ISRCTN10756993 https://doi.org/10.1186/ISRCTN10756993

Assessing the effectiveness of a mindfulness psychoeducation programme at preventing physical and psychological symptoms among cancer survivors

Submission date
18/01/2022

Recruitment status
No longer recruiting

Registration date
29/04/2022

Overall study status
Completed

Last Edited
29/08/2024

Condition category
Signs and Symptoms

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
In Singapore, the prevalence of cancer has been rising with 14,148 cases in 2015. Alarmingly, every four out of five Singaporeans may develop cancer. Despite advanced technology and treatments for cancer, many patients still report physical and psychological symptoms such as pain, depression, and anxiety. As such, there is a need to deliver interventions to prevent or alleviate the pain, depression, and anxiety that cancer patients and survivors may face, as well as to enhance their psychological well-being.
This study aims to examine the effectiveness of a mindfulness intervention programme developed specifically for cancer survivors (MindCAN) that includes cancer-specific knowledge and several mindfulness practices (such as mindful breathing and body scan). Specifically, the MindCAN programme may be offered in clinical settings for cancer survivors to help them better cope with stress, thus preventing possible psychological (depression and anxiety) and physical (pain) symptoms.

Who can participate?
Adult cancer survivors aged 21 to 75 years who have completed all cancer and related treatments as prescribed by their attending physician.

What does the study involve?
Participants will be randomly assigned to one of three conditions: a) a waitlist group (passive control group) to receive treatment at a later date, b) a general mindfulness intervention (Pilouse Mindfulness; active control group), or c) a cancer-specific mindfulness intervention (MindCAN; treatment group).

What are the possible benefits and risks of participating?
Participants in the general and cancer-specific intervention groups will receive mindfulness therapy sessions that may help to prevent or alleviate certain negative physical and psychological symptoms associated with cancer such as pain, depression, and anxiety.

Participants in the waitlist group will receive an intervention plan similar to the general or cancer-specific (if shown to be effective) intervention groups at a later date. These treatments will be provided at no cost to all participants. There are no risks expected from participating in this study.

Where is the study run from?
1. National University Cancer Institute (Singapore)
2. National University of Singapore (Singapore)

When is the study starting and how long is it expected to run for?
June 2020 to August 2026

Who is funding the study?
National University of Singapore (NUS) (Singapore)

Who is the main contact?
Dr Piyanee Yobas
nurpk@nus.edu.sg

Contact information

Type(s)
Principal investigator

Contact name
Dr Piyanee Yobas

Contact details
MD11, 10 Medical Drive
Level 2, Clinical Research Centre
Alice Lee Centre for Nursing Studies
National University of Singapore
Singapore
Singapore
117597
+65 (0)6516 7789
nurpk@nus.edu.sg

Additional identifiers

Protocol serial number
DSRB Ref: 2021/00083

Study information

Scientific Title
Preventing physical and psychological symptoms among cancer survivors through a mindfulness psychoeducation programme: a randomised controlled trial

Acronym

MindCAN

Study objectives
H1: In comparison with a waitlist-control group, cancer survivors who complete the MindCAN programme will report significantly lower levels of objective stress, subjective stress, depression, anxiety, and pain at post-intervention and 3-month follow up.
H2: In comparison with an active control group (receiving Palouse Mindfulness), cancer survivors who complete the MindCAN programme will report significantly lower levels of objective stress, subjective stress, depression, anxiety, and pain at post-intervention and 3-month follow up.
H3: In comparison with a waitlist-control group, cancer survivors who complete the MindCAN programme will report significantly higher levels of mindfulness, resilience, and psychological well-being at post-intervention and 3-month follow up.
H4: In comparison with an active control group (receiving Palouse Mindfulness), cancer survivors who complete the MindCAN programme will report significantly higher levels of mindfulness, resilience, and psychological well-being at post-intervention and 3-month follow up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/01/2023, NHG Domain Specific Review Board (DSRB, 3 Fusionopolis Link, Singapore 138543; +65 6496 6600; no email provided), ref: 2021/00083

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Alleviation of negative physical and psychological symptoms for cancer survivors

Interventions
Before commencing the sample recruitment, the principal investigator will use IBM SPSS Statistics to generate three sets of non-duplicating random numbers for the three study groups. These numbers will range from one to 150. During the recruitment period, each enrolled participant will receive a unique identification number (ID) based on his/her entry to the study. Participants with an ID that matches the numbers in each of the three study groups will be allocated to the groups accordingly.

