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A randomized controlled trial of a wearable technology-based intervention for increasing moderate to vigorous physical activity and reducing sedentary behavior in breast cancer survivors: The ACTIVATE Trial

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Condensed abstract: This randomized controlled trial evaluated a 12-week wearable technology-based intervention to increase moderate-vigorous physical activity (MVPA) and reduce sitting in breast cancer survivors. The intervention increased total MVPA (between group change = 69 min/week, 95% CI: 22, 116) and decreased total sitting time (-37 min/day, 95% CI: -72, -2).

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administration, writing - review and editing. Christine Friedenreich: conceptualization, funding acquisition, writing - review and editing. Dallas English: conceptualization, funding acquisition, methodology, project administration, supervision, writing - review and editing.

ABSTRACT

Background: The benefits of an active lifestyle after a breast cancer diagnosis are well recognized, but the majority of survivors are insufficiently active. The ACTIVATE Trial examined the efficacy of an intervention (Garmin Vivofit2®; behavioral feedback and goal setting session; and, five telephone-delivered health coaching sessions) to increase moderate-vigorous physical activity (MVPA) and reduce sedentary behavior in breast cancer survivors.

Methods: This randomized controlled trial recruited 83 inactive, postmenopausal women diagnosed with stage I-III breast cancer who had finished primary treatment. Participants were randomly assigned to the intervention group or to the control group, and the intervention was delivered over a 12-week period. MVPA and sedentary behavior were measured by Actigraph® and activPAL™ accelerometers at baseline (T1) and end of intervention (T2).

Results: Retention in the trial was high, with 80 (96%) of participants completing T2 data collection. At T2, there was a significant between group difference in MVPA (69 min/wk; 95% CI: 22, 116) favoring the intervention group. The trial resulted in a statistically significant decrease in both total sitting time and prolonged bouts (≥20 mins) of sitting, with between group reductions of 37 min/day (95% CI: -72, -2) and 42 min/day (95% CI: -83, -2), respectively, favoring the intervention group.

Conclusions: Results from the ACTIVATE Trial suggest that use of wearable technology presents an inexpensive and scalable opportunity to facilitate more active lifestyles for cancer survivors. Whether or not such wearable technology-based interventions can create sustainable behavioral change should be tested in future research.

MESH keywords: Fitness Trackers; Exercise; Sedentary Lifestyle; Breast Neoplasms; Survivors; Accelerometry; Randomized Controlled Trial

Clinical trial registration: ACTRN12616000175471.

INTRODUCTION

For breast cancer survivors, regular participation in moderate-vigorous physical activity (MVPA) is associated with prolonged survival,[1, 2] diminished treatment side-effects[2-4] and enhanced quality of life.[2, 5] Despite these benefits, many breast cancer survivors do not achieve physical activity recommendations (i.e., 150 minutes of MVPA per week).[6, 7] Less is

known about the health effects of sedentary behavior (defined as any waking behavior that expends ≤1.5 metabolic equivalents while sitting, reclining or lying down).[8] However, preliminary evidence from studies of breast cancer survivors suggests too much sitting may be adversely associated with adiposity,[9] quality of life,[10] and fatigue.[10, 11]

Supervised exercise interventions delivered to breast cancer survivors, as either individual or group sessions, typically result in significant improvements in MVPA, as well as a number of physiological adaptations including improved body composition, cardiorespiratory fitness, and physical function.[12, 13] However, access to such interventions may be limited by cost, geographic reach, and availability of facilities and appropriately qualified health professionals.[14, 15] Even when supervised, structured exercise programs are offered to cancer survivors at no cost, uptake and adherence may be low.[14] To achieve higher rates of physical activity participation by breast cancer survivors, a variety of interventions need to be developed, tested, and translated into standard models of care.

Wearable technology, including activity monitors ('wearables'), have the potential to facilitate changes in physical activity and sedentary behavior.[16] A small number of pilot studies have used wearables as key components of an intervention to increase cancer survivors' physical activity,[17-19] although there are dozens of studies of this nature underway.[20] Some early interventions incorporating wearables (typically single group designs) have demonstrated improvements in physical activity.[21-23] Wearables provide automated (and often real-time) feedback on the intensity and duration of physical activity and non-movement time, which may in itself prompt change.[16] A review of 13 different wearables and associated apps found that they used many of the behavior change techniques typically used by traditional physical activity interventions (e.g. self-monitoring, social support, and goal-setting).[24] Given their low cost and wide reach, wearables are ideal tools for scalable health promotion programs.[16] Phillips *et al*. noted that wearables alone are unlikely to generate meaningful, sustained behavior change, and suggested adopting a stepped-care approach to provide adjunct behavior change tools and support to individuals who need them.[16]

