# Behavioural Intervention Trial to Improve Physical Activity in Cancer Survivors at Cardiovascular Risk

## Study investigators

Principal Investigator: Chloe Maxwell-Smith, PhD student at Curtin University

Email: [chloe.maxwell-smith@postgrad.curtin.edu.au](mailto:chloe.maxwell-smith@postgrad.curtin.edu.au)

Co-investigator: Dr Sarah Hardcastle, PhD supervisor

Email: [sarah.hardcastle@curtin.edu.au](mailto:chloe.maxwell-smith@postgrad.curtin.edu.au)

Co-investigator: Dr Paul Cohen, PhD supervisor

Email: [Paul.Cohen@sjog.org.au](mailto:Paul.Cohen@sjog.org.au)

Co-investigator: Prof. Cameron Platell, PhD supervisor

Email: [cameron.platell@uwa.edu.au](mailto:cameron.platell@uwa.edu.au)

Co-investigator: Dr Nik Zeps, PhD supervisor

Email: [nzeps@me.com](mailto:nzeps@me.com)

## Background and Rationale

Improvements in detection and treatment of cancer has led to an increase in survival rates (Australian Government, 2016). With 61% of cancer survivors being aged 65 or over, comorbidities are common. In fact, cancer survivors are at increased risk of secondary cancers, cardiovascular disease and other comorbidities compared to those without a cancer history (Mosher et al., 2009).

Cancer survivors are a high-risk group for lifestyle related comorbidities such as diabetes, heart disease, hypercholesterolemia and hypertension (Rock et al., 2012). Grimmett et al. (2011) found that 58% of colorectal cancer survivors were overweight or obese and 82% were insufficiently physically active. Furthermore, research by Mowls, Brame, Martinez and Beebe (2016) comparing US cancer survivors to non-cancer survivors revealed that after their cancer recovery, cancer survivors were no more likely to practice health behaviours than those who did not receive a cancer diagnosis. Despite the benefits of a healthy diet and regular exercise for reducing risk factors in cancer survivors (Holick et al., 2008), many cancer survivors continue to lead unhealthy lifestyles (Mosher et al., 2009).

Health behaviour interventions aiming to improve physical activity and healthy eating can be effective for reducing comorbidities in cancer survivors who may be at future cardiovascular risk (Lynch, Courneya, Sethi, Patrao & Hawkes, 2014; Morey et al., 2009; Pinto, Papandonatos, Goldstein, Marcus & Farrell, 2013). Specifically, health behaviour interventions that incorporate psychological components such as goal-setting, group and peer interactions, counselling and feedback to influence behaviour change have recently yielded promising findings (Bennett, Lyons, Winters-Stone, Nail & Scherer, 2007; Valle, Tate, Mayer & Allicock, 2013; von Gruenigen, Courneya, Gibbons, Kavanagh, Waggoner & Lerner, 2008). Furthermore, interventions that meet support needs and offer opportunities for self-monitoring have been found to be effective in improving health behaviours in cancer survivors (Rock et al., 2015; James et al., 2015; Rogers et al., 2016).

Rock et al. (2015) recently implemented the Exercise and Nutrition to Enhance Good Health for You (ENERGY) trial, to promote weight loss in overweight and obese breast cancer survivors. Based in the United States, this 2-year intervention involves 693 breast cancer survivors undergoing intensive group sessions in conjunction with telephone/email contact for individualised guidance. Although follow-up assessment for this trial is still underway, preliminary data indicates that physical activity levels significantly increased, such that participants in the treatment group lost 6% of their baseline body weight and completed 238 minutes of moderate physical activity per week, compared to a 1.5% weight loss and 163 minutes of moderate physical activity per week in the less-intensive control group at 6 months (Rock et al., 2015).

A smaller scale intervention was implemented by James et al. (2015) to improve the health of cancer survivors and carers. The Exercise and Nutrition Routine Improving Cancer Health (ENRICH) trial randomized 174 survivors and carers to an 8-week group-based intervention aimed to improve self-management and maintenance of health behaviours. Specifically, group sessions addressed multiple health behaviours, including walking, muscular strength and healthy eating, delivered in group activities, information sessions and goal-setting (James et al., 2015). Intervention findings revealed that at 20-week follow-up, the treatment group completed significantly more steps and had a significant increase in vegetable intake, compared to the usual care control group (James et al., 2015).

Rogers et al. (2015) implemented a 3-month behaviour change randomised controlled trial for 222 breast cancer survivors aiming to increase physical activity. The Better Exercise Adherence after Treatment for Cancer (BEAT Cancer) trial incorporated the social-cognitive theory, including supervised exercise sessions, face-to-face counselling sessions, a heart-rate monitor and information book. The intervention resulted in a significant increase in moderate physical activity in the treatment group post-intervention (3 months), with significant effects in self-reported physical activity remaining at 6 months. Another recent intervention by Lahart, Metsios, Nevill, Kitas and Carmichael (2016) aimed to increase physical activity in breast cancer survivors with a 6-month home-based intervention design. Intervention materials included face-to-face and telephone counselling aimed at encouraging achievement. Findings revealed a significant increase across total, leisure and vigorous physical activity for the intervention group, compared to a usual care control (Lahart et al., 2016). Both Rogers et al. (2016) and Lahart et al. (2016) have recognised the importance of incorporating psychological components into effective physical activity interventions. Based on the effectiveness of recent interventions and recent qualitative work (Hardcastle et al., 2016; Maxwell-Smith et al., 2016), it is apparent that addressing support needs and facilitating self-monitoring strategies for cancer survivors are helpful components for improving health behaviours.

