JAWATANKUASA ETIKA UNIVERSITI UNTUK PENYELIDIKAN MELIBATKAN MANUSIA (JKEUPM)
UNIVERSITI PUTRA MALAYSIA, 43400 UPM SERDANG,
SELANGOR, MALAYSIA

FORM 2.4: RESPONDENT'S INFORMATION SHEET AND INFORMED CONSENT FORM

Please read the following information carefully and do not hesitate to discuss any questions you may have with the researcher.

1. STUDY TITLE : EFFECTIVENESS OF HOME-BASED PHYSICAL ACTIVITY FOR SURVIVORS (HoPS) PROGRAMME IN ENHANCING PHYSICAL ACTIVITY AMONG NATIONAL CANCER SOCIETY OF MALAYSIA'S VOLUNTEERS

2. INTRODUCTION:

You are invited to participate in a research study because you are a breast or colorectal cancer survivors. Please take your time to read through and consider this information carefully before you decide if you are willing to participate. After you are properly satisfied that you understand this study, and that you wish to participate, you must sign this informed consent form. To participate in this study, you may be required to provide your doctor with information on your health history; you may harm yourself if you are not truthful with the information provided. Your participation in this study is voluntary. You do not have to be in this study if you do not want to. You may also refuse to answer any questions you do not want to answer. If you volunteer to be in this study, you may withdraw from it at any time. If you withdraw, any data collected from you up to your withdrawal will still be used for the study. Your refusal to participate or withdrawal will not affect any medical or health benefits to which you are otherwise entitled. This study has been approved by the Jawatankuasa Etika Universiti untuk Penyelidikan Melibatkan Manusia Universiti Putra Malaysia (JKEUPM) and has been registered to Medical Research and Ethics Committee, Ministry of Health Malaysia.

In this study, an interventional programme called HoPS (Home-based Physical Activity for Survivors) that employs a theory-based intervention will be conducted among the participants. A total of 106 breast and colorectal cancer survivors from National Cancer Society of Malaysia's (NCSM) volunteers at three branches which are Kuala Lumpur, Negeri Sembilan and Melaka will be choosen for this study.

Most of the time, the main focus following a diagnosis of cancer is medical treatment. Less attention is given towards non-pharmacological treatment although it has almost no side effect if it is executed correctly following approved guidelines. Physical activity is an increasingly important area in the management of cancer survivorship. Developed countries such as United State (US), Canada, United Kingdom, Australia and Belgium have made PA as part of the prescription for cancer treatment following diagnosis. ***Physical activity is defined as any movement of the body that requires energy expenditure such as walking, climbing stairs and even doing house chores. This study aims to improve physical activity level among participants and eventually will lead to improvement of quality of life.***

3. WHAT WILL YOU HAVE TO DO?

a) All study respondents will be assessed for eligibility for inclusion and exclusion criteria. This include obtaining medical clearnce form filled by the primary treating physician given earlier.
b) All respondents that are suitable for the study will be included in the research trial and baseline information will be colleceted including sociodemographic status and physiological measuremnets such as height, weight and

functional status. There is no invasive procedures involved in this study
c) The participants will be randomly assigned to behavioural intervention programme or waitlist group. Group assignment will be determined by the researchers and you will be blinded to the procedure.
d) Those who are in the behavioural intervention group will be received an interventional programme called HoPS. HoPS is intended to train its members to become an active cancer survivors in 2 months period from 2 sessions of meeting group discussions that will be conducted at NCSM's office and a non-tailored printed material booklet. WhatsApp will be used for direct remote contact on physical activity feedback strategy.
e) While participants in the wait list group will received the intervention after the interventional group completed the data collection.
f) Both groups will have to fill in questionnaire at several points of time during the study period.
g) The study period is expected to finished within 4 months.
h) All the information provided in this study is confidential and used for research purpose only.