The primary aim of the ACTIVity And TEchnology (ACTIVATE) Trial was to determine the efficacy of a 12-week intervention (use of a wearable, coupled with goal setting and telephone-delivered brief behavioral counselling) for increasing MVPA and reducing

sedentary behavior for postmenopausal breast cancer survivors. We hypothesized that the intervention arm would increase MVPA by at least 75 minutes per week and reduce sedentary behavior by at least 75 minutes per day, compared with the control arm.

MATERIALS AND METHODS

The design and methods of the ACTIVATE Trial have been previously reported in detail.[25] The study utilized a randomized controlled trial design with a waitlist control arm. This paper reports upon the first 12-week period of the ACTIVATE Trial (the randomized controlled trial portion of the study). Findings from the second 12-week period (a maintenance phase for the primary intervention group, and an abridged intervention for the wait-list control group) are reported separately.[26] The ACTIVATE Trial protocol was approved by Cancer Council Victoria's Human Research Ethics Committee (HREC-1602), and all participants provided written informed consent prior to randomization.

Participants

To be eligible for the ACTIVATE Trial, women were postmenopausal at the time of breast cancer diagnosis (or aged ≥50 at diagnosis if menopausal status was uncertain), and diagnosed with stage I-III breast cancer. When the trial commenced recruitment was only open to women diagnosed within the past five years. This eligibility criterion was dropped in October 2016 to facilitate recruitment. Participants had completed primary treatment (ongoing hormone therapy excepted), had no contraindications to commencing physical activity, were able to understand and speak English fluently, and had daily access to a smart phone, mobile device, or personal computer. Finally, women had to report less than 75 minutes of MVPA per week and more than seven hours of sedentary behavior per day.

Recruitment

The main method for recruitment was via Register4 and the Breast Cancer Network of Australia's Review and Survey Group, two national registers of volunteers who had indicated their interest in participating in cancer research. Other recruitment strategies included placement of paid advertisements on Facebook® and promotion through newsletters published by Counterpart (a Melbourne-based not-for-profit group supporting women diagnosed with breast and gynecological cancer), the National Breast Cancer Foundation (a national breast cancer charity), and Cancer Council Victoria. Finally, posters and

promotional postcards were sent to Melbourne oncology clinics and general practice clinics. Women who enquired about the ACTIVATE Trial were administered a brief, telephone-delivered screening questionnaire to confirm their eligibility. Recruitment was conducted between July 2016 and July 2017.

Intervention

Intervention arm

The primary intervention was composed of three components, delivered over a 12-week period.

(i) Behavioral feedback and goal-setting session: Participants attended a single face-to-face session at Cancer Council Victoria with an ACTIVATE Trial team member, where they received a workbook on the health consequences of physical inactivity and sedentary behavior and common barriers to behavior change. Participants were also provided with a report on their weekly physical activity and sitting time from their baseline Actigraph® and activPAL™ data (see Measures, below) and asked to think and record how they could increase their physical activity and reduce their sedentary behavior. Participants generated behavior change goals guided by a motivational interviewing approach.[27] The ACTIVATE Trial team member then trained participants in the set up (including downloading and installing the smartphone/tablet/PC application) and use of their wearable technology activity monitor.

(ii) Wearable technology activity monitor: Participants were provided with a Garmin Vivofit 2® activity monitor which they were asked to wear for 12 weeks. The decision to select this device was based on earlier qualitative work.[28] The Garmin Vivofit 2® is wrist-worn and displays steps, distance, calories, and sleep/rest time. The device provides inactivity alerts visually via a red 'move' bar on the display and an audible beep. The move bar builds in 15-minute blocks, and is reset by walking for a few minutes. The activity monitor stores movement data for up to 7 days, and data are uploaded to the Garmin app via Bluetooth®. Participants were encouraged to access their physical activity data daily via the smartphone/tablet/PC application. The ACTIVATE Trial team members were able to access participants' data via an application programming interface (API) developed and administrated by Garmin, allowing them to monitor compliance with the intervention.

