ORIGINAL ARTICLE

Effectiveness of an independent physical activity programme in improving physical activity amongst breast and colorectal cancer survivors: Study protocol for a randomized controlled trial

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ABSTRACT

Background: Previous research has documented the benefits of physical activity (PA) for cancer survivors which include improved quality of life, physical, physiological, emotional and social functioning, reduced relapse of cancer and the mitigation of cancer mortality. This study aims to evaluate the effects of an independent PA programme based on PA level, quality of life, self-efficacy, outcome expectations, reinforcement, behavioural capability and observational learning amongst registered National Cancer Society Malaysia’s (NCSM) cancer survivors.

Methods: A two-armed, parallel, double-blinded, randomized, controlled trial, intervention and wait-list control groups will be conducted amongst 106 NCSM’s cancer survivors. The programme is developed based on a Social Cognitive Theory that combines both psychoeducation and social media approaches to behavioural intervention. The duration of intervention will be 2 months, in which data will be collected at baseline, 2-month (immediately post-intervention) and 4-month. The primary outcome of the study is to determine the PA level of the participant which will be measured as MET-minutes/week of PA using the International Physical Activity Questionnaire (IPAQ). There are four measurements of PA that are measured which are moderate and vigorous PA (MVPA) MET-minutes/week, light PA MET-minutes/week, moderate PA MET-minutes/week and vigorous PA MET-minutes/week. A Generalised Estimating Equation (GEE) analysis will be used to evaluate the effectiveness of the intervention, adjusted for baseline covariates on both continuous and categorical outcomes. This study will utilize a significance level of 0.05 with a confidence interval of 95% for means estimation in rejecting null hypothesis. The trial registered to the Australian New Zealand Clinical Trials (ANZCTR) with the Registration Number, ACTRN12620000039987.

Conclusion: The programme will be useful as a supplementary prescription to assist policy makers to strengthen non-pharmacological cancer management options and to empower cancer survivors to be self-reliant and self-sufficient to include PA as part of their recovery process.

KEYWORDS:
Independent physical activity, Cancer survivor, Social Cognitive Theory

INTRODUCTION

Cancer is a growing public health concern worldwide. According to a World Health Organization (WHO) report in 2018, cancer is the second most leading cause of mortality globally, which accounted for 9.6 million deaths.¹ In Malaysia, previous studies have documented the escalating cases of cancer incidence.²,³ Compared to 2006, the incidence of cancer nearly doubled from 21,773 to 41,236 new cancer cases in 2016.⁴ Despite the increase in new cancer cases over the years in Malaysia, the 5-year cancer survival rate is improving.³ The 5-year survival rate for breast cancer survivors from 2000 until 2005 was 49.0%.⁴ According to the MyScan 2018 report, an improving trend was observed whereby the 3-year survival rate from the data collected from 2007 until 2011 was 66.8%.³ With the increase of incidence of cancer and the 5-year survival rate improvement, the chances of cancer survivors living longer is getting higher. Therefore, survivorship in cancer has become an important discussion in recent literature.

Meta-analysis and systematic reviews reported that any mode of physical activity (PA) intervention was proven to improve health-related quality of life, sleep quality, emotional well-being, self-esteem, cancer-related fatigue, social functioning, anxiety, aerobic fitness and functional capacity, reduced the risk of cancer relapses and mitigated cancer mortality for both breast and colorectal cancer patients.⁵-⁷ Despite the many benefits of PA for cancer survivors, the level of PA performed by cancer survivors is expected to decline and many did not meet the recommended level of PA.⁸⁻¹⁰ In Malaysia, there is a lack of PA national surveillance amongst the local cancer population. A case control study that was conducted on 51 breast cancer survivors who were diagnosed between 2005 to
2010 reported that only 23.5% engaged in the recommended level of PA.12