4. WHO SHOULD NOT PARTICIPATE IN THE STUDY?
a) Breast or colorectal cancer survivors who were diagnosed above than stage III or stage IIIA for breast cancer
b) Cancer survivors who are currently receiving (and plan to receive during the duration of study enrollment) chemotherapy or radiation therapy
c) Less than 8 weeks post-surgical procedure
d) Post-treatment less than three months
e) Cancer survivors who did not obtained medical clearnce filled by the primary treting physician
f) Cancer survivors who are participating, 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
g) Cancer survivors who have medical or psychological condition that would interfere with the ability to fully participate during the study enrollment (e.g., psychosis, schizophrenia, etc.)
h) Cancer survivors with recurrent disease
i) Cancer survivors with above grade 1 of ECOG Performance Status

5. WHAT WILL BE THE BENEFITS OF THE STUDY:

(a) TO YOU AS THE SUBJECT?
HoPS is indicated to empower cancer survivors to perform physical activity as part of their routine. Studies have reported on positive health outcomes from physical activity for cancer survivorship. Systematic reviews, meta-analysis and trial studies concluded that PA intervention improves quality of life, physical function, reduce relapse of cancer and mitigate cancer mortality.

(b) TO THE INVESTIGATOR?

Information obtained from this study will help improve the treatment or management of other participants with the same condition. It will facilitates healthcare personnel to prescribe physical activity management programmes that incorporate customized PA for cancer survivors.

6. WHAT ARE THE POSSIBLE RISKS?

There is no treatment given in this participation only group session meeting on prescription of physical activity and questionnaire. Your routine follow up at health clinics will resume as usual. You do not have to participate in this study to get treatment for your disease or condition. You do not lose any of your legal rights by signing this form. ***If you are injured while on this study, you should contact your doctor for further treatment and there is no compensation. Three guidelines which are the American College of Sports Medicine, the Belgian Health Care***

Knowledge Centre and the Canadian guideline as well as systematic reviews concluded that physical activity is safe during active treatment and after treatment.

Therefore, it is important for each participant to complete a medical clearance form filled by the primary treating physician to ensure the participant's overall safety prior to participating in this intervention programme. The researcher will assist as necessary to ensure the welfare of the participant throughout the study.

7. WILL THE INFORMATION THAT YOU PROVIDE AND YOUR IDENTITY REMAIN CONFIDENTIAL?

All your information obtained in this study will be kept and handled in a confidential manner, in accordance with applicable laws and/or regulations. When publishing or presenting the study results, your identity will not be revealed without your expressed consent. Individuals involved in this study and in your medical care, qualified monitors and auditors or its affiliates and governmental or regulatory authorities may inspect and copy your medical records, where appropriate and necessary.

Data from the study will be archived and may be published in international journal, but your identity will not be revealed at any time. the study monitor(s), auditor(s), the JKEUPM Ethics Review Panel, and regulatory authorities will be granted direct access to participant's medical records for purposes ONLY of verification of clinical trial procedures and data

8. WHO SHOULD YOU CONTACT IF YOU HAVE ADDITIONAL QUESTIONS DURING THE COURSE OF THE RESEARCH?

If you have any questions about the study, please contact:

1. Dr Mardiana Binti Omar

   Telephone number: 016 2200662

   Email: mardianaomar87@gmail.com

2. Assoc. Prof. Dr. Nor Afiah Mohd. Zulkefli

   Telephone number: 012 5289553

   Email: norafiah@upm.edu.my

Please initial here if you have read and understood the contents of this page_____

9. CONSENT

I …… Identity Card No. …… address……...

……..hereby voluntarily agree to take part in the research stated above *(~~clinical /drug trial/video recording/ focus group/interview-based/~~ questionnaire-based).

I have been informed about the nature of the research in terms of methodology, possible adverse effects and complications (as written in the Respondent's Information Sheet). I understand that I have the right to withdraw from this research at any time without giving any reason whatsoever. I also understand that this study is confidential and all information provided with regard to my identity will remain private and confidential.

I* wish / do not wish to know the results related to my participation in the research

I agree/do not agree that the images/photos/video recordings/voice recordings related to me be used in any form of publication or presentation (if applicable)

* delete where necessary

Signature ……..…… Signature ……..…….
(Respondent) (Witness)

Date :…….….. Name :…….…..

I/C No. :…….…..

I confirm that I have explained to the respondent the nature and purpose of the above-mentioned research.

Date ……..…… Signature ……..…….
(Researcher)