(iii) Telephone-delivered behavioral counselling: Each intervention arm participant received five telephone calls (the first two calls were weekly, followed by two calls made a fortnight apart, and a final call one month later) from an ACTIVATE Trial team member to facilitate adoption and maintenance of behavior change. Calls focused on behavioral change strategies, and issues of non-wear (as ascertained via the API) were discussed. Goals were revised and updated during the telephone calls. Calls also helped troubleshoot any technical difficulties experienced.

Control arm

Participants randomized to the control arm were informed that they were randomized to a delayed intervention and would be provided with a Garmin Vivofit 2® in approximately three months, following the second data collection time point (T2).

Data collection

Women eligible after screening were mailed the baseline (T1) assessment package: a study information sheet and consent form; an Actigraph® GT3X+ accelerometer on an elasticized waist band; an activPAL™ and several 3M™ Tegaderm™ transparent dressings to adhere the device to the thigh; written instructions on how to wear each accelerometer; a diary to record accelerometer wear across the seven days; a written baseline questionnaire; and a reply-paid envelope to return these materials. The follow-up data collection package (containing the same items, except for a modified follow-up questionnaire) was mailed to all participants at the end of the 12-week intervention period (T2).

Measures

Outcomes

MVPA was assessed using the Actigraph® GT3X+ accelerometer (Actigraph, Pensacola, FL), worn on an elasticized belt on the waist over one hip, during waking hours for seven consecutive days at each data collection time point. The accelerometer data were downloaded and processed using 60-second epochs, using the ActiLife 6.0 software package (Actigraph, Pensacola, FL). A customized program in SAS 9.4 (SAS Institute Inc., Cary, NC, USA) was applied to reduce count data into summary variables. Non-wear time was defined as intervals of at least 60 consecutive minutes of zero counts, with allowance for up to two minutes of observations of less than 50 counts per minute (cpm) within the non-wear

interval. To be considered valid, days of data collection require at least 600 minutes (10 hours) of wear time and no excessive counts (>20,000 cpm).

Movement count thresholds (cut points) were used to derive MVPA from the Actigraph® data. The Actigraph® GT3X+ accelerometer measures accelerations on three planes (vertical, antero-posterior and medio-lateral), generating activity counts as a composite vector magnitude of these three axes.[29] Thus, we used the Sasaki vector magnitude cut point (utilizing tri-axial data) of ≥2,690 cpm[30] to quantify MVPA. In order to allow direct comparison with past research that has applied different cutpoints, we also generated secondary measures of MVPA using the Freedson cut point of ≥1,952 cpm[31] and the Matthews cut point of ≥760 cpm,[32] both of which utilize data from the vertical axis only. MVPA was examined as average weekly time accumulated (min/wk), and time in 'bouts' of ten consecutive minutes or more (min/wk). We acknowledge that the concept of 10-minute bouts for MVPA is no longer incorporated in the Physical Activity Guidelines for Americans, reflecting the contemporary view that total volume of MVPA effects health outcomes, regardless of how it is accumulated.[33] Nonetheless, we present 10-minute bout data to be consistent with our published protocol.[25]

Sedentary behavior was measured using an activPAL™ (PAL Technologies Limited, Glasgow, UK), which records time spent in different postures (sitting/lying; standing; stepping) and the number of postural changes. The device was secured to the anterior midline of the right thigh using a Tegaderm™ dressing. The activPAL™ is considered the most accurate device for assessing actual sitting time in adults.[34] Participants wore the device continuously (24hours/day) for seven consecutive days, only removing it for swimming or bathing.

Data were initially processed using activPAL™ software version 7.2.32 (PAL Technologies Limited, Glasgow, UK) using default settings. These data were then processed using a customized program in SAS 9.4 (SAS Institute Inc., Cary, NC, USA) that combined activPAL™ and diary (see paragraph, below) data. Time spent sleeping, monitor non-wear, and invalid days (wear for <80% of waking hours and waking wear time <10 hours when diary data on sleep were missing) were removed. For each valid day we calculated: time spent sitting (min/day); sitting in prolonged bouts of 20 consecutive minutes or more

(minutes/day), which corresponds to clinical changes in cardio-metabolic biomarkers;[35] time spent standing (minutes/day); number of sit-stand transitions; and number of daily steps.

Participants were asked to fill in an activity monitor diary each day to record the time they put the Actigraph® GT3X+ on and removed it, the time they went to bed, and the time they woke up. Participants also record any time the activPAL™ was removed. Diaries were used to cross-check data.