Various standalone methods to increase the uptake of PA participation amongst cancer survivors have been utilized, such as supervised training, non-tailored print materials, non-tailored internet sites, video-based aids or physician-directed approaches. However, a complex health awareness intervention module that is integrated with a solid theoretical framework has proven to be more superior than non-theory based intervention modules.13 A theoretical framework, such as Social Cognitive Theory (SCT), considers a unique way for an individual to achieve a particular behaviour, in this case, a targeted PA level. In the intervention programme reported in this paper, the five constructs of SCT used are self-efficacy, behavioural capability, observational learning, reinforcements and outcome expectations. In conducting an intervention programme that involves behavioural change, a theory-based intervention has shown to have a positive impact in achieving the desired result.14 The same applies to independent PA programs, which according to SCT, an important factor for encouraging a behaviour is by obtaining feedback and providing encouragement.14,15

The objective of this study is to implement and evaluate the effects of an independent exercise intervention programme based on PA level, quality of life, self-efficacy, behavioural capability, reinforcements, observational learning and outcome expectations amongst cancer survivors registered with the National Cancer Society Malaysia (NCSM).

MATERIALS AND METHODS

Study location
The NCSM (also referred as Persatuan Kesihatan Kanzer Malaysia) is a non-profit, tax exempt, charitable organization which was established in 1966 in terms of the laws of the Malaysian Societies Act and Registrar of Societies Malaysia.14 NCSM is the first cancer organization in Malaysia which provides a holistic approach on education, care and support services for people affected by cancer and their caregivers. Currently NCSM has branches in six states (Johor, Negeri Sembilan, Melaka, Perak, Penang and Sarawak).15

Study design
This study trial is designed as randomized, controlled, patient and outcome assessor blinded with two parallel groups, intervention and wait-list control groups. Randomization will be 1:1 allocation ratio of intervention and control group using block randomization. It will be conducted amongst 106 NCSM’s cancer survivors. The programme is developed based on a SCT that combines both psychoeducation and social media approaches to behavioural intervention. The duration of intervention will be 2 months, in which data will be collected at baseline, 2-month (immediately post-intervention) and 4-month. The primary outcome of the study is to determine the PA level of the participant and it is measured as MET-minutes/week of PA using the International Physical Activity Questionnaire (IPAQ). The secondary outcome of the study comprises two parts, quality of life and Social Cognitive Theory constructs. Quality of life (QoL) outcomes is measured using the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC-QLQ) version 3.

Study duration
The study will be conducted from February 2020 to December 2021.

Study population and study setting
The sampling frame is both self-registered breast cancer and colorectal cancer patients attending or are active members of any of the two NCSM branches in Kuala Lumpur (KL) and Melaka. The recruitment process began in August 2019 until December 2020. The recruitment process to identify the eligible study population involves the distribution of flyers containing information regarding this study. The flyers shall be circulated internally within NCSM via Facebook, Instagram and WhatsApp groups. In addition, the study shall be promoted to its members in each NCSM event. Interested cancer survivors will be screened for eligibility by the researcher and randomly assigned to intervention or control groups. The inclusion criteria are as follows:

i. Malaysian citizen cancer patient between the age of 18 years old and 65 years old who are registered with NCSM and actively involved with NCSM KL and Melaka

ii. Stage I to III (or IIIA for breast cancer) who are not currently receiving (and do not plan to receive during the duration of study enrollment) chemotherapy or radiation therapy. The stagings are according to the American Joint Committee on Cancer Staging Manual 7th edition.

iii. More than 8 weeks post-surgical procedure

iv. Post-treatment three months

v. Obtained medical clearance from physician

vi. Grade 0 or 1 for Eastern Cooperative Oncology Group (ECOG) Performance Status

Exclusion criteria are as follows:

i. Participated, on average, 30 to 60 min per day (≥150 min per week) of moderate intensity for at least 5 days per week or 20 to 30 min per day (≥75min per week) of vigorous intensity for at least 5 days per week or an equivalent combination of the two

ii. Medical or psychological condition that would interfere with the ability to fully participate during the study enrollment (e.g., psychosis, schizophrenia, etc.)

iii. Recurrent disease,

iv. Elective surgery planned during the duration of the intervention that would interfere with intervention participation (e.g., breast reconstructive surgery) and

v. Planned travel that interferes with the scheduled study sessions (i.e., no travel in the first 4 weeks and no travel in the last week of the intervention).

