Author/s:
Lynch, BM;Nguyen, NH;Moore, MM;Reeves, MM;Rosenberg, DE;Boyle, T;Milton, S;Friedenreich, CM;Vallance, JK;English, DR

Title:
Maintenance of physical activity and sedentary behavior change, and physical activity and sedentary behavior change after an abridged intervention: Secondary outcomes from the ACTIVATE Trial

Date:
2019-08-15

Citation:
Lynch, B. M., Nguyen, N. H., Moore, M. M., Reeves, M. M., Rosenberg, D. E., Boyle, T., Milton, S., Friedenreich, C. M., Vallance, J. K. & English, D. R. (2019). Maintenance of physical activity and sedentary behavior change, and physical activity and sedentary behavior change after an abridged intervention: Secondary outcomes from the ACTIVATE Trial. Cancer, 125 (16), pp.2856-2860. https://doi.org/10.1002/cncr.32142.

DR. BRIGID LYNCH (Orcid ID : 0000-0001-8060-547X)

Article type : Original Article

BRIEF REPORT

Manuscript title: Maintenance of physical activity and sedentary behavior change, and physical activity and sedentary behavior change after an abridged intervention: secondary outcomes from the ACTIVATE Trial

Running title: Secondary outcomes from the ACTIVATE Trial

Authors and affiliations: Brigid M. Lynch, PhD;[1,2,3] Nga H. Nguyen, PhD;[1] Melissa M. Moore, MBBS PhD FRACP;[4] Marina M. Reeves, PhD APD;[5] Dori E. Rosenberg, PhD MPH;[6] Terry Boyle, PhD;[7] Shakira Milton, MSc;[8] Christine M. Friedenreich, PhD;[9,10] Jeff K. Vallance, PhD;[11] Dallas R. English, PhD[1,2]

[1] Cancer Epidemiology and Intelligence Division, Cancer Council Victoria, Melbourne, Australia

[2] Centre for Epidemiology and Biostatistics, Melbourne School of Population and Global Health, The University of Melbourne, Australia

[3] Physical Activity Laboratory, Baker Heart and Diabetes Institute, Melbourne, Australia

[4] Medical Oncology, St Vincent's Hospital, Melbourne, Australia

[5] Cancer Prevention Research Centre, School of Public Health, The University of Queensland, Brisbane, Australia

[6] Kaiser Permanente Washington Health Research Institute, Seattle, USA

[7] Australian Centre for Precision Health, School of Health Sciences, University of South Australia Cancer Research Institute, Adelaide, Australia

[8] Department of General Practice, Melbourne Medical School, The University of Melbourne, Australia

[9] Department of Cancer Epidemiology and Prevention Research, Alberta Health Services, Calgary, Canada

[10] Departments of Oncology and Community Health Sciences, Cumming School of Medicine, University of Calgary, Calgary, Canada.
[11] Faculty of Health Disciplines, Athabasca University, Athabasca, Canada
Correspondence: Brigid M. Lynch, Cancer Epidemiology and Intelligence Division, Cancer Council Victoria, 615 St Kilda Road, Melbourne VIC 3004 AUSTRALIA. T: +61 3 9514 6209 F: +61 3 9514 6800 E: brigid.lynch@cancervic.org.au
Word count (abstract): 246
Word count (text): 1,499
Tables: 0 + 2 supplementary (supporting information)
Figures: 2
References: 9
Funding sources: This work was enabled by a grant from the World Cancer Research Fund – International (2015/1397). Lynch was supported by a National Breast Cancer Foundation Fellowship (ECF-15-012); Boyle was supported by a National Health and Medical Research Council Early Career Fellowship (1072266); Vallance was supported by the Canada Research Chairs program.
Conflict of interest: None to declare.
Acknowledgements: This research was supported by Register4 through its members' participation in research and/or provision of samples and information. Thanks also to the National Breast Cancer Foundation, the Breast Cancer Network of Australia, and Counterpart for their promotion of the ACTIVATE Trial and assistance with recruitment.
Condensed abstract: Participants who received the ACTIVATE Trial intervention successfully maintained their increased level of MVPA across the 12-week follow-up period, but the reduction in sedentary behavior was eroded. Receipt of the GarminVivofit2® alone was associated with a significant increase in MVPA and reduction in sedentary behavior within the waitlist control arm.
Author Contributions: Brigid Lynch: conceptualization, formal analysis, funding acquisition, investigation, methodology, project administration, supervision, writing – original draft, writing – review and editing. Nga Nguyen: data curation, formal analysis, investigation, project administration, software, and writing - review and editing. Melissa Moore: conceptualization, funding acquisition, methodology, writing - review and editing. Marina Reeves: conceptualization, funding acquisition, methodology, writing - review and editing. Dori Rosenberg: conceptualization, funding acquisition, methodology, writing - review and editing. Terry Boyle: conceptualization, writing - review and editing. Shakira