Covariates

The following variables were assessed by the baseline questionnaire: marital status (never married, married, separated/divorced, widowed); education (some high school, high school, diploma/trade qualification, university, post graduate degree); country of birth (Australia, UK/Ireland, New Zealand, Europe, Middle East, Asia, Other); smoking status (never, former, current); alcohol intake (average drinks per week); chronic disease comorbidities (heart disease, diabetes, high blood pressure, high cholesterol, stroke, arthritis, lung disease, osteoporosis, other cancer than breast, depression, cognitive impairment, heart failure, Parkinson's disease); body mass (kg); and height (cm). Breast cancer stage at diagnosis and treatment received were reported during a telephone call to assess eligibility, prior to study enrolment.

Sample size

Sample size calculations have previously been reported.[25] In summary, 41 participants in each arm were needed to detect a 75 minute per week between group change in MVPA with 80% power and a Type I error of 5% (two-tailed). This sample size would also provide 99% power to detect a difference of 75 minutes per day of sedentary behavior between groups.

Randomization

Once baseline data had been collected, participants were randomly assigned using a random number generator in Stata version 14 (Statacorp, College Station, TX, USA). The allocation process was concealed, conducted by an ACTIVATE Trial team member who was blinded to participant details until allocation had been completed; this team member was not involved in recruitment of participants or delivering the intervention. The nature of the intervention precluded blinding of staff and participants.

Statistical analysis

Baseline characteristics were summarized for the two arms using descriptive statistics. Linear mixed model analysis was used to investigate within- and between-group changes in MVPA and sedentary behavior variables across the intervention period. Models were adjusted for valid accelerometer wear time (Actigraph® derived variables) and awake time (activPAL™ derived variables). The linear mixed models included random effects associated with the units of analysis (participants), and allowed residuals associated with the longitudinal measures on the same unit of analysis to be correlated. This approach includes all available data at each time point.

We conducted sensitivity analyses where participants with less than four valid days of accelerometer data were excluded. For the Actigraph® MVPA sensitivity analyses, four participants from the intervention arm were excluded at T1 and four control arm participants were excluded at T2. For the activPAL™ sedentary behaviour sensitivity analyses, we excluded one participant from the intervention arm and one from the control arm at T1, and six control arm participants at T2. All analyses were carried out using Stata version 14 (Statacorp, College Station, TX, USA).

RESULTS

A total of 83 women were randomized (43 to the intervention arm; 40 to the control arm) in the ACTIVATE Trial (Figure 1). The baseline characteristics of the two arms were similar (Table 1). There were slightly fewer women with partners (married or common-law) in the intervention (64%) versus the control arm (84%). More women in the intervention arm had been treated with surgery plus chemotherapy and radiation therapy (63%) versus the control arm (40%). Retention in the trial was very high with only three women from the intervention arm dropping out of the trial (Figure 1). Another three women from the intervention arm were missing activPAL™ data (one did not wear the device due to skin sensitivities; two wore the device but the battery was no longer working and did not wish to repeat the measurement). Health issues that potentially affected adherence to the intervention were reported by three intervention arm participants: two reported difficulties with osteoarthritis, and one participant underwent surgery during the intervention period. No adverse events were reported during the ACTIVATE Trial.

INSERT FIGURE 1 and TABLE 1 ABOUT HERE

Good compliance with the telephone-delivered behavioral counselling was achieved: 27 (68%) of the intervention arm participants received all five calls, while 10 (25%) received four and three (7%) participants received three calls. The average Actigraph® wear time at T1 was 820 min/day (intervention arm) and 837 min/day (control arm); at T2 it was 832 min/day (intervention arm) and 846 min/day (control arm).

The intervention achieved increases in MVPA and MVPA accrued in bouts of at least 10 consecutive minutes, while at the same time reducing total and prolonged sitting time (Table 2). There was a statistically significant difference in MVPA between groups at T2 (69 min/wk; 95% CI: 22, 116; $p<0.01$), favoring the intervention arm. The trial resulted in a statistically significant difference in both total sitting time (-37 min/day; 95% CI: -72, -2; $p=0.01$) and prolonged bouts of at least 20 minutes duration (-42 min/day; 95% CI: -83, -2; $p=0.04$), favoring the intervention arm.