Sample size
The sample size calculation is based on the detection of mean differences of total PA MET-min/week within an intervention group at 12 weeks (immediately after intervention) using the standard formula for trials using individual randomization.17 At 95% level of significance, 80% power and 10% of non-participation among eligible participants, the number of participants for each intervention and control group is determined to be 53. Therefore, the total number of participants in this study, which includes both the intervention and the control groups shall be 106.
Table I: A summary of HoPS programme to improve physical activity among cancer survivors

<table>
<thead>
<tr>
<th>Week</th>
<th>Components</th>
<th># Method</th>
<th>SCT constructs</th>
<th>What and How</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Group education: Health education - Group discussion</td>
<td>1x 2-hour and 30 minutes face-to-face meeting session</td>
<td>Behavioural capability Outcome expectations Reinforcements</td>
<td>The first 30 minutes is health education on physical activity knowledge, benefits of PA, goal setting, barriers of physical activity and motivation through a role model The next two hours are a coached exercise session</td>
</tr>
<tr>
<td>2</td>
<td>Structured direct remote contact feedback strategy</td>
<td>1x individual WhatsApp</td>
<td>Self-efficacy Behavioural capability</td>
<td>Online IPAQ survey and weekly feedback on physical activity progress</td>
</tr>
<tr>
<td>3</td>
<td>Structured direct remote contact feedback strategy</td>
<td>1x individual WhatsApp</td>
<td>Self-efficacy Behavioural capacity</td>
<td>Online IPAQ survey and weekly feedback on physical activity progress</td>
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<td>4</td>
<td>Structured direct remote contact feedback strategy</td>
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<td>5</td>
<td>Structured direct remote contact feedback strategy</td>
<td>1x individual WhatsApp</td>
<td>Self-efficacy Behavioural capacity</td>
<td>Reminder on physical activity knowledge Online IPAQ and feedback on journaling</td>
</tr>
<tr>
<td>6</td>
<td>Structured direct remote contact feedback strategy</td>
<td>1x individual WhatsApp</td>
<td>Outcome expectations Self-efficacy Behavioural capacity Reinforcements</td>
<td>Reminder on goal setting Online IPAQ and feedback on journaling</td>
</tr>
<tr>
<td>7</td>
<td>Structured direct remote contact feedback strategy</td>
<td>1x individual WhatsApp</td>
<td>Self-efficacy Behavioural capacity Reinforcements</td>
<td>Reminder on barriers of physical activity Online IPAQ and feedback on journaling</td>
</tr>
<tr>
<td>8</td>
<td>Structured direct remote contact feedback strategy</td>
<td>1x individual WhatsApp</td>
<td>Self-efficacy Behavioural capacity</td>
<td>Reminder on motivation Online IPAQ and feedback on journaling</td>
</tr>
<tr>
<td></td>
<td>Practical session</td>
<td>1x 2-hour face-to-face meeting session</td>
<td>Self-efficacy Behavioural capacity</td>
<td>The next two hours are a coached exercise session</td>
</tr>
</tbody>
</table>

# = Frequency, += and IPAQ = International Physical Activity Questionnaire

Randomization, allocation concealment and blinding
The method used to generate the sequence in which subjects will be randomized is the block randomization by computer generated random sequence method. A double-blinded technique is employed in which the participating cancer survivors and the outcome assessor are unaware of the group allocation. Third-party assignment is to be used, in which each eligible participant is number-coded by the researcher. Only the researcher will have access to the cancer survivor names and codes to ensure safe keeping and confidentiality of all records. The allocation process shall involve contacting the holder of the allocation schedule who is ‘off-site’ using the code list. Participants will be contacted centrally by telephone once the allocation is assigned. Each participant in the HoPS programme shall be provided with a non-tailored printed booklet, videos and a gradual tapering down of face-to-face remote feedback communication method to enable supervised home-based PA. The independent PA programme is a 2-month intervention programme. The study flow has two phases; a training phase (2-month) and follow-up phase at 2-month (immediately post-intervention) and at 4-month (Table I).