Milton: project administration, writing - review and editing. Christine Friedenreich: conceptualization, funding acquisition, writing - review and editing. Jeff Vallance: conceptualization, writing – original draft, writing - review and editing. Dallas English: conceptualization, funding acquisition, methodology, project administration, supervision, writing - review and editing.

ABSTRACT

Background: This brief report examines maintenance of moderate-vigorous physical activity (MVPA) and sedentary behavior changes approximately 12 weeks after the delivery of the ACTIVATE Trial primary intervention (Garmin Vivofit2®; behavioral feedback and goal setting session; and, five telephone-delivered health coaching sessions). We also examine the efficacy of an abridged intervention (use of the Garmin Vivofit 2® only) in the waitlist control group.

Methods: A pre-post design was employed to examine the secondary aims of the ACTIVATE Trial (n=80; mean age=62 years). MVPA and sedentary behavior were measured by Actigraph® and activPAL™ accelerometers after delivery of the primary intervention (T2), and again 12 weeks later (T3). Linear mixed models with random effects examined within-group changes in MVPA and sitting time variables.

Results: After the 12-week follow-up period, women in the primary intervention group had maintained their higher levels of MVPA (change from T2 to T3=14 min/week, 95% CI: -18, 46; p=0.37). However, their sitting time slightly increased (by 7 min/day, 95% CI: -20, 34; p=0.58), but it did not return to its pre-intervention level. After receiving the Garmin Vivotfit2®, the waitlist control group increased their MVPA (by 33 min/week, 95% CI: 3, 64; p=0.03) and reduced their sitting time (by 38 min/day, 95% CI: -69, -7; p=0.02) over the same 12-week period.

Conclusions: The secondary outcomes from the ACTIVATE Trial suggest that wearable technology may generate sustainable changes in MVPA and sitting time. Wearable technology alone may be sufficient to change behavior, at least in the short-term.

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

Clinical trial registration: ACTRN12616000175471.

INTRODUCTION

The ACTIVATE Trial examined the efficacy of a wearable technology-based intervention (using the Garmin Vivofit 2®, coupled with a behavioral feedback and goal setting session, and five telephone-delivered health coaching sessions) delivered over a 12-week period (T1 -

T2) to increase moderate-vigorous physical activity (MVPA) and reduce sitting time in breast cancer survivors. The intervention successfully increased MVPA (between group change = 69 min/week, 95% CI: 22, 116) and decreased sitting time (-37 min/day, 95% CI: -72, -2).[1]

Here, we report the secondary aims of the study, which were: (i) to examine maintenance of MVPA and sitting time changes in the primary intervention group, approximately 12 weeks post-intervention (T3); and (ii) to determine the efficacy of an abridged intervention (use of the Garmin Vivofit 2® only) in the waitlist control group.

MATERIALS AND METHODS

The ACTIVATE Trial protocol was approved by Cancer Council Victoria's Human Research Ethics Committee (HREC-1602), and all participants provided written, informed consent. An overview of the ACTIVATE Trial methods (primary and secondary outcomes) has previously been published.[2] A brief summary of methods relating to the secondary aims of the study are outlined, below.

Primary intervention arm – maintenance

Following data collection at T2, participants in the primary intervention group underwent a 12-week maintenance period (T2 – T3). Participants retained their Garmin Vivofit 2® but its use during this period was discretionary (i.e. not monitored).

Waitlist control arm – abridged intervention

After T2 data collection, waitlist control participants were provided with the same training in the set up (including downloading and installing the smartphone/tablet/PC application), calibration and use of the Garmin Vivofit 2® that the primary intervention group received following T1. The abridged intervention (wearable technology only) period was also 12 weeks (T2 – T3).