INSERT TABLE 2 ABOUT HERE

Within each arm, there was considerable variation in behavior change between T1 and T2. Twenty-seven (68%) of the intervention arm participants increased their MVPA over the intervention period, while 13 (32%) reduced their MVPA. In the control arm 21 (53%) participants increased their MVPA and 19 (47%) decreased their MVPA. There was also inter-individual variation in total sitting time change. In the intervention arm, 23 (62%) decreased their average daily sitting, whereas 14 (38%) increased over the period. In the control arm, 18 (45%) decreased their average daily sitting, whereas 22 (55%) increased. Figures plotting MVPA and sitting time change between T1 and T2 against T1 levels are presented as Supporting Information.

Results from sensitivity analyses (where participants with less than four valid days of accelerometer data were excluded) were not materially different from the results obtained utilizing all data available.

DISCUSSION

The ACTIVATE intervention, using a combination of mobile health tools and coaching, successfully increased MVPA and decreased sitting time in a sample of Australian postmenopausal breast cancer survivors. We found clear inter-individual differences in the patterns of behavior change at the individual level, within both the intervention and control arms.

Strengths of the ACTIVATE Trial include the high rate of adherence to the intervention, and the low dropout rate during the trial. Our use of the Actigraph® and activPAL™ devices to measure our outcome variables reduced the measurement error that is associated with self-reported estimates of physical activity and sedentary behavior. Furthermore, we applied three different accelerometer cut points to estimate MVPA, because each method has advantages and limitations.[36] The Sasaki cut point was employed as the primary measure of MVPA because this method utilizes the acceleration recorded across three axes.[29] While the Freedson cut point is the most widely used, it only uses data from the vertical axis, and is based on indirect calorimetry data from university students with a mean age of 24 years.[31] The Matthews cut point also only uses data from a single axis, but its lower threshold captures a broader range of lifestyle and ambulatory activities than the Freedson cut point.[37, 38]

Limitations include a sample size that was slightly less than the target set by our sample size calculations (80 versus 82 women) and some missing activPAL™ data for three intervention arm participants. Due to the convenience sampling framework used for recruitment, participants in this trial may have been more motivated and readier to change their behavior than the general breast cancer survivor population, reducing the generalizability of the findings. Further, the multicomponent nature of our intervention, comprising behavioral feedback (weekly summary of baseline Actigraph® and activPAL™ data) and a goal-setting session; the Garmin Vivofit 2®; and telephone-delivered behavioral counselling, means that we cannot discern the efficacy of individual components.

There have been few wearable technology-based intervention trials delivered to cancer survivors. In a pre-post study of 24 adult cancer survivors, Gell *et al*. combined use of the Fitbit® One with tailored text messages, self-monitoring, and three brief health coaching sessions to promote maintenance of physical activity after finishing a supervised exercise training program.[17] Participants reported that the Fitbit® feedback increased their motivation and prompted engagement in physical activity. Accelerometer-measured levels of MVPA

and step count were maintained over the four week period following the supervised program, but use of the Fitbit® One did not increase activity.[17] Pope *et al*. did not observe any significant between-group differences following the delivery of their wearable technology-based intervention, designed to increase MVPA and reduce sedentary behavior in breast cancer survivors. They used the Polar M400, which their post-intervention user survey suggested was challenging to use.[39] Our focus group testing of various commercial devices prior to commencing the ACTIVATE Trial ensured that the wearable we used (Garmin Vivofit2®) was acceptable to participants.[28]

Wearable technology has also incorporated into a pilot study that aimed to prevent weight gain in African American breast cancer survivors.[19] Participants (n=35) were randomized to daily self-weighing using smart scales that provided tailored tracking and feedback via an app or website only; daily self-weighing plus physical activity tracking (using a Withings® Pulse fitness band); or a control condition. The daily self-weighing plus wearable condition resulted in a small within-group increase in energy expenditure after six months (432 kcal/day) and a small change in weight (0.94% reduction).[19]

Despite the growing body of evidence relating to the health risks associated with sedentary behavior,[40, 41] only a handful of trials have attempted to reduce sitting time in cancer survivors.[42, 43] Trinh *et al*. demonstrated that a web-based intervention, combined with use of a Jawbone wearable device, reduced sedentary behavior in prostate cancer survivors receiving androgen deprivation therapy. This pilot trial (n=46) resulted in a 455 min/wk reduction in sedentary behavior post intervention.[44] In a feasibility trial comparing email-delivered diet and activity interventions delivered to a sample of racial and ethnic minority breast cancer survivors, Paxton *et al*. achieved similar reductions in sitting time (304 minutes per week in the activity intervention arm; 59 minutes per week in the diet intervention arm).[43] These findings were, however, based on self-report, rather than activPAL™ assessment. A multiple health behavior intervention, delivered to colorectal cancer survivors, found that telephone-delivered health coaching reduced self-reported sitting. The difference between intervention and control groups at the primary endpoint (six months after the six month intervention had concluded) was 39 minutes per day (95% CI: -82, 4; p=0.06).[42]