Participants will be randomly assigned to one of three groups:
1. Waitlist-control group (no treatment)
2. Active control group (active control intervention)
3. Treatment group (intervention)

2. Active control intervention: The Palouse Mindfulness
The Palouse Mindfulness (Potter, 2020) is a mindfulness-based stress reduction programme (MBSR) developed and modified based on Kabat-Zinn’s MBSR. Each session lasts 90 minutes. The

Palouse Mindfulness is a general stress reduction programme without contents specific for cancer. Participants will be asked to do mindfulness practice at home for 10-30 minutes per day. The Principal Investigator (Dr Piyanee Yobas), who specialises in Mental Health Nursing and received MBSR training, will serve as a group facilitator.

3. Intervention: The MindCAN programme
The MindCAN programme was developed by Dr Piyanee Yobas with the aim to help cancer survivors learn to manage stress and regulate emotions. The contents of the programme include information specific for cancer survivors (such as stress concerning cancer symptoms and treatments). The eight weekly, group-based MindCAN programme comprises two components: education and mindfulness practice. Each session lasts 90 minutes. Participants are asked to do mindfulness practice at home for 10-30 minutes per day. The Principal Investigator (Dr Piyanee Yobas) will serve as a group facilitator.

Measurement procedure for each group
1. The MindCAN group
- Time 1, Week 1, before Session 1: Complete the self-reported questionnaire and demographic form
- Time 2, Week 4, End of Session 4: Complete the self-reported questionnaire
- Time 3, Week 8, End of Session 8: Complete the self-reported questionnaire
- Week 8, End of session 8: Focus group interview
- Week 1-8, before and after each intervention session (90 minutes apart), measure skin temperature, heart rate, SpO_2 and perceived relaxation (16 times)

2. The Palouse Mindfulness
- Time 1, Week 1, before Session 1: Complete the self-reported questionnaire and demographic form
- Time 2, Week 4, End of Session 4: Complete the self-reported questionnaire
- Time 3, Week 8, End of Session 8: Complete the self-reported questionnaire
- Week 8, End of session 8: Focus group interview
- Week 1-8, before and after each intervention session (90 minutes apart), measure skin temperature, heart rate, SpO_2 and perceived relaxation (16 times)

3. The wait-listed control group
- Time 1, Week 1, Complete the self-reported questionnaire and demographic form
- Time 2, Week 4, Complete the self-reported questionnaire
- Time 3, Week 8, Complete the self-reported questionnaire
- Week 1-8, measure skin temperature, heart rate, SpO_2 and perceived relaxation twice each week, on the same day of the week, 90 minutes apart (16 times). The 90 minutes between the two measurements are in line with the data collection in the intervention groups to ensure standardisation across groups.

While waiting for the second measurement, participants in the wait-listed control group may sit quietly or do any activity in the provided room at NUS/NUH. Alternatively, they may go out /perform other activities and come back for the second measurement 90 minutes later.

All measurements will be collected face-to-face. For the two intervention groups, all data will be collected during the intervention sessions. For the wait-listed control group, the researcher will schedule a face-to-face session with the participants at NUH or NUS to collect data at their convenience.

However, if there are restrictions in the face-to-face interaction due to the COVID-19 pandemic, the researchers will collect data via a real-time individual Zoom platform. The self-reported questionnaire will be shared on the Zoom screen during an individual Zoom meeting and each participant will provide answers during the meeting. Furthermore, the researchers will loan the stress thermometer and Honor 5 to all participants in advance. Each participant then can use the stress thermometer and Honor band to measure the objective stress (skin temperature, heart rate and SpO_2), and present the reading during the Zoom session. Additionally, the focus group interview can be conducted via a real-time Zoom group session.