Data collection

At T3 participants were sent: an Actigraph® GT3X+ accelerometer (Actigraph, Pensacola, FL); an activPAL™ (PAL Technologies Limited, Glasgow, UK), and several hypoallergenic dressings to adhere the device to the thigh; written instructions on how to wear each accelerometer; a diary to record accelerometer use over a seven day period; a follow-up questionnaire; and a reply-paid envelope to return these materials.

As per our primary outcomes methods,[1] we used the Actigraph® GT3X+ to assess MVPA. 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. We used the Sasaki vector magnitude cut point (utilizing tri-axial data) of ≥2,690 cpm[3] to quantify MVPA (we also applied the Freedson[4] and Matthews[5] cutpoints; data presented as Supporting Information only). Sitting time was assessed by the activPAL™, which participants were asked to wear 24 hours/day. Data were processed using activPAL™ software version 7.2.32 (PAL Technologies Limited, Glasgow, UK) and by a customized program in SAS that combined activPAL™ and diary data.

Statistical analysis

Baseline characteristics were summarized for both groups (separately for participants who completed and did not complete T3). Linear mixed models with random effects, adjusted for accelerometer wear time (Actigraph® derived variables) and awake time (activPAL™ derived variables), examined within-group changes in MVPA and sitting time variables for both arms between each timepoint. We only considered the within-group changes because there is no appropriate control condition for either group. All analyses were carried out using Stata version 14 (Statacorp, College Station, TX, USA).

RESULTS

Of the 83 women enrolled in the ACTIVATE trial, there were 72 (87%; MVPA) and 66 (80%; sitting time) with complete data who were included in these analyses. The primary intervention arm had 36 women with valid Actigraph® data, and 30 women with valid activPAL™ data; 36 women in the waitlist control arm had complete data for both MVPA and sitting time. The baseline characteristics of participants who did and did not complete T3 are provided as Supporting Information.

Primary intervention arm – maintenance

The increase in MVPA attributed to the primary intervention was successfully maintained during the 12-week follow-up period (T2 – T3). On average, participants in this arm increased their MVPA by a further 14 min/week (95% CI: -18, 46; p=0.37). The MVPA of

participants in the primary intervention arm was 86 min/week (95% CI: 47, 125; p<0.01) higher at T3 than at T1.

Maintenance was also observed for ten-minute bouts of MVPA; the mean change between T2 and T3 was 8 min/week (95% CI: -17, 33; p=0.52). The average increase in MVPA accrued in 10-minute bouts between T1 and T3 was 51 min/week (95% CI: 24, 78; p <0.01). See Figure 1 and Supporting Information for more results for different accelerometer cutpoints.

INSERT FIGURE 1 ABOUT HERE

In contrast, we observed a small rebound effect for sitting time. After successfully reducing total sitting time by nearly 30 min/day between T1 and T2, average daily sitting time increased by seven min/day (95% CI: -20, 34; p =0.58) between T2 and T3. This increase meant that, across the whole trial period (from T1 to T3) sitting time was reduced by 21 min/day (95% CI: -62, 19; p =0.29).

The rebound effect for bouts of sitting time was even more pronounced: an average daily increase of 25 minutes was seen between T2 and T3 (95% CI: -2, 52; p=0.07). Thus, the average decrease in prolonged bouts of sitting between T1 and T3 was only 16 min/day (95% CI: -62, 29; p value=0.47). See Figure 2 and Supporting Information for more detail about changes in sitting time.

INSERT FIGURE 2 ABOUT HERE

Waitlist control arm – abridged intervention

After receiving the Garmin Vivofit 2® at T2, the waitlist control participants had increased their MVPA by 33 min/week (95% CI: 3, 64; p=0.03) at T3. The average increase in MVPA was even greater from T1 (38 min/week, 95% CI: 4, 73; p=0.03). MVPA accrued in bouts of 10 minutes or more also increased across the abridged intervention (19 min/day, 95% CI: -0, 38; p value=0.05). When we examined change from T1 to T3, the average weekly increase was 25 minutes (95% CI: 4, 46; p=0.02). See Figure 1 and Supporting Information for more detail on MVPA changes in the waitlist control arm.