Epidemiologic and experimental evidence suggests that reducing sedentary behavior (and breaking up prolonged bouts of sitting) may improve cardiometabolic health. Prolonged

sitting results in compromised glucose and insulin regulation,[35, 45] and is associated with a higher risk of type 2 diabetes and cardiovascular mortality in the general population.[41, 46] Given that cardiovascular disease is an important cause of death for breast cancer survivors,[47, 48] there is a need for further evidence on the specific applicability of sedentary behavior reduction interventions for breast cancer survivors.

Conclusion

We have demonstrated that a wearable technology-based intervention can achieve significant changes in MVPA and sedentary behavior in breast cancer survivors, making it a suitable intervention to administer in larger trials to examine biological and psychosocial endpoints of interest. In particular, the intervention's potential capacity to improve cardiometabolic health in this population is of interest, given its combination of increasing MVPA and decreasing sedentary behavior. Future research is also warranted to examine maintenance of behavior change, and whether possible attenuation over time may be reduced by re-introduction of telephone counselling, or by other forms of support such as personalized text messaging. In the longer term, the use of wearable technology has the potential to be an inexpensive and sustainable addition to care provided by clinicians and allied health professionals, or used in broad-reach interventions delivered via telephone support services.

Figure legend

Figure 1. CONSORT diagram: flow of participants through the ACTIVATE Trial, Melbourne, Australia, 2016 - 2017.

Supporting information

Supporting information 1. Scatterplot of difference in MVPA

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Table 1. Baseline (T1) characteristics of participants randomized to the intervention and control arms of the ACTIVATE Trial, Melbourne, Australia, 2016 - 2017 (n=83)

	Overall (n=83)	Intervention (n=43)	Control (n=40)
Age (years)	61.6 (6.4)	61.3 (5.9)	61.9 (7.0)
Marital status			

Never married	2 (2.4%)	2 (4.7%)	0 (0%)
Married/Common-law	61 (73.5%)	28 (65.1%)	33 (82.5%)
Separated/Divorced	17 (20.5%)	11 (26.0%)	6 (15.0%)
Widowed	3 (3.6%)	2 (4.7%)	1 (2.5%)
Country of birth			
Australia/New Zealand	63 (75.9%)	32 (74.4%)	31 (77.5%)
UK/Europe/Middle East	16 (19.3%)	9 (21%)	7 (18%)
Asia	2 (2.4%)	1 (2.3%)	1 (2.5%)
Other	2 (2.4%)	1 (2.3%)	1 (2.5%)
Education			
High school	26 (31.3%)	10 (23.3%)	16 (40%)
Diploma/University	38 (45.8%)	23 (53.5%)	15 (37.5%)
Postgraduate	19 (22.9%)	10 (23.3%)	9 (22.5%)
Household income			
< $40,000 AUD	18 (21.7%)	10 (23.3%)	8 (20%)
$40,000 - $79,999 AUD	27 (32.5%)	15 (34.9%)	12 (30%)
$80,000 AUD	8 (9.6%)	5 (11.6%)	3 (7.5%)
≥ $100,000 AUD	14 (16.9%)	9 (20.9%)	5 (12.5%)
Preferred not to answer	16 (19.3%)	4 (9.3%)	12 (30%)
Employment status			
Part-time	39 (47.0%)	19 (44.2%)	20 (50%)
Full-time	25 (30.1%)	13 (30.2%)	12 (30%)
Not working	19 (22.9%)	11 (25.6%)	8 (20%)
Smoking status			
Never smoker	47 (56.6%)	23 (53.5%)	24 (60%)
Former smoker	32 (38.6%)	17 (39.5%)	15 (37.5%)
Current smoker	4 (4.8%)	3 (7.0%)	1 (2.5%)
Alcohol intake (drinks per week)	3.1 (5.0)	2.9 (5.7)	3.4 (4.2)
Number of chronic comorbidities	1.9 (1.7)	1.9 (1.6)	1.9 (1.8)
Body mass index (kg/m^2)	29.0 (6.0)	29.4 (5.6)	28.5 (6.4)
Breast cancer stage at diagnosis			
I	23 (28.8%)	10 (23.8%)	13 (34.2%)
II	38 (47.5%)	21 (50.0%)	17 (44.7%)
III	19 (23.8%)	11 (26.9%)	8 (21.1%)
Treatment completed			
Surgery only	13 (15.7%)	5 (11.6%)	8 (20.0%)

