{--}5724\text{cpm}$), vigorous (5725+cpm), and MVPA (1952+cpm). Sedentary behavior was also considered in 20-minute bouts ($<100\text{cpm}$).

Cardiovascular risk

Blood pressure and BMI indicated modifiable cardiovascular risk factors. Blood pressure was measured twice and averaged using an Omron IC-10 Upper-Arm Monitor (HEM 7070-E).

BMI was calculated using participants' weight at each assessment and height measured at T1.

Sample size

To detect a small-to-moderate effect ($f^2=.17$), as identified in similar designs,¹¹ a group by time interaction for the primary outcome of MVPA with 80% power and an alpha level of 0.05, 56 participants were required (28 per group). We recruited an additional 20% to allow for attrition.

Statistical methods

All analyses were performed using SPSS Statistics v24 (SPSS Inc., Chicago Ill, USA).

Demographic characteristics at baseline are reported for both groups (Table I). Since MV10 included a large proportion of true zero minutes/week values, models produced a poor fit.

MV10 was therefore dichotomized into insufficiently active (<150-minutes/week) vs.

sufficiently active (≥ 150 -minutes/week). Other continuous outcomes were inspected to

determine appropriate distributions for the Generalized Linear Mixed Models (GLMM).

Residual and deviance distributions were visually inspected to ensure they were consistent

with the assumption of normality for continuous outcomes. The specific GLMM used to

analyse each measure is listed in Supplementary-Materials A. We report the *estimated* means from the models for continuous measures as these are the best representation of central

tendency of the data given the distributions of the outcome variables. Observed means based

on the usual assumption of normality, however, are reported in Supplementary-Materials B

for the purpose of comparison with other studies.

All models included the fixed effects group (intervention, control), time (T1, T2) and group by time interaction, with a random intercept for participant. All models were subsequently adjusted for minutes of accelerometer wear, age, gender, and cancer type, but these factors did not alter the results.

We performed sensitivity analyses only including participants who had specific cardiovascular risk factors (Supplementary-Materials C) and excluding seven participants who did not adhere to the assigned condition (Supplementary-Materials D). The data that support the findings of this study are available from the corresponding author upon reasonable request.

Results

Figure I displays the flow of randomized participants to intervention ($n=34$) and control ($n=34$) groups. Non-response bias analyses revealed no significant differences across age, ASA score, BMI, cancer grade, gender, surgeon, hospital site, cancer type, or adjuvant therapies between responders and non-responders to the invitation letter. Responders had a shorter follow-up time since diagnosis (2.2 vs. 2.9-years) compared to non-responders ($t(276)=3.22, p < .05$).

Demographic characteristics were similar across groups at baseline, except that the intervention arm contained more endometrial survivors (Table I). Sixty-four participants (94%) completed the 12-week assessment. Intervention adherence was excellent, with 94% attendance across group sessions. Most participants (88%, $n=29$) in the intervention group accepted the Fitbit friend request. Fitbit engagement was high with 86% ($SD=29$) of valid wear-days over the 12-weeks ($n=28$). A step count of ≥ 1000 steps per day was defined as a valid wear-day. Three participants did not appear to engage with their Fitbit beyond week-four, and one experienced syncing errors. Mean daily steps across the intervention are

reported in Figure II, with steps ranging from 8233/day in week-2 to 10,318/day in week-12 (mean=9217, $SD=705$). Despite all participants reporting as insufficiently active during phone screening, eight participants completed ≥ 150 -minutes/week of MV10 at baseline, according to uniaxial estimates. These participants have been included for the purposes of intention-to-treat analyses.

Intention-to-treat analyses

Activity measures. Intention-to-treat analyses identified a significant increase of 45-minutes in MVPA/week in the intervention group compared to a reduction of 21-minutes/week in the control group; $F(1,126)=5.14, p=.025$) using triaxial estimates. Table II demonstrates that uniaxial estimates are consistently lower than triaxial estimates (+16 vs. -20 minutes/week in intervention and control groups respectively; $F(1,127)=2.29, p=.133$). The group by time interaction for the dichotomized MV10 was non-significant (Table II). However, the observed mean increases in MV10 were higher in the intervention group vs. controls on both triaxial (29 vs. 8 minutes/week) and uniaxial measures (31 vs. 7-minutes/week) of MVPA accumulated in bouts of at least 10-minutes. Sedentary time decreased significantly from T1 to T2 by 2.94 and 2.61 hours/week for the intervention and control group respectively ($F(1,126)=10.04, p<.01$). Sedentary behavior in ≥ 20 -minute bouts decreased for both groups ($F(1,127)=13.61, p<.001$). Group x time interactions were non-significant (Table II).