A systematic review by Goode, Lawler, Brakenridge, Reeves and Eakin (2015) assessed telephone, print and web-based interventions for promoting health behaviours among cancer survivors. Findings indicated that, despite these interventions being effective for initiating behaviour change, the current literature centres largely around breast cancer survivors (Goode et al., 2015). There are limited research studies that implement a behaviour change intervention to increase physical activity specifically in endometrial and colorectal cancer survivors, despite these groups being associated with high cardiovascular risk (Leach et al., 2015). Up to 70% of endometrial cancer survivors are obese (von Gruenigen, Gil, Frasure, Jenison & Hopkins, 2005), and these survivors are twice as likely to die from CVD than cancer (Ward, Shah, Saenz, McHale & Plaxe, 2012). Additionally, only 20-25% of colorectal cancer survivors are currently meeting the government’s physical activity guidelines (Fisher, Smith & Wardle, 2016). Given that these two cancer types have a high rate of survival, and that a significant proportion of these individuals have comorbidities that result in increased cardiovascular risk, interventions to increase physical activity in these patient populations are important.

Fitbits are relatively new devices for monitoring physical activity. Previous physical activity interventions for cancer survivors have relied heavily on the use of pedometers as a form of self-monitoring activity (Frensham, Zarnowiecki, Parfitt, Stanley & Dollman, 2014; James et al., 2015; Lee et al., 2013; Ligibel et al., 2012; Park et al., 2015). The Fitbit may be more pleasant and practical to use than a pedometer as it can be worn around the wrist and replaces a watch. The device also links to the Fitbit website and mobile application, where users can self-monitor their health behaviours, create a network to promote accountability and peer-support amongst other Fitbit users, and compete with others to achieve health-related goals.

Several studies have already assessed the efficacy of using the Fitbit to promote physical activity in non-cancer groups. Cadmus-Bertram, Marcus, Patterson, Parker and Morey (2015) conducted a randomized trial using the Fitbit to increase physical activity in a 16-week intervention for post-menopausal, inactive women. Findings indicated that activity in women who wore the Fitbit increased significantly, compared to non-significant increases in women who wore a pedometer (Cadmus-Bertram et al., 2015). Similarly, Wang et al. (2015) reported an increase in moderate to vigorous physical activity in overweight and obese adults who wore a Fitbit as a part of a physical activity intervention. In this study, a Fitbit was more effective for maintaining increased in physical activity at follow-up, compared to SMS booster messages (Wang et al., 2015). A trial to assess the efficacy of active video games to promote physical activity in children with cancer is currently underway (Kauhanen et al., 2014). To the best of our knowledge, no study has assessed the effectiveness of Fitbits to increase physical activity in adult cancer survivors.

Physical activity intervention designs that are based on theoretical underpinnings have been found to be more successful for improving health-related outcomes compared to those that are atheoretical (Baker et al., 2008; Fortier, Duda, Guerin & Teixeira, 2012; Parschau et al., 2014). The Health Action Process Approach (HAPA) is a behavioural change theory that attempts to overcome the ‘intention-behaviour gap’ (Schwarzer, 1992). The theory proposes two over-arching phases that are required for behaviour change; motivation and volition. Motivational processes involve initial recognition of risk perception and outcome expectances associated with behavioural change. The individual must also believe that they can implement this change, and form an intention to do so. Individuals graduate to volitional processes and should then begin to act on their intentions to change. This will require planning and self-efficacy for the proposed behaviour, before taking the initial steps of performing the new behaviour. After an individual initiates action, they must also engage in self-regulation to monitor and maintain the behaviour change (Schwarzer & Luszczynska, 2008).

Interventions that employ the HAPA model to improve health behaviours have showed promise in a range of clinical settings including patients with type 2 diabetes mellitus (MacPhail, Mullan, Sharpe, MacCann & Todd, 2014), coronary artery disease (Platter et al., 2016), and pregnant women (Gaston & Prapavessis, 2014). A recent intervention by Ungar, Sieverding, Weidner, Ulrich and Wiskemann (2016), employed the HAPA model and the concept of self-regulation to increase physical activity in cancer patients. The randomized trial consisted of a 4-week intervention with a 10-week follow-up for 72 cancer patients who were inactive at the time of recruitment. The intervention focused on components of social support and self-regulation within the HAPA model, by providing the intervention group with HAPA-based counselling to enhance self-regulation, in conjunction with role model support (Ungar et al., 2016). Results revealed that there were significantly more participants in the counselling group who were meeting the physical activity guidelines post-intervention (46%), than in the active control group (19%). Within the counselling group, participants who received role model support were significantly more likely to adhere to the recommended physical activity guidelines (Ungar et al., 2016).

Given the promise of the HAPA model and self-regulation for improving health behaviours (Weidner, Sieverding & Chesney, 2016), physical activity interventions for cancer survivors that involve monitoring and motivational tools are warranted. Furthermore, the use of a Fitbit as a self-monitoring and motivational device to increase physical activity in cancer survivors is yet to be explored and a novel perspective of the proposed study.

## Aims

The objective of the current study is to determine whether a behavioural intervention increases physical activity in cancer survivors who are at increased risk of cardiovascular disease. A secondary aim to assess the feasibility of the administration of this intervention in a clinical setting, that could be incorporated into routine after-care for cancer survivors who have completed active treatment.