The abridged intervention also appeared to reduce sitting time. Average daily sitting was reduced by 38 min/day (95% CI: -69, -7; p=0.02) in the waitlist control arm between T2 and T3. Sitting time at T3 was only 23 minutes less than at T1 (95% CI: -54, 8; p=0.15). The abridged intervention also decrease prolonged sitting: between T2 and T3 there was a 28 min/ day reduction (95% CI: -60, 5; p=0.09). Sitting time accrued in bouts of 20 minutes or more at T3 was 19 minutes less than it was at T1 (95% CI: -52, 14; p=0.24). See Figure 2 and Supporting Information for more detail about changes in sitting time.

DISCUSSION

The primary intervention appeared to facilitate sustained physical activity change in our population of breast cancer survivors. While there was some attenuation of the positive intervention effects on sitting time, the average duration spent sitting (and in prolonged sitting) at the end of the maintenance phase (T3) was still approximately 20 minutes per day less than at T1. Participants in the waitlist control group demonstrated significant improvements in MVPA and sitting time after receiving the wearable device alone.

Many of the strengths and limitations described in the ACTIVATE Trial primary outcomes paper[1] apply to this brief report. Due to funding constraints we were unable to test the efficacy of wearable technology alone in a randomized trial setting: a three-armed trial comparing the primary intervention, the abridged intervention and a control condition would have been ideal. We do not have any maintenance data for the waitlist control group, therefore we do not know whether the changes in MVPA and sitting time that occurred between T2 and T3 were sustained in the longer term. Bias due to the convenience sampling approach used for recruitment, and the drop-out of 11 participants (13%) over the course of the 24-week study (T1 – T3), should be considered when interpreting our results.

Few distance-based physical activity interventions for cancer survivors have reported follow-up outcomes. A recent review and meta-analysis of such interventions indicated that, of 29 randomized controlled trials published within the past five years, only ten reported follow-up information.[6] Wearable-based interventions for cancer survivors have recently emerged, however, most are feasibility and/or pilot studies using single group designs (e.g.[7-9]), and no follow-up data have been published to date. Results of the ACTIVATE Trial suggest that

wearable technology can facilitate a more active lifestyle for cancer survivors beyond the active intervention phase.

There is emerging evidence that wearables can promote physical activity and reduce sitting time across the cancer continuum, from pre-habilitation right through to long term survivorship. Wearable technology may be particularly helpful in reaching those living in rural and remote areas, or facing barriers to attending exercise facilities. Future studies with larger sample sizes, appropriate control or comparison groups, and assessment at follow up time points will allow stronger inferences to be made regarding the effectiveness of consumer wearables for cancer survivors.

Figure legend

Figure 1. Change in MVPA across the three timepoints of the ACTIVATE Trial (n=72)

Figure 2. Change in sitting time and prolonged sitting time across the three timepoints of the ACTIVATE Trial (n=66)

References

1. Lynch BM, Nguyen NH, Moore MM, et al. A randomized controlled trial of a wearable technology-based intervention for increasing moderate-vigorous physical activity and reducing sedentary behavior in breast cancer survivors: the ACTIVATE Trial. Cancer Submitted.

2. Lynch BM, Nguyen NH, Reeves MM, et al. Study design and methods for the ACTIVity And TEchnology (ACTIVATE) trial. Contemp Clin Trials 2018;64: 112-17.