Cardiovascular risk outcomes. Systolic blood pressure (SBP) ($F(1,128)=17.36, p<.001$), diastolic blood pressure (DBP) ($F(1,128)=4.43, p<.05$), and BMI ($F(1,128)=35.31, p<.01$) improved significantly over time across both groups. Group by time interactions for these three outcomes were non-significant (Table II), however, the reduction in SBP and DBP for the intervention group was more than twice that of the control group (-14 vs. -6mmHg,

respectively for SBP and -5 vs. -1mmHg for DBP). For participants with DBP of ≥ 90 mmHg at baseline ($n=36$), there was a significant group by time interaction ($F(1,66)=4.89, p=.031$) with a net reduction of 9.89mmHg in the intervention group. Reductions in SBP in those with hypertension ($n=47 \geq 140/90$ mmHg) were not significantly different between the intervention and control groups respectively (-17 vs. -9mmHg) (Supplementary-Materials C).

Sensitivity analyses

Excluding seven participants due to non-adherence (Supplementary-Materials D) resulted in significant interactions on MVPA for triaxial ($F(1,112)=14.93, p<.001$) and uniaxial ($F(1,113)=8.96, p=.003$) estimates with net increases of 103- and 64-minutes respectively in favour of the intervention. MV10 yielded a significant group by time interaction on uniaxial estimates ($F(1,113)=4.30, p=.040$), with six participants becoming sufficiently active in the intervention group, compared to two in controls at T2.

Discussion

Our trial is one of the first to utilize wearables in combination with action-planning and goal-setting to increase PA in cancer survivors. Intention-to-treat analyses revealed a significant between group net-difference of 66-minutes/week of MVPA favoring the intervention group (45-minute increase at 12-weeks). Sedentary behavior reduced significantly by ~3-hours/week for both groups. This reduction remained when examining bouts of ≥ 20 -minutes, suggesting that wearing an accelerometer in itself may prompt less sedentary behavior. Given that replacing one-hour of sedentary time per day with an equal amount of activity is associated with reduced all-cause mortality in older adults completing little activity,³⁴ further investigation of strategies for reducing sedentary behavior is warranted.

For those classified as hypertensive for DBP, there was a significant reduction in the intervention group of 9.77mmHg compared to controls and a trend towards reduction for SBP. Our findings are substantial given the effects of previous PA interventions on blood pressure.³⁵ However, our findings are consistent with a review on walking interventions on blood pressure control that reported mean changes ranging from -5.2 to -11mmHg for SBP and -3.8 to -7.7mmHg for DBP.³⁶

Previous PA interventions for survivors have typically demonstrated small to moderate effect sizes.³⁷ The WATAAP trial yielded promising findings when compared to similar designs with net changes of 24-minutes/week³⁸ and 33-minutes/week³⁹ of self-reported MVPA. A similar low-intensity intervention produced an increase of 18-minutes/week of MVPA following a Fitbit intervention for overweight and obese adults.⁴⁰ Further, a 10-week wearable device and social media-based intervention yielded an increase of 25-minutes MVPA/week in breast cancer survivors.²⁵ The considerable increase of 45-minutes/week of MVPA observed in our intervention is almost double that of most previous studies^{25,37,40} and may be because of the evidence-based BCTs that are now incorporated into smart-tracker technology including self-monitoring, goal-setting and behavioral feedback. A recent higher-intensity Fitbit intervention with breast cancer survivors supports this finding, demonstrating a 103-minutes/week net improvement in MVPA.²⁴ Fitbit engagement was high throughout the intervention (86%) displaying promise for low-intensity interventions.

Conclusions

Study limitations

Limitations include a relatively brief intervention with a small sample of primarily female Caucasian survivors from private hospitals in Perth, Western Australia. Our findings concerning blood pressure should be interpreted with caution, since we did not assess

medication change. Despite the significant increase in MVPA, the change in proportion of participants meeting the guidelines in relation to MV10 did not significantly differ by group. Future research would do well to promote more deliberate and continuous bouts of MVPA in accordance with the guidelines. Our sample may be subject to a participation bias, as it is likely that we have recruited a particularly motivated cohort. Including survivors of other cancers and public hospitals may improve the external validity of our findings.