## Null hypothesis

A behavioural intervention for cancer survivors will be no more effective in improving physical activity than receiving generic information on the physical activity guidelines. Specifically, there will be no statistical difference in physical activity following 12 weeks of wearing a Fitbit and attending two group sessions which cover action planning, goal-setting and self-monitoring, compared to routine care.

## Methods

### Study design

The intervention design is shown in the attached schematic (Appendix A). The intervention will be 12 weeks in duration, beginning from when participants are randomized following their baseline assessment. At the three assessment points (baseline, 12 weeks and 24 weeks), participants’ initial BMI (body weight & height will be recorded), blood pressure, physical activity (using Actigraph GT3X accelerometer readings), self-reported physical activity (using the International Physical Activity Questionnaire, Short Form; IPAQ-SF), physical activity attitudes (using the Health Action Process Approach; HAPA items), and quality of life (using the Medical Outcomes Survey – Short Form; MOS-SF-12) will be measured. The IPAQ-SF, subscales of the MOS-SF-12, and HAPA items have been amalgamated into a questionnaire (Appendix B). Participants will also be asked to give a qualitative assessment of intervention feasibility, practicality and additional feedback soon after the 12-week follow-up has been completed (see Appendix C for feedback guide).

An independent statistician not involved in the recruitment or intervention will conduct the process of randomisation following the baseline assessment. Randomisation will be stratified by age, gender, cancer type, cancer stage, BMI and physical activity level. Upon randomisation, participants will be evenly split between a treatment group (N=32) and a control group (N=32).

## Participant Eligibility

## Inclusion Criteria

1) Cancer survivors undergoing follow-up at St. John of God Subiaco Hospital, WOMEN Centre in West Leederville, and Hollywood Private Hospital in Nedlands, Western Australia.

2) Patients have completed active cancer treatment (surgery and/or radiotherapy and/or chemotherapy) within the last 5 years (excluding hormone therapy).

3) Have comorbidities resulting in increased CVD risk, as identified through hospital medical records (i.e., on blood pressure medication or have blood pressure >150/90mm Hg, BMI >28, hypercholesterolemia >5.2mmol/L), OR an American Society of Anaesthesiologists (ASA) score of 2 or 3 (in the absence of appropriate medical records).

4) Are in remission at the time of recruitment.

5) Are aged 18-80 years at recruitment.

6) Are English-reading and speaking.

7) Live locally within 100km of Perth.

8) Have no surgery planned during the 6 months following recruitment.

9) Are willing and able to give informed consent to participate in the study.

10) Are willing to maintain contact with the investigators for the 6 months following recruitment.

As described above in criteria 3), comorbidity will be assessed using available medical records of BMI, blood pressure and cholesterol. In the absence of this data, individuals will be recruited based on their ASA score at time of treatment. Only those with an ASA score of 2 or 3 will be eligible for recruitment. An ASA score from 1-4 is assigned to patients upon admission to hospital for a surgical procedure. A low ASA score indicates that the patient is at minimal cardiovascular risk, and a higher ASA score suggests that the patient suffers from comorbidities that may pose a threat to their life. Participants with ASA scores of 2 or 3 will have comorbidities such as hypertension, hypercholesterolemia, hyperlipidaemia, and elevated BMI, putting them at risk of CVD. The ASA score is globally recognised as an indicator of physical health status of patients prior to undergoing surgery (Owens, Felts & Spitznagel, 1978).

### Exclusion criteria

1) Undergoing treatment for cancer.

2) Have completed cancer treatment >5 years prior to recruitment.

3) Have an ASA score of 1 or 4.

4) Are younger than 18 years or older than 80 years of age.

5) Have recurrent or metastatic disease.

6) Have a diagnosis of a severe psychiatric illness.

7) Have cardiac abnormalities including unstable angina or recent myocardial infarction.

8) Have any severe disability that may affect physical function including severe arthritis.

9) Are currently enrolled in a health behaviour trial or program such as Weight Watchers.

Individuals who have been diagnosed with uterine carcinosarcoma (MMMT), uterine serous carcinoma, or ovarian cancer will be excluded during the screening process. These cancer subtypes are typically associated with a poor prognosis. By excluding these subtypes, we hope to avoid attempting to contact individuals who may be deceased.

Individuals with an ASA score of 1 are unlikely to benefit from the project as it is expected that cardiovascular health improvements will be minimal in patients who are already in good health. Additionally, those with an ASA score of 1 do not fall into the target sample of ‘cancer survivors at high cardiovascular risk’. Individuals with an ASA score of 4 are considered to have significant life threatening comorbidities, deeming the intervention inappropriate for this group.

### Sample size

Power calculations suggest that a sample size of 56 is sufficient to detect a significant difference in physical activity between intervention and control groups. According to G\*Power, at an alpha level of .05, 56 participants (28 per group) will provide an 80% chance of capturing a ‘small to moderate’ group x time interaction. We aim to recruit 64 participants into the trial to allow for loss to follow-up. This ensures that, even if 12% are lost to follow-up, the intervention will still be adequately powered at 80% to detect a meaningful change. A dropout rate of 12% is a reasonable estimation, given previous dropout rates of around 10% in 3-month and 6-month health behaviour interventions for cancer survivors (Lahart et al., 2016; Rogers et al., 2009; Short et al., 2015).