Face-to-face group meetings
There will be 2 meet up sessions for all participants in the HoPS group. The sessions will provide a standard lecture delivered by the researcher using Microsoft Powerpoint slides followed by a coached exercise session. The first session will include a lecture on health education that explains the HoPS program, PA knowledge, barriers to PA and goal setting. The lecture will then be followed by a sharing session by a role model (a cancer survivor) who shall share their experiences in engaging in PA. In each of the session, a coached exercise session will then conducted by a certified exercise instructor with at least 3 years of experience. The focus will be to train the participants on how to perform the exercise routine correctly for cancer survivors. This shall involve both aerobic and resistance exercises.

Intervention
The name of the intervention programme is called Home-based Physical Activity for Survivors (HoPS) which is an independent programme that aims to improve PA level participation amongst cancer survivors, in particular breast and colorectal cancer survivors by applying SCT in the development of the program. Both psychoeducation and social media approaches shall be combined to implement behavioural intervention. Each participant in the HoPS programme shall be provided with a non-tailored printed booklet, videos and a gradual tapering down of face-to-face group meetings to improve knowledge and skills relevant to PA. WhatsApp media is to be used as a structured direct remote feedback communication method to enable supervised home-based PA. The independent PA programme is a 2-month intervention programme. The study flow has two phases; a training phase (2-month) and follow-up phase at 2-month (immediately post-intervention) and at 4-month (Table I).
A non-tailored or standardized printed booklet will be given to each HoPS participant which will serve as a handout for the lectures given in the face-to-face group meetings and include a personal PA dairy. As this booklet has been designed specifically for this study, it is written in the Malay language. It is a standardized booklet and participants are taught on how to set goals as well as schedule and track their PA.

WhatsApp messages
A structured direct remote contact feedback strategy using WhatsApp media will be used to channel supervised feedback to the HoPS participants. From week 2 to week 8, participants are to be requested to complete a short weekly International Physical Activity Questionnaire (IPAQ) in order to assess their PA level. The results will be analyzed to determine their daily and weekly activity patterns in relation to physical activities of moderate intensity. Participants will receive WhatsApp messages each week containing graphical presentation of individual progress of PA.

Video supplementation
A series of video-based aid will be given to the participants as supplementation for independent PA. The content of this video is a series of exercises which shall be one taught during coached exercise session. This video is hoped to serves as aid to guide on right technique exercises for cancer survivors.

The HoPS programme is a two-month intervention program. In the training phase, the face-to-face group meetings are to be held on week 1 and 8, while the structured remote feedback strategy will be delivered weekly during the training phase starting from week 2. From week 5 to 8, weekly standardized WhatsApp messages shall be sent to the participants which reiterates the salient points of the lectures covered during the face-to-face group meetings.

Participants in the control group will continue receiving standard care provided by their physician during the intervention period. They will receive the HoPS programme once the final data collection has been completed or wait-list control.

Outcomes
The primary outcome of the study is to determine the PA level of the participant. It will be measured as MET-minutes/week of PA using the IPAQ. There are four measurements of PA that are measured which are moderate and vigorous PA (MVPA) MET-minutes/week, light PA MET-minutes/week, moderate PA MET-minutes/week and vigorous PA MET-minutes/week. The study will only include moderate and vigorous PA MET-minutes/week.
Fig. 1: Study design and process of the independent physical activity program.

Inclusion criteria:

i. A Malaysian citizen diagnosed with breast or colorectal cancer between the age of 18 and 65 years old, is registered with the National Cancer Society Malaysia (NCSM) and is actively involved any of the 3 branches of NCSM in Kuala Lumpur and Melaka,

ii. With Stage I to III cancer (or IIIA for breast cancer) who is not currently receiving and does not plan on receiving chemotherapy or radiation therapy for the duration of study enrollment,

iii. Is more than 8 weeks post-surgical procedure,

iv. Is post-treatment for three months,

v. Has obtained medical clearance from a physician,

vi. Has obtained Grade 0 or 1 for Eastern Cooperative Oncology Group (ECOG) Performance Status.