Clinical implications

The WATAAP intervention yielded a clinically meaningful increase in MVPA and reduction in DBP amongst intervention participants that were hypertensive (DBP ≥ 90 mmHg), displaying promise for the use of low-intensity interventions using smart wearables. BMI and SBP also improved but not significantly between the groups. Investigation of the extended-term efficacy of wearables for PA maintenance and reduced sedentary behavior is essential. Future work could examine the active ingredients of the intervention and explore the support needs required for prolonged engagement with smart wearables and long-term exercise adherence.

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Declaration of interest

None.

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Table I. Baseline characteristics of participants.

	Overall (n=68)	Intervention (n=34)	Control (n=34)	p-value
Age (mean, <i>SD</i>)	64.07 (7.94)	65.26 (7.41)	62.88 (8.37)	.218
Gender				.069
Female	34 (50%)	21 (61.8%)	13 (38.2%)	
Marital status				.359
Married/In a relationship	52 (76.4%)	25 (73.5%)	27 (79.4%)	
Divorced/Separated	9 (13.2%)	6 (17.6%)	3 (8.8%)	
Single	6 (8.8%)	2 (5.9%)	4 (11.8%)	
Widowed	1 (1.5%)	1 (2.9%)	0	
Education				.670
University degree	33 (48.5%)	17 (50%)	16 (47.1%)	
Post-school training	17 (25%)	9 (26.5%)	8 (23.5%)	
High school	18 (26.5%)	8 (23.5%)	10 (29.4%)	
Ethnicity				1.000
Caucasian	66 (97.1%)	33 (97.1%)	33 (97.1%)	
Indian	2 (2.9%)	1 (2.9%)	1 (2.9%)	
Household income (AUD)				.339
≤\$30,000	7 (10.3%)	5 (14.7%)	2 (5.9%)	
\$30,001-\$52,000	18 (26.5%)	11 (32.4%)	7 (20.6%)	
\$52,001-\$104,000	20 (29.4%)	7 (20.6%)	13 (38.2%)	
\$104,001-\$156,000	13 (19.1%)	6 (17.6%)	7 (20.6%)	
≥\$156,000	9 (13.3%)	4 (11.7%)	5 (14.7%)	
Missing	1 (1.5%)	1 (2.9%)	0	
Smoking status				.562
Non-smoker	55 (80.9%)	26 (76.5%)	29 (85.3%)	

Ex-smoker	11 (16.2%)	7 (20.6%)	4 (11.8%)	
Current smoker	2 (2.9%)	1 (2.9%)	1 (2.9%)	
Comorbidities				
Overweight	25 (36.8%)	12 (35.3%)	13 (38.2%)	.582
Obese	24 (35.3%)	14 (41.2%)	10 (29.4%)	.318
Hypertensive	49 (72.1%)	25 (73.5%)	24 (70.6%)	.787
Hypercholesterolemic	15 (22.1%)	8 (23.5%)	7 (20.6%)	.770
Diabetic	9 (13.2%)	3 (8.8%)	6 (17.6%)	.283
Insufficiently active	60 (88.2%)	32 (94.1%)	28 (82.4%)	.215
Cancer type				.042*
Colorectal	53 (77.9%)	23 (67.6%)	30 (88.2%)	
Gynaecologic	15 (22.1%)	11 (32.4%)	4 (11.8%)	
Treatment				.760
Surgery only	35 (51.5%)	16 (47.1%)	19 (55.9%)	
Surgery with chemotherapy	17 (25%)	11 (32.4%)	6 (17.6%)	
Surgery with radiation therapy	2 (2.9%)	2 (5.9%)	0	
Surgery with chemotherapy and radiation therapy	14 (20.6%)	5 (14.7%)	9 (26.5%)	
Body Mass Index (mean, <i>SD</i>)	28.26 (4.95)	28.86 (4.93)	27.66 (4.96)	.322

Note. *cancer type differed between groups, $p < .05$. Hypertensive: $\geq 140/90$ mmHg or taking antihypertensive medication. Hypercholesterolemic: total cholesterol > 5.2 mmol/L or taking antihypercholesterolemic medication. Insufficiently active: completing < 150 -minutes/week of MVPA in bouts of ≥ 10 -minutes.

Table II. Estimated means for physical activity and cardiovascular risk factors.