Therefore, participants will be randomized into treatment (N=32) and control (N=32) groups following baseline assessment.

## Study setting

### Assessments at baseline, 12 weeks and 24 weeks will be conducted in a clinic room at St. John of God Hospital in Subiaco. The baseline assessment will be performed by co-investigator CMS, prior to randomization. Subsequent assessments will be performed by a trial co-ordinator who is blinded to group allocation and not involved in the administration of the intervention. Group sessions will also be held at St. John of God Hospital in a vacant meeting room, and will be led by the primary investigators of this study (Chloe Maxwell-Smith and Dr Sarah Hardcastle). Participants will receive a parking/travel reimbursement to the value of $5 for each time they visit the hospital for an assessment or group session.

### Recruitment

Participants are cancer survivors (N = 64) who have completed active treatment within the past five years for gynaecological and colorectal cancers, and are at cardiovascular risk as indicated by an ASA score of 2 or 3. Participants will be recruited from St. John of God Hospital in Subiaco, WOMEN Centre, West Leederville, and Hollywood Private Hospital, Nedlands. Eligible survivors will be invited to participate in the trial via letter of invitation (Appendix D).

#### Procedure for invitation via letter

Following ethical approval, we will assess eligibility from hospital records for each participating colorectal surgeon and gynaecologic oncologist. Individuals who are considered eligible will be mailed an invitation letter from their treating specialist (Appendix D) and instructions to contact the study investigators by phone, text message or email to confirm their consent to participate. Individuals who do not reply to this invitation letter will be contacted by the researchers via telephone after 14 days to confirm whether they wish to participate.

## Intervention

### Treatment group

All participants will receive printed information on the government guidelines for physical activity, making physical activity goals, and action planning, at baseline (Appendix E).

The treatment group will be able to collect the Fitbit post-randomisation. Participants will be able to pick the Fitbit up from the hospital, signing it out upon collection at their first group meeting. They will be asked to wear the Fitbit as much as possible during the 12-week intervention (at least 8 hours per day, preferably all waking hours), and will be encouraged to download Fitbit software that will assist in tracking their physical activity. Use of the Fitbits will provide participants with a practical and convenient method for monitoring their activity.

Throughout the 12-week intervention, participants in the treatment group will be required to attend two 1-hour group sessions. The first group session will be held in week 1, and the second in week 4 of the study. Session one will focus on introducing participants to the Fitbit and giving instructions on how to use this device as a self-monitoring tool. Participants will complete goal-setting worksheets (Appendix F) to set their activity goals for the following 12 weeks. Behaviour change specialists SH and CMS will assist participants with effective action planning, goal-setting and self-monitoring.

Session two will attend to support needs and help participants to plan for and overcome barriers to increasing their physical activity level. Participants will also be able to adjust previously established goals, if necessary. This session will also allow for trouble-shooting of any problems or queries that participants encounter regarding Fitbit wear and use.

Participants will take all worksheets from the sessions home with them, to assist with achieving their goals. At the end of the 12-week intervention, all participants should have completed two group sessions. Although this is not required, it is recommended that participants will also meet and build rapport with other participants in their neighbourhood outside of the meetings to boost their support and provide a sense of accountability. A final booster message will be sent to participants via text message or email (according to participant preference) at week 6. In keeping with the theme of self-monitoring and support needs, this booster message will contain a brief note of encouragement and a recommendation to track physical activity, with the aim of meeting the government guidelines. Participants will attend their end of intervention assessment at 12 weeks, where they will also be invited to assess the feasibility of the intervention. At 24 weeks (twelve weeks post-intervention), participants will attend their final follow-up assessment. Participants will be required to return their Fitbit within the fortnight following the 24-week intervention.

### Control group

Control participants will also receive printed information on the government guidelines for physical activity, making physical activity goals, and action planning, at baseline (Appendix E). These resources are comparable to the generic recommendations that cancer survivors have reported receiving post-treatment (Maxwell-Smith, Zeps, Hagger, Platell & Hardcastle, 2016), and therefore represent a usual care condition. In addition to these print materials, participants will also receive goal-setting and problem solving worksheets (Appendix F). These materials will be identical to those that will be given to the treatment group during group sessions. However, members of the research team will not direct the control group or engage with them regarding the activities. Participants will receive a booster text message or email at 6 weeks. For the control group, this message will be a reminder of the government guidelines and encourage participants to aim for these recommendations. Participants will undergo the end of intervention assessment at 12 weeks, and their final follow-up assessment at 24 weeks (12 weeks post-intervention). The control group will not receive a Fitbit to assist with self-monitoring of activity during the 12-week intervention. After the completion of the study, participants from the control group will be given the opportunity to trial the Fitbit for 6 weeks.

## Measures

#### Physical activity

##### Objective physical activity reading

All participants will be asked to wear an Actigraph GT3X accelerometer to track their activity for seven days at baseline, 12 weeks and 24 weeks (Actigraph, LLC, Pensacola, Florida, USA). Accelerometer readings will be used as an objective measure of physical activity.

##### Self-reported physical activity - IPAQ-SF

The International Physical Activity Questionnaire, Short Form (IPAQ-SF (Craig et al., 2003) assesses self-reported physical activity over a 7-day period. This questionnaire is scored based on the amount and intensity of accumulated minutes of exercise per week, with participants falling into high, medium or low categories. The questionnaire was developed by an International Consensus Group in 1998, and is recognised to be reliable (Craig et al., 2003; van Poppel et al., 2010) and valid (Tran et al., 2013).