Participants in the wait-listed control group will be asked to attend a Zoom session and conduct the first assessment. While waiting for the second assessment, participants may sit quietly in the same location, but they are not required to stay online. Alternatively, they may go out and do any activities as they wish. After 90 minutes, the participants will be asked to attend another Zoom session to provide the second assessment.

Intervention Type
Other

Primary outcome(s)
Psychological well-being measured with the 18-item Psychological Well-being scale before the beginning of the first intervention session, and at the end of sessions 4 and 8 (middle- and end-point of the intervention)

Key secondary outcome(s)
1. Objective stress measured by peripheral skin temperature using a stress thermometer, and heart rate and SpO_2 variability measured using Honour Band 5. Measured before and after each of the eight intervention sessions.
2. Subjective stress, depression, and anxiety measured with the 21-item Depression Anxiety and Stress scale (DASS-21) before the beginning of the first intervention session, and at the end of sessions 4 and 8 (middle- and end-point of the intervention)
3. Perceived relaxation assessed by the perceived relaxation scale before and after each of the eight intervention sessions
4. Mindfulness measured with the 15-item Mindful Attention Awareness Scale (MAAS) before the beginning of the first intervention session, and at the end of sessions 4 and 8 (middle- and end-point of the intervention)
5. Resilience assessed by the 10-item Connor-Davidson Resilience Scale before the beginning of the first intervention session, and at the end of sessions 4 and 8 (middle- and end-point of the intervention)
6. Participants' perceptions toward the two mindfulness interventions will be captured via focus-group interviews conducted after the last of the eight intervention sessions

Completion date
31/08/2026

Eligibility

Key inclusion criteria
Current inclusion criteria as of 29/08/2024:
1. Adults of any gender aged 21 to 75 years
2. Having a confirmed diagnosis of any type of cancer stage 0 to III by their attending physician
3. Have completed all cancer and related treatments (such as chemotherapy, surgery, and

radiotherapy, as prescribed by their attending physician), with the exception of hormonal therapy between 2 weeks to 2 years (Lengacher et al., 2016)

Previous inclusion criteria:
1. Adults of any gender aged 21 to 65 years
2. Having a confirmed diagnosis of any type of cancer stage 0 to III by their attending physician
3. Have completed all cancer and related treatments (such as chemotherapy, surgery, and radiotherapy, as prescribed by their attending physician), with the exception of hormonal therapy between 2 weeks to 2 years (Lengacher et al., 2016)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
21 Years

Upper age limit
75 Years

Sex
All

Key exclusion criteria
1. Having a diagnosis of severe mental disorders (e.g., schizophrenia, mood disorders, bipolar disorder, and substance-related disorders)
2. Having a severe medical condition requiring hospitalisation
3. Is pregnant

Date of first enrolment
11/04/2022

Date of final enrolment
31/08/2025

Locations

Countries of recruitment
Singapore

Study participating centre
Alice Lee Centre for Nursing Studies
Clinical Research Centre, Alice Lee Centre for Nursing Studies
National University of Singapore

MD11, 10 Medical Drive
Singapore
Singapore
117597

Study participating centre
National University Cancer Institute, Singapore
NUH Medical Centre (NUHMC) @ Levels 8-10
5 Lower Kent Ridge Road
Singapore
Singapore
119074

Sponsor information

Organisation
National University of Singapore

ROR
https://ror.org/01tgyzw49

Funder(s)

Funder type
University/education

Funder Name
National University of Singapore

Alternative Name(s)
National University Singapore, National University of Singapore: NUS, National University of Singapore (NUS), nus_singapore, National University of SG, Straits Settlements and Federated Malay States Government Medical School, King Edward VII College of Medicine, University of Malaya, Singapore campus, University of Singapore, Nanyang University, NUSingapore, Universiti Nasional Singapura, ¿¿¿¿¿¿¿¿¿¿ ¿¿¿¿¿ ¿¿¿¿¿¿¿¿¿¿¿¿¿, ¿¿¿¿¿¿¿, NUS

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Singapore

Results and Publications

Individual participant data (IPD) sharing plan
Due to DSRB regulations, participant-level data is confidential and the researchers are unable to share such data with people outside the research team.

IPD sharing plan summary
Not expected to be made available