	All participants (<i>n</i> =67)							
	Baseline		12-weeks		Intervention change (& <i>CI</i> s)	Mean control change (& <i>CI</i> s)	Group x time <i>F</i> (1,126)	Group x time <i>p</i>
	Intervention (mean & <i>CI</i> s)	Control (mean & <i>CI</i> s)	Intervention (mean & <i>CI</i> s)	Control (mean & <i>CI</i> s)				
Triaxial estimates								
MVPA (minutes/week)	267 (207, 344)	261 (202, 337)	312 (242, 402)	240 (185, 311)	+45 (2, 88)	-21 (-59, 17)	5.14	.025*
Moderate PA (minutes/week)	254 (198, 325)	247 (192, 317)	295 (230, 379)	217 (168, 280)	+41 (0, 83)	-29 (-65, 7)	6.77	.010*
Sedentary time (hours/week)	72 (68, 75)	72 (68, 75)	69 (66, 72)	69 (65, 72)	-3 (-5, -1)	-3 (-5, 0)	.04	.851
MV10 (completing ≥150 min/week)	<i>n</i> =6 (18%)	<i>n</i> =5 (15%)	<i>n</i> =9 (27%)	<i>n</i> =7 (21%)	<i>n</i> =+3	<i>n</i> =+2	.00	.989
	All participants (<i>n</i> =67)							
	Baseline		12-weeks		Mean intervention change (& <i>CI</i> s)	Mean control change (& <i>CI</i> s)	Group x time <i>F</i> (1,127)	Group x time <i>p</i>
	Intervention (mean & <i>CI</i> s)	Control (mean & <i>CI</i> s)	Intervention (mean & <i>CI</i> s)	Control (mean & <i>CI</i> s)				

Uniaxial estimates								
MVPA (minutes/week)	170 (128, 225)	158 (119, 211)	186 (140, 247)	138 (103, 185)	+16 (-21, 53)	-20 (-52, 12)	2.29	.133
Moderate PA (minutes/week)	164 (125, 216)	152 (115, 201)	178 (135, 235)	127 (96, 168)	+14 (-21, 50)	-25 (-56, 5)	3.13	.079
Sedentary time (hours/week)	64 (60, 67)	64 (60, 67)	61 (57, 64)	60 (57, 64)	-3 (-5, 0)	-4 (-6, -1)	.13	.717
Sedentary ≥20-min bouts (hours/week)	27 (23, 31)	28 (24, 32)	23 (19, 27)	24 (20, 28)	-4 (-7, -1)	-4 (-8, -1)	.09	.767
MV10 (completing ≥150 min/week)	<i>n</i> =2 (6%)	<i>n</i> =5 (15%)	<i>n</i> =8 (24%)	<i>n</i> =6 (18%)	<i>n</i> =+6	<i>n</i> =+1	1.66	.199

All participants (*n*=68)

Baseline		12-weeks		Mean intervention change (& <i>CI</i> s)	Mean control change (& <i>CI</i> s)	Group x time <i>F</i> (1,128)	Group x time <i>p</i>
Intervention (mean & <i>CI</i> s)	Control (mean & <i>CI</i> s)	Intervention (mean & <i>CI</i> s)	Control (mean & <i>CI</i> s)				

Cardiovascular risk factors

Body mass index (kg/m ²)	28.86 (27.17, 30.54)	27.66 (25.98, 29.34)	28.41 (26.73, 30.10)	27.19 (25.51, 28.87)	-.44 (-.65, -.23)	-.47 (-.69, -.25)	.04	.848
Systolic blood pressure (mmHg)	145.15 (138.96, 151.33)	139.82 (133.64, 146.01)	131.34 (125.08, 137.60)	133.63 (127.21, 140.05)	-13.80 (-20.44, -7.17)	-6.19 (-12.98, .60)	2.52	.115
Diastolic blood pressure (mmHg)	88.00 (83.99, 92.01)	84.15 (80.14, 88.15)	82.60 (78.55, 86.66)	82.96 (78.80, 87.12)	-5.40 (-9.73, -1.07)	-1.19 (-5.62, 3.24)	1.81	.181

Note. Means are predicted from the models accounting for clustering between participants. N(%) are reported for binary logistic regression analyses on MV10.

Figure I. CONSORT diagram of trial

Figure II

Fitbit recorded daily step-count averaged across participants for each week of the intervention.