#### Blood pressure & BMI

These two measures are useful as general indicators of cardiovascular and morphological changes in participants throughout the intervention. Comparisons of blood pressure and BMI across baseline, 12-week and 24-week assessments may suggest trends in the data that can be attributed to the intervention.

#### Quality of life, exercise attitudes & feasibility

Quality of life and exercise attitudes will be assessed by a range of quantitative scales which will be administered in conjunction with the IPAQ-SF at baseline, 12 weeks and 24 weeks. Quality of life will be measured using the general health (1 item), social functioning (1 item), mental health (2 items) and vitality (1 item) subscales from the MOS-SF-12 Health Survey (Ware, Kosinski & Keller, 1996). This instrument has demonstrated psychometric reliability and validity for assessing psychological well-being (Ware & Sherbourne, 1992). Exercise attitudes will be measured using items from the HAPA scale (Schwarzer & Luszczynska, 2008). This approach considers psychological constructs such as intention and planning to help explain health attitudes. Specifically, the constructs that will be assessed by the HAPA scale are: risk perception (4 items), outcome expectancy (3 items), action self-efficacy (5 items), maintenance self-efficacy (9 items), intention (2 items), and action planning (1 item). Appendix B shows the questionnaire that will be administered to participants, which includes the above measures. Feasibility will be assessed using a qualitative feedback sheet (Appendix C) after 12 weeks. Within the feasibility assessment, participants will be able to share their opinions about effective and ineffective components of the intervention.

## Data collection, management and analysis

Data will be collected by CMS at baseline, and by an independent trial co-ordinator post-intervention (12 weeks) and at follow-up (24 weeks). Physiological indicators such as BMI and blood pressure will be recorded with pen and paper. Established measures, such as the IPAQ-SF for measuring physical activity will be filled into printed forms with pen and paper. This data will later be amalgamated and entered into statistical software for analysis.

The analysis will be a mixture of quantitative and qualitative approaches. Quantitative data will be analysed in the statistical software program, SPSS version 24, to establish the overall distribution and trends within the data. A mixed ANOVA will allow us to examine between-group physiological and psychological differences that could be attributed to the effect of the behavioural intervention, as well as within-subject effects across time. The primary outcome variable will be physical activity per week, pre- and post-intervention. The group x time interaction will display any intervention effect. According to G\*Power, at an alpha level of .05, our sample of 56 participants (28 per group) will provide an 80% probability of capturing a small to moderate (f = .17) interaction. Qualitative data from the 24-week follow-up will be analysed using inductive thematic analysis to identify common themes associated with feedback and feasibility.

Once this data has been entered into the statistical software for analysis, it can no longer be linked to participant identity. The data set will be analysed and interpreted holistically, with no single participant’s data being individually examined after the data cleaning stage. Data will be stored on a password protected electronic storage device, on password protected computers, and/or in a locked cupboard in a secure location at Curtin University.

## Budget

The research team has been offered $5000AUD to from St. John of God to support this project. These funds will be used to purchase Fitbits and Accelerometers. We also have access to a HDR consumables allowance of $2000AUD, which will be used for consumable items and services, such as stationery, printing and parking reimbursements.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Item | Category of funds | Quantity | Cost | Funds Remaining |
| Fitbits\* | SJOG grant | 15 | $120 x 15= $1800 | $3200 |
| Accelerometers (Actigraph GT3X)\*\* | SJOG grant | 10 | $300 x 10= $3000 | $200 |
| Envelopes (for invitation letters) | HDR consumables | 400 | $1.50 x 400= $600 | $1400 |
| Printing (for invitation letters) | HDR consumables | 400 pages | 10c x 400= $40 | $1360 |
| Printing (intervention materials, packages, worksheets etc.) | HDR consumables | 600 (10 pages per participant) | 10c x 600= $60 | $1300 |
| Parking/travel reimbursements ($5) | HDR consumables | 30 participants w/ 3 visits & 30 participants w/ 5 visits | $5 x 30 x 8=  $1200 | $100 |

\*Fitbit model is yet to be determined. Fifteen Fitbits will be borrowed from fellow researchers.

\*\* Twenty accelerometers will be borrowed from fellow researchers.

## Ethical Issues

## There are no ethical issues identified with the proposed study. Every effort will be made to minimise the risk of writing to deceased patients. Patients with cancer types that are associated with a poorer prognosis have been excluded during screening. In the case that the research team attempts to contact deceased patient, the treating specialist will be notified and a letter of apology sent to the deceased patient’s next of kin.

## References

Australian Government. (2016). *Cancer in Australia Statistics*. Retrieved from https://canceraustralia.gov.au/affected-cancer/what-cancer/cancer-australia-statistics

Baker, G., Gray, S.R., Wright, A., Fitzsimons, C., Nimmo, M., Lowry, R. & Mutrie, N. (2008). The effect of a pedometer-based community walking intervention “Walking for Wellbeing in the West” on physical activity levels and health outcomes: a 12-week randomized controlled trial. *International Journal of Behavioral Nutrition and Physical Activity, 5*, 44-58. doi: 10.1186/1479-5868-5-44

Basen-Engquist, K., Carmack Taylor, C.L., Rosenblum, C., Smith, M.A., Shinn, E.H., Greisinger, A.,…Rivera, E. (2006). Randomized pilot test of a lifestyle physical activity intervention for breast cancer survivors. *Patient Education and Counseling, 64,* 225-234. doi: 10.1016/j.pec.2006.02.006

Bennett, J.A., Lyons, K.S., Winters-Stone, K., Nail, L.M. & Scherer, J. (2007). Motivational interviewing to increase physical activity in long-term cancer survivors: a randomized controlled trial. *Nursing Research, 56*(1), 18-27.