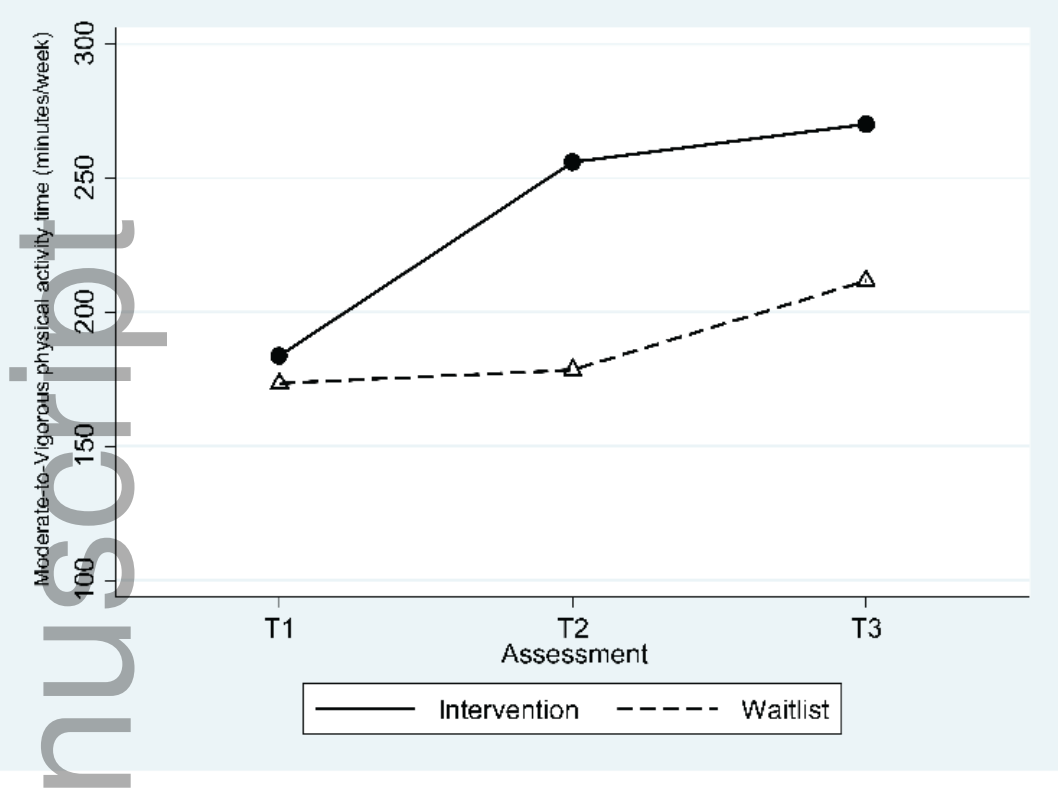
3. Sasaki JE, John D, Freedson PS. Validation and comparison of ActiGraph activity monitors. J Sci Med Sport 2011;14(5): 411-6.

4. Freedson PS, Melanson E, Sirard J. Calibration of the Computer Science and Applications, Inc. accelerometer. Medicine and Science in Sports and Exercise 1998;30(5): 777-81.

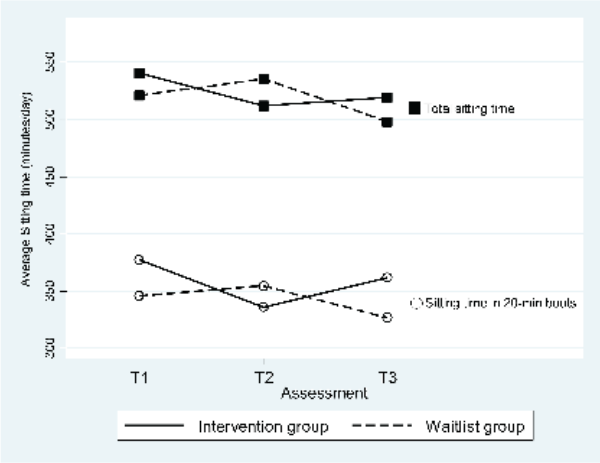
5. Matthew CE. Calibration of accelerometer output for adults. Med Sci Sports Exerc 2005;37(11 Suppl): S512-22.

6. Groen WG, van Harten WH, Vallance JK. Systematic review and meta-analysis of distance-based physical activity interventions for cancer survivors (2013-2018): We still haven't found what we're looking for. Cancer Treat Rev 2018;69: 188-203.

7. Gell NM, Grover KW, Humble M, Sexton M, Dittus K. Efficacy, feasibility, and acceptability of a novel technology-based intervention to support physical activity in cancer survivors. Support Care Cancer 2017;25(4): 1291-300.
8. Le A, Mitchell HR, Zheng DJ, et al. A home-based physical activity intervention using activity trackers in survivors of childhood cancer: A pilot study. Pediatr Blood Cancer 2017;64(2): 387-94.
9. Rossi A, Frechette L, Miller D, et al. Acceptability and feasibility of a Fitbit physical activity monitor for endometrial cancer survivors. Gynecol Oncol 2018;149(3): 470-75.



cncr_32142_f1.tif



cncr_32142_f2.tif