Exclusion criteria

i. Participating in PA, on average, 30 to 60 minutes per day (greater than or equal to 150 minutes per week) of moderate intensity for at least 5 days per week or 20 to 30 minutes per day (greater than or equal to 75 minutes per week) of vigorous intensity for at least 5 days per week or an equivalent combination of the two,\textsuperscript{11}

ii. Has a medical or psychological condition that would interfere with the ability to fully participate in the study

iii. Has a recurring disease,

iv. Has an elective surgery planned during the duration of the intervention that would interfere with their participation in the intervention program, and

v. Has travel plans which would interfere with the scheduled study sessions.
vigorou PA for the first PA level measurement (MVPA MET-
minutes/week), complying with the international guidelines
recommendation of health or fitness benefits gained from
these two PA levels for cancer survivors 11.

The secondary outcome of the study comprises will be of two
parts, namely quality of life and SCT constructs. QoL
outcomes is measured using the European Organization for
Research and Treatment of Cancer Quality of Life
Questionnaire (EORTC-QLQ) version 3 which is composed of
three measurements which are functional scales, symptom
scales and a global health status / QoL scale. The scales range
in score from 0 to 100. A high scale score represents a higher
response level. Thus, a high score for a functional scale
represents a high / healthy level of functioning, a high score
for the global health status / QoL represents a high QoL, but
a high score for a symptom scale / item represents a high
level of symptomatology / problems 18. SCT construct covers
four measurements included in the study which are self-
efficacy, behavioural capability, reinforcements, outcome
expectations and observational learning. The covariates of
the study include age, marital status, ethnicity, education,
stage/grade, treatment plan, co-morbidities and social
support. The assessment tools used are described in Table II.

Data Collection and Data Entry
There will be three stages of data collection which are at
baseline, 2-month and 4- month. The baseline data will be
collected via a self-reported questionnaire and to optimize
validity of responses, a face-to-face meeting will be held to
ensure clarity of the questions. This is important as the other
two stages of data collection will be carried out utilizing an
online survey. To minimize loss in follow-ups, and if the
online questionnaire is not feasible, a telephone interview
will be conducted. All the details of the respondents and the
information will be kept confidential and used only for the
research purposes.

Quality control
Questionnaire validation and reliability testing
There will be two types of validation conducted for the
questionnaire which are content validity and face validity.
The content of the questionnaires will be assessed and
checked by Public Health Specialists, Public Health Specialists
in Cancer Management, exercise specialist and
psychometrics. All feedback and comments by the experts
will be taken into consideration for further improvement of
the questionnaires. The questions will be prepared in English
and follow translational process according to the WHO
guidelines (https://www.who.int/substance Abuse/research_
tools/translation/en/) to maintain the meaning of the
questions when it is translated to Malay. The face validity of
questionnaire will be conducted among a group cancer
survivor in NCSM’s KL and these will not be included.

The reliability testing of the questionnaire will be conducted
among 30 eligible individuals from KL branch of NCSM.
Internal consistency reliability (using Cronbach’s alpha for
an item with Likert scale answer) and test-retest reliability
(Intraclass correlation) will be used. The questionnaires will be
administered twice to all the participants with an interval
of two weeks for the test-retest reliability. The IPAQ
questionnaire that contains continuous data will be assessed
using test-retest reliability while the EORTC-QLQ and SCT
constructs questionnaires that have Likert scale answers will be
assessed using internal consistency reliability.