Cadmus-Bertram, L.A., Marcus, B.H., Patterson, R.E., Parker, B.A. & Morey, B.L. (2015). Randomized trial of a Fitbit-based physical activity intervention for women. *American Journal of Preventative Medicine, 49*(3), 414-418. doi: 10.1016/j.amepre.2015.01.020

Craig, C.L., Marshall, A.L., Sjöström, M., Bauman, A.E., Booth, M.L., Ainsworth, B.E….Oja, P. (2003). International Physical Activity Questionnaire: 12-Country Reliability and Validity. *Medicine & Science in Sports & Exercise, 35*(8), 1381-1395. doi: 10.1249/01.MSS.0000078924.61453.FB

Djuric, Z., Mirasolo, J., Kimbrough, L., Brown, D.R., Heilbrun, L.K., Canar, L.,…Simon, M.S. (2009). A pilot trial of spirituality counseling for weight loss maintenance in African American breast cancer survivors. *Journal of the National Medical Association, 101*(6), 552-564.

Fisher, A., Smith, L. & Wardle, J. (2016). Physical activity advice could become part of routine care for colorectal cancer survivors. *Future Oncology, 12*(2), 139-141. doi: 10.2217/fon.15.269

Flynn, M.M. & Reinert, S.E. (2010). Comparing an olive-oil enriched diet to a standard lower-fat diet for weight loss in breast cancer survivors: A pilot study. *Journal of Women’s Health, 19*(2), 1155-1161. doi: 10.1089/jwh.2009.1759

Fortier, M.S., Duda, J.L., Guerin, E. & Teixeira, P.J. (2008). Promoting physical activity: Development and testing of self-determination theory-based interventions. *The International Journal of Behavioral Nutrition and Physical Activity, 9*(1), 20-33. doi: 10.1186/1479-5868-9-20

Frensham, L.J., Zarnowiecki, D.M., Parfitt, G., Stanley, R.M. & Dollman, J. (2014). Steps toward improving diet and exercise for cancer survivors (STRIDE): a quasi-randomised controlled trial protocol. *BMC Cancer, 14*(1), 428-434. doi: 10.1186/1471-2407-14-428

Gaston, A. & Prapavessis, H. (2014). Using a combined protection motivation theory and health action process approach intervention to promote exercise during pregnancy. *Journal of Behavioral Medicine, 37*(2), 173-184. doi: 10.1007/s10865-012-9477-2

Greenlee, H.A., Crew, K.D., Mata, J.M., McKinley, P.S., Rundle, A.G., Zhang, W.,…Hershman, D.L. (2013). A pilot randomized controlled trial of a commercial diet and exercise weight loss program in minority breast cancer survivors. *Obesity, 21,* 65-76. doi: 10.1038/oby.2012.177

Grimmett, C., Bridgewater, J., Steptoe, A. & Wardle, J. (2011). Lifestyle and quality of life in colorectal cancer survivors. *Quality of Life Research, 20*(8), 1237-1245. doi: 10.1007/s11136-011-9855-1

Holick, C.N., Newcomb, P.A, Trentham-Dietz, A., Titus-Ernstoff, L., Bersch, A.J., Stampfer, M.J….Willett, W.C. (2008). Physical activity and survival after diagnosis or invasive breast cancer. *Cancer Epidemiology Biomarkers & Prevention, 17*(2), 379-386. doi: 10.1158/1055-9965.EPI-07-0771

James, E.L., Stacey, F.G., Chapman, K., Boyes, A.W., Burrows, T., Girgis, G.,…Lubans, D.R. (2015). Impact of a nutrition and physical activity intervention (ENRICH: Exercise and Nutrition Routine Improving Cancer Health) on health behaviours of cancer survivors and carers: a pragmatic randomized controlled trial. *BMC Cancer, 15*(1)*,* 710-725. doi: 10.1186/s12885-015-1775-y

Kauhanen, L., Järvelä, L., Lähteenmäki, P.M., Arola, M., Heinonen, O.J., Axelin, A.,…Salanterä, S. (2014). Active video games to promote physical activity in children with cancer: A randomized clinical trial with follow-up. *BMC Pediatrics, 14*, 94-103. doi: 10.1186/1471-2431-14-94

Kim, S.H., Shin, M.S., Lee, H.S., Lee, E.S., Ro, J.S., Kang, H.S.,…Yun, Y.H. (2011). Randomized pilot test of a simultaneous stage matched exercise and diet intervention for breast cancer survivors. *Oncology Nursing Forum, 38*(2), E97-E106. doi: 10.1188/11.ONF.E97-E106

Lahart, I.M., Metsios, G.S., Nevill, A.M., Kitas, G.D. & Carmichael, A.R. (2016). Randomised controlled trial of a home-based physical activity intervention in breast cancer survivors. *BMC Cancer, 16*(1), 234-247. doi: 10.1186/s12885-016-2258-5