Surgery with one adjuvant therapy (chemotherapy or radiotherapy)	27 (32.5%)	11 (25.6%)	16 (40.0%)
Surgery with two adjuvant therapies	43 (51.8%)	27 (62.8%)	16 (40.0%)

Data are mean (SD) or n (%)

Table 2. Changes in accelerometer measured moderate-vigorous physical activity and sedentary behavior (T1; baseline to T2; 12 weeks) within and between intervention and control arms in the ACTIVATE Trial, Melbourne, Australia, 2016 - 2017.

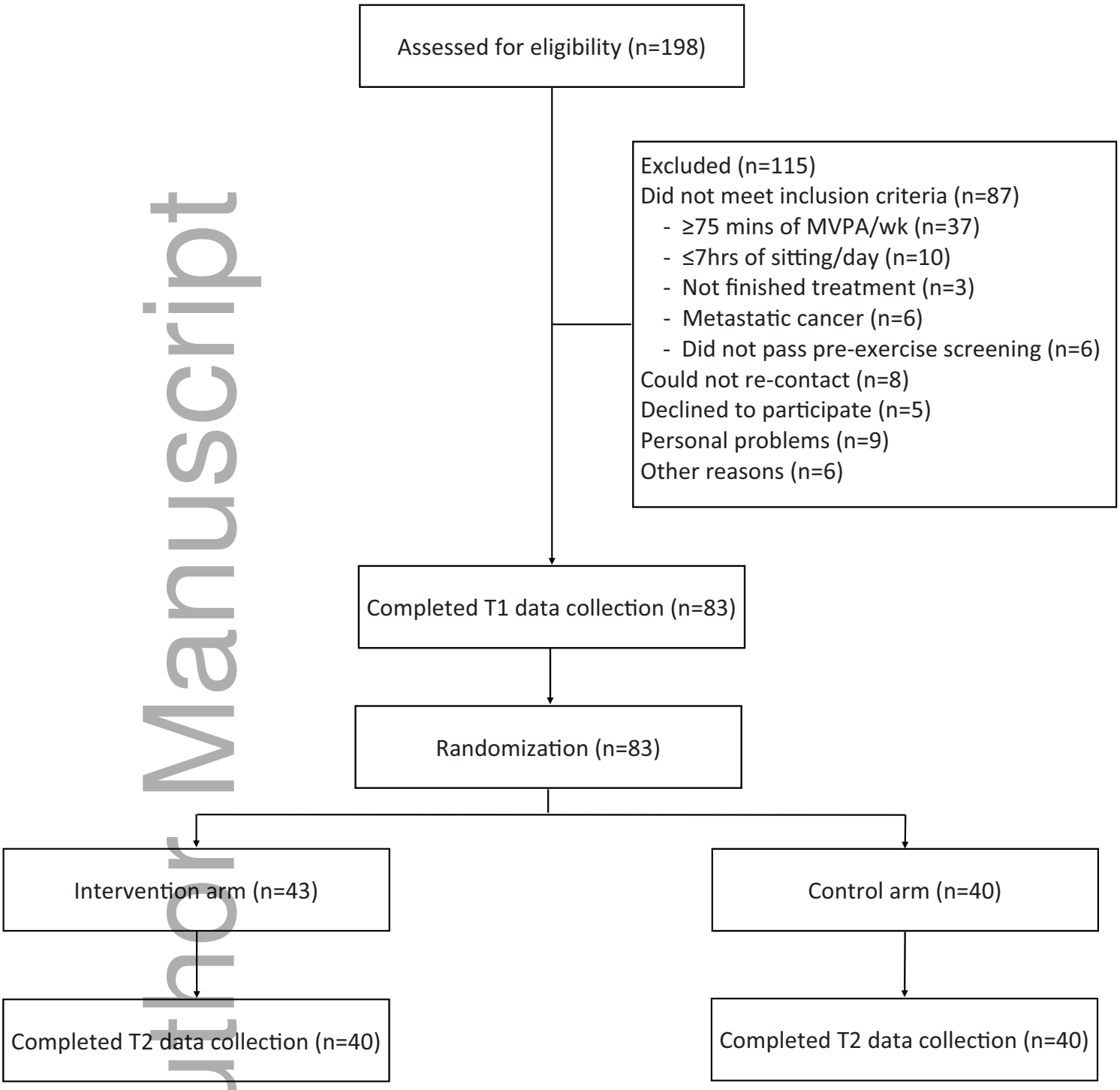
		Mean (SD)		Within arm change			Difference in change between arms		
	N	T1	T2		95%CI	p		95%CI	p
Actigraph® measured MVPA (min/wk)									
Sasaki MVPA (≥2,690 cpm, triaxial)							68.7	(21.7, 115.6)	<0.01
Intervention	40	180.3 (122.3)	249.6 (159.7)	66.5	(33.3, 99.8)	<0.01			
Control	40	169.7 (125.3)	170.1 (127.9)	-2.1	(-35.4, 31.1)	0.92			
Sasaki MVPA bouts[a] (≥2,690 cpm, triaxial)							38.7	(12.7, 64.7)	<0.01
Intervention	40	25.5 (37.4)	67.2 (77.4)	40.4	(22.0, 58.8)	<0.01			
Control	40	34.1 (61.0)	36.8 (62.0)	1.7	(-16.7, 20.1)	0.86			
Freedson MVPA (≥1,952 cpm, uniaxial)							40.6	(1.67, 79.5)	0.04
Intervention	40	104.7 (83.1)	159.0 (127.2)	52.0	(24.4, 79.6)	<0.01			
Control	40	103.9 (102.0)	117.1 (109.9)	11.4	(-16.1, 40.0)	0.41			
Freedson MVPA bouts[a] (≥1,952 cpm, uniaxial)							28.2	(4.7, 51.7)	0.02
Intervention	40	21.3 (36.2)	56.3 (70.4)	33.8	(17.1, 50.4)	<0.01			
Control	40	29.3 (54.2)	35.8 (59.9)	5.6	(-11.0, 22.18)	0.51			
Matthews MVPA (≥760 cpm, uniaxial)							69.6	(-19.6, 158.7)	0.13
Intervention	40	533.8 (224.7)	609.2 (313.9)	69.7	(6.5, 132.8)	0.03			
Control	40	505.6(250.7)	510.8 (235.0)	0.10	(-63.0, 63.2)	0.98			
Matthews MVPA bouts[a] (≥760 cpm, uniaxial)							44.4	(3.6, 85.2)	0.03
Intervention	40	63.0 (68.8)	119.0 (114.9)	54.4	(25.5, 83.3)	<0.01			