Intervention module validation
Content validity and pre-testing as well as cognitive
interviewing with cancer survivors will be conducted for the
intervention module. The content of the intervention module
from booklet, video, structured messages in WA and slides
presented in face-to-face group meeting will be vetted by
public health specialists, public health specialist in cancer
management, clinical psychologist and exercise specialists.
The intervention module will then pre-tested with five cancer
survivors from NCSM. During this session, cognitive
interviewing will be also conducted to assess the
understanding of the whole module with the participants.
Further constructive comments and cues that may indicate
an issue, including hesitation or information provided that
seems to conflict will be discussed and improved prior to the
commencing of this study.

Statistical analyses
Statistical Package of Social Sciences System (SPSS) version 25
will be used to analyze the data for this study. The data will
be collected and analyzed using intention-to-treat analysis.
Before the data analyse, screening will be conducted to detect
any error. Any out of range data or any error will be checked
with the respective respondents’ questionnaire and correction
is done accordingly. For inferential statistic, t-test / Mann
Whitney U test and Chi square test/Fisher exact tests are
conducted for continuous and categorical measurements
respectively. These tests are formulated at baseline to look for
homogeneity as well as at post-intervention to determine the
differences between the intervention group and the control
group. Generalised Estimating Equation (GEE) analysis will
be used to evaluate the effectiveness of the intervention,
adjusted for baseline covariates in both continuous and
categorical outcomes. This study uses a significance level of
0.05 with a confidence interval of 95% for means estimation
reject the null hypothesis.

Discussion
The independent PA programme proposed here will introduce
a Malaysian tailored approach in two branches of NCSM.
The work will contribute to the current knowledge in the area
of implementation and the effectiveness of PA programme
for cancer survivors. Until now there is minimal evidence
from randomized community trials that proves the
effectiveness of a PA programme on PA level improvement
amongst cancer patients. This evidence is necessary to
substantiate the urgency to invest in a comprehensive
community (inter)national PA program. The presented
intervention covers the different needs of prospective cancer
survivors by providing both health education and remote
feedback strategy related to PA. This supports the view that
most prospective cancer survivors will benefit from evidence-
based information to prepare themselves for cancer
survivorship.
Whilst not every cancer survivor has access to resources and time to exercise, providing them with an independent PA programme would overcome the low uptake of PA. Cancer survivors appreciate the anonymity of PA programs that have face-to-face supervision and feedback with an exercise instructor or a health professional. However, cancer survivors have difficulties in complying with frequent physical meetings. The structure of this HoP programme is developed to reduce the number of physical meetings, from a meeting for a group discussion to home-based PA. This is supported by previous publications relating to the preference of cancer survivors as reported in a systematic review where they preferred the intervention to be conducted at home with self-paced activity.19 However, according to SCT, positive reinforcement is substantial in both creating and maintaining behavioural change.14,15 In addition, healthcare or expert collaboration in health promotion can result in an effective outcome for those involved. The strength of this independent PA programme is the use of IR 4.0 which is culturally tailored to Malaysians by relying on feedback using WhatsApp, a communication media that is widely and trusted by Malaysia’s multicultural population.20 A structured direct remote contact feedback strategy is the continuous feedback of progress of PA through healthcare collaboration or even other professional experts. It is remote as there is no physical meeting to supervise the progress of PA. The development of this feedback strategy is structured in a way so as to enable all cancer survivors to receive a personal graphical presentation of their own PA progress and standardized messages delivered by healthcare professionals or exercise experts using Whatsapp. When effectively facilitated, healthcare collaborations can enable fundamental improvements in community development and supports health promotion.

CONCLUSION
The development of the independent PA programme is expected to improve Malaysian cancer survivors PA level and will be useful as a supplementary prescription in cancer management that will help to improve cancer survivors’ QoL during their cancer survivorship.

AUTHORS’ CONTRIBUTIONS
MO developed the initial intervention protocol. NAMZ, NA, TKA and MM supervised the development of the study protocol. MO and NAMZ were applicants in applying for the MoU between Universiti Putra Malaysia and NCSM. MO wrote the manuscript and all authors reviewed the manuscript. All authors read and approved the final manuscript.

CONFLICT OF INTEREST
The authors of this work have nothing to disclose.

FUNDING
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Study protocol for a randomized controlled trial