Leach, C.R., Weaver, K.E., Aziz, N.M., Alfano, C.M., Bellizzi, K.M., Kent, E.E., …Rowland, J.H. (2015). The complex health profile of long-term cancer survivors: prevalence and predictors of comorbid conditions. *Journal of Cancer Survivorship, 9*(2), 239-251. doi: 10.1007/s11764-014-0403-1

Lee, D.H., Kim, J.Y., Lee, M.K., Lee, C., Min, J.H., Jeong, D.H.,…Jeon, J.Y. (2013). Effects of a 12-week home-based exercise program on the level of physical activity, insulin, and cytokines in colorectal cancer survivors: a pilot study. *Supportive Care in Cancer, 21,* 2537-2545. doi: 10.1007/s00520-013-1822-7

Ligibel, J.A., Meyerhardt, J., Pierce, J.P., Najita, J., Shockro, L., Campbell, N.,…Shapiro, C. (2012). Impact of a telephone-based physical activity intervention upon exercise behaviors and fitness in cancer survivors enrolled in a cooperative group setting. *Breast Cancer Research and Treatment, 132,* 205-213. doi: 10.1007/s10549-011-1882-7

Lynch, B.M., Courneya, K.S., Sethi, P., Patrao, T.A. & Hawkes, A.L. (2014). A randomized controlled trial of a multiple behavior change intervention delivered to colorectal cancer survivors. *Cancer, 120*(17), 2665-2672. doi: 10.1002/cncr.28773

MacPhail, M., Mullan, B., Sharpe, L., MacCann, C. & Todd, J. (2014). Using the health action process approach to predict and improve health outcomes in individuals with type 2 diabetes mellitus. *Diabetes, Metabolic Syndrome and Obesity: Targets and Therapy, 7,* 469-479. doi: 10.2147/DMSO.S68428

Maxwell-Smith, C., Zeps, N., Hagger, M.S., Platell, C. & Hardcastle, S.J. (2016). Barriers to physical activity participation in colorectal cancer survivors at high risk of cardiovascular disease. *Psycho-Oncology.* doi: 10.1002/pon.4234

Mosher, C.E., Sloane, R., Morey, M.C., Clutter Snyder, D., Cohen, H.J., Miller, P.E. & Demark-Wahnefried, W. (2009). Associations between lifestyle factors and quality of life among older long-term breast, prostate, and colorectal cancer survivors. *Cancer, 115*(17), 4001-4009. doi: 10.1002/cncr.24436

Morey, M.C., Snyder, D.C., Sloane, R., Cohen, H.J., Peterson, B., Hartman, T.J.,…Demark-Wahnefried, W. (2009). Effects of home-based diet and exercise on functional outcomes among older, overweight long-term cancer survivors: RENEW a randomized controlled trial. *Journal of the American Medical Association, 301*(18), 1883-1891. doi: 10.1001/jama.2009.643

Mowls, D.S., Brame, L.S., Martinez, S.A. & Beebe, L.A. (2016). Lifestyle behaviors among US cancer survivors. *Journal of Cancer Survivorship, 10*(4), 692-698.

Park, J.H., Lee, J., Oh, M., Park, H., Chae, J., Kim, D.I.,…Jeon, J.Y. (2015). The effect of oncologists’ exercise recommendations on the level or exercise and quality of life of breast and colorectal cancer: A randomized controlled trial. *Cancer, 121*(16), 2740-2748. doi: 10.1002/cncr.29400

Parschau, L., Barz, M., Richert, J., Knoll, N., Lippke, S. & Schwarzer, R. (2014). Physical activity among adults with obesity: Testing the health action process approach. *Rehabilitation Psychology, 59*(1), 42-49. doi: 10.1037/a0035290

Pinto, B.M., Papandonatos, G.D., Goldstein, M.G., Marcus, B.H. & Farrell, N. (2013). Home-based physical activity intervention for colorectal cancer survivors. *Psycho-Oncology, 22*, 54-64. doi: 10.1002/pon.2047

Pinto, B.M, Stein, K. & Dunsiger, S. (2015). Peers promoting physical activity among breast cancer survivors: A randomized controlled trial. *Health Psychology, 34*(5), 463-472. doi: 10.1037/hea0000120

Platter, M., Hofer, M., Hölzl, C., Huber, A., Renn, D., Webb, D. & Höfer, S. (2016). Supporting cardiac patient physical activity: a brief health psychological intervention. *The Central European Journal of Medicine, 128,* 175-181. doi: 10.1007/s00508-016-0968-y

Rock, C.L., Doyle, C., Demark-Wahnefried, W., Meyerhardt, J., Courneya, K.S., Schwartz, A.L….Gansler, T. (2012). Nutrition and physical activity guidelines for cancer survivors. *Ca: a Cancer Journal for Clinicians, 62*(4), 242-274. doi: 10.3322/caac.21142

Rock, C.L., Flatt, S.W., Byers, T.E., Colditz, G.A., Demark-Wahnefried, W., Ganz, P.A.,…Wyatt, H. (2015). Results of the exercise and nutrition to enhance recovery for you (ENERGY) trial: A behavioral weight loss intervention in overweight or obese breast cancer survivors. *Journal of Clinical Oncology, 33*(28), 3169-3176. doi: 10.1200/JCO.2015.61.1095

Rogers, L.Q., Courneya, K.S., Anton, P.M., Hopkins-Price, P., Verhulst, S., Vicari, S.K.,…McAuley, E. (2015). Effects of the BEAT Cancer physical activity behavior change intervention on physical activity, aerobic fitness, and quality of life in breast cancer survivors: a multicenter randomized controlled trial. *Breast Cancer Research and Treatment, 149,* 109-119. doi: 10.1007/s10549-014-3216-z