	Control	40	65.5 (87.2)	76.7 (93.4)	10.0	(-18.9, 38.9)	0.50		
activPAL™ measured sedentary behavior									
Sitting time (min/day)								-36.6	(-71.7, -1.6)	0.01
	Intervention	37	538.4 (95.0)	530.0 (103.6)	-23.5	(-49.0, -2.0)	0.07		
	Control	40	512.6 (112.7)	553.8 (176.7)	13.1	(-11.1, 37.3)	0.29		
Sitting time bouts[b] (min/day)								-42.1	(-82.7, -1.6)	0.04
	Intervention	37	377.54 (114.6)	357.1 (117.0)	-32.3	(-61.8, -2.8)	0.03		
	Control	40	340.5 (128.0)	380.1 (184.4)	9.8	(-18.2, 37.8)	0.50		
Standing time (min/day)								27.2	(-2.2, 56.5)	0.07
	Intervention	37	234.2 (68.6)	244.9 (91.1)	11.5	(-9.8, 32.9)	0.29		
	Control	40	270.3 (106.4)	265.1 (86.1)	-15.6	(-35.9, 4.6)	0.13		
Number of sit to stand transitions								2.3	(-2.2, 6.9)	0.31
	Intervention	37	42.4 (11.2)	45.9 (10.7)	2.5	(-0.7, 5.8)	0.13		
	Control	40	44.9 (12.9)	44.7 (11.5)	0.2	(-2.9, 3.4)	0.89		
Number of steps								933	(-215, 2082)	0.11
	Intervention	37	6821 (2343)	8193 (3301)	1241	(408, 2074)	0.04		
	Control	40	7197 (2424)	7539 (3404)	308	(-486, 1102)	0.45		

Actigraph® data are adjusted for daily wear time; activPAL™ data are adjusted for waking hours.

[a] MVPA bouts of 10 consecutive minutes or more

[b] Sitting time bouts of 20 consecutive minutes or more



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