Rogers, L.Q., Courneya, K.S., Anton, P.M., Hopkins-Price, P., Verhulst, S., Robbs, R.S…McAuley, E. (2016). Social cognitive constructs did not mediate the BEAT cancer intervention effects on objective physical activity and behavior based on multivariable path analysis. *Annals of Behavioral Medicine,* 1-6. doi: 10.1007/s12160-016-9840-6

Rogers, L.Q., Hopkins-Price, P., Vicari, S., Markwell, S., Pamenter, R., Courneya, K.S.,…Verhulst, S. (2009). Physical activity and health outcomes three months after completing a physical activity behavior change intervention: Persistent and delayed effects. *Cancer Epidemiology, Biomarkers & Prevention, 18*(5), 1410-1418. doi: 10.1158/1055-9965.EPI-08-1045

Schwarzer, R. (1992). Self-effiacy in the adoption and maintenance of health behaviours: Theoretical approaches and a new model. In R. Schwarzer (Ed.), *Self-efficacy: Thought control of action* (pp. 217-243). Washington, DC: Hemisphere.

Schwarzer, R. & Luszczynska A. (2008). How to overcome health compromising behaviors: The health action process approach. *European Psychologist, 13*(2), 141-151. doi: 10.1027/1016-9040.13.2.141

Sheppard, V.B., Hicks, J., Makambi, K., Hurtado-de-Mendoza, A., Demark-Wahnefried, W. & Adams-Campbell, L. (2016). The feasibility and acceptability of a diet and exercise trial in overweight and obese black breast cancer survivors: The stepping STONE study. *Contemporary Clinical Trials, 46,* 106-113. doi: 10.1016./j.cct.2015.12.005

Short, C.E., James, E.L., Girgis, A., D’Souza, M.I. & Plotnikoff, R.C. (2015). Main outcomes of the Move More for Life Trial: a randomised controlled trial examining the effects of tailored-print and targeted-print materials for promoting physical activity among post-treatment breast cancer survivors. *Psycho-Oncology, 24,* 771-778. doi: 10.1002/pon.3639

Tran, D.V., Lee, A.H., Au, T.B., Nguyen, C.T. & Hoang, D.V. (2013). Reliability and validity of the International Physical Activity Questionnaire-Short Form for older adults in Vietnam. *Journal of the Australian Health Promotion Association, 24*(2), 126-131. doi: 10.1071/HE13012

Ungar, N., Sieverding, M., Weidner, G., Ulrich, C.M. & Wiskemann, J. (2016). A self-regulation-based intervention to increase physical activity in cancer patients. *Psychology, Health & Medicine, 21*(2), 163-175. doi: 10.1080/13548506.2015.1081255

Valle, C.G., Tate, D.F., Mayer, D.K., Allicock, M. & Cai, J. (2013). A randomized trial of a Facebook-based physical activity intervention for young adult cancer survivors. *Journal of Cancer Survivorship, 7,* 355-368. doi: 10.1007/s11764-013-0279-5

van Poppel, M.N., Chinapaw, M.J., Mokkink, L.B., van Mechelen, W. & Terwee, C.B. (2010). Physical activity questionnaires for adults: a systematic review of measurement properties. *Sports Medicine, 40*(7), 565-600. doi: 10.2165/11531930-000000000-00000

von Gruenigen, V.E., Courneya, K.S., Gibbons, H.E., Kavanagh, M.B., Waggoner, S.E. & Lerner E. (2008). Feasibility and effectiveness of a lifestyle intervention program in obese endometrial cancer patients: a randomized trial. *Gynecologic Oncology, 109*, 19-26. doi: 10.1016/j.ygyno.2007.12.026

von Gruenigen, V.E., Gil, K.M., Frasure, H.E., Jenison, E.L. & Hopkins, M.P. (2005). The impact of obesity and age on quality of life in gynecologic surgery. *American Journal of Obstetrics and Gynecology, 193*(4), 1369-1375. doi: 10.1016/j.ajog.2005.03.038

Wang, J.B., Cadmus-Bertram, L.A., Natarajan, L., White, M.M., Madanat, H., Nichols, J.F.,…Pierce, J.P. (2015). Wearable sensor/device (Fitbit One) and SMS text-messaging prompts to increase physical activity in overweight and obese adults: a randomized controlled trial. *Telemedicine and e-Health, 21*(10), 782-792. doi: 10.1089/tmj.2014.0176

Ward, K.K., Shah, N.R., Saenz, C.C., McHale, M.T. & Plaxe, S.C. (2012). Cardiovascular disease is the leading cause of death among endometrial cancer survivors. *Gynecologic Oncology, 126*(2), 176-179. doi: 10.1016/j.ygyno.2012.04.013

Ware, J.E., Kosinski, M. & Keller, S.D. (1996). A 12-Item short form health survey: Construction of scales and preliminary tests of reliability and validity. *Medical Care, 34*(3), 220-233.

Ware, J.E. & Sherbourne, C.D. (1992). The MOS 36-item short form health survey (SF-36). *Medical Care, 30*(6), 473-483.

Weidner, G., Sieverding, M. & Chesney, M.A. (2016). The role of self-regulation in health and illness. *Psychology, Health & Medicine, 21*(2), 135-137. doi: 10.1080/13548506.2015.1115528