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A pilot trial of a tailored mindfulness-based group intervention for psychological distress and adjustment in an oncology population

Submission date
04/09/2024

Recruitment status
No longer recruiting

Registration date
03/10/2024

Overall study status
Completed

Last Edited
16/07/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
This project aims to trial a tailored six-session mindfulness-based psychological group intervention for bone marrow transplant (BMT) outpatients at the Royal Melbourne Hospital. The proposed research will also examine the acceptability and feasibility of the tailored treatment.

Who can participate?
To join the study, you need to be at least 18 years old and have a diagnosis of a blood cancer. You also must have had a stem cell transplant at least 30 days before enrolling in the study.

What does the study involve?
The trial will offer a mindfulness-based intervention involving attending six weekly 1.5-hour group therapy sessions and practising recommended home exercises. The intervention will be similar to mindfulness treatments applied in previous research with oncology populations. However, the number and duration of sessions will be reduced. Sessions will run in groups of up to 10 people at the Royal Melbourne Hospital. Participants will be asked to complete questionnaires before the group intervention, post-intervention and 3 months follow-up. The questionnaires will ask questions about the BMT procedure and experience with cancer. They will also measure symptoms of anxiety and depression, quality of life, psychological adjustment, mindfulness abilities, emotion regulation and engagement in worry. The set of questionnaires participants will be asked to complete post-intervention will include a treatment evaluation questionnaire. After the intervention participants will be invited to participate in an individual semi-structured interview on their views about the usefulness and acceptability of the tailored group mindfulness treatment.

What are the possible benefits and risks of participating?
There are no known risks associated with participation in this research study. However, if participants become upset or distressed as a result participation in the research, counselling or

other appropriate support will be arranged by the researchers. Any counselling or support will be provided by staff who are not members of the research team. Participants may choose to suspend or end participation in the research if distress occurs.

Where is the study run from?
Royal Melbourne Hospital (Australia)

When is the study starting and how long is it expected to run for?
January 2016 to January 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Associate Professor Litza Kiropoulos, litzak@unimelb.edu.au

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title

Feasibility study of a tailored mindfulness-based group intervention for psychological distress and adjustment for allogeneic hematopoietic stem cell transplant outpatients

Study objectives
It was hypothesised that the intervention would lead to improvements in symptoms of anxiety and depression, quality of life, psychological adjustment to illness, mindfulness skills, emotion regulation strategies, and cancer-related pain, fatigue, and physical functioning.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 05/01/2015, The University of Melbourne Human Research Ethics Committee and Melbourne Health Human Research Ethics Committee (Grattan Street, Parkville, 3010, Australia; +61; not@provided.com), ref: 2014.156

Study design
Pilot/feasibility trial pre- post- 3-month follow-up intervention with no comparative/control group

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Tailored mindfulness-based group intervention for psychological distress and adjustment for allogeneic hematopoietic stem cell transplant outpatients

Interventions
The intervention included elements of both Mindfulness Based Stress Reduction and Mindfulness Based Cognitive Therapy. Each mindfulness group consisted of six 1.5-hour face-to-face weekly group sessions delivered by two provisionally registered psychologists. The senior author provided mindfulness training, including a half-day workshop and weekly supervision to all psychology registrars. Sessions consisted of psychoeducation on mindfulness, stress and cancer, unhelpful thinking styles, and relapse prevention planning in addition to mindfulness practices including body scan, eating meditation, sitting meditation. There was no control /comparative control intervention as part of this design. Participants completed questionnaires at baseline (T1), at post-intervention (6 weeks) (T2) and at 3 months post-intervention follow up (T3).Demographic and clinical characteristics were recorded at baseline. Level of depression was measured with the Beck Depression Inventory (BDI-II). Level of anxiety was measured with the State-Trait Anxiety Inventory (STAI), and quality of life was measured with the Functional Assessment of Cancer Therapy – Bone Marrow Transplant (FACT-BMT). Level of psychological adjustment was measured with the Mini Mental Adjustment to Cancer Scale (Mini-MAC). Mindfulness skills were assessed using the Five Facet Mindfulness Questionnaire (FFMQ). Emotion regulation skills were measured with the Emotion Regulation Questionnaire (ERQ), and decentring was measured with the Experiences Questionnaire (EQ). The ERQ was used to examine an individual’s use of two emotion regulation strategies: reappraisal (i.e., construing a potentially emotion-eliciting stimulus in a way that alters its emotional impact) and suppression

(i.e., inhibiting emotion-expressive behaviour). The EQ measures decentring, or the tendency to have a detached perspective of one's internal thoughts and experiences. The Patient-Reported Outcome Measurement Information System (PROMIS) Cancer Scales, were used to examine fatigue, pain interference, physical functioning, and emotional distress. The program's acceptability and feasibility were evaluated through a treatment evaluation questionnaire and participants will be asked to participate in an optional 30-minute qualitative interview.

Intervention Type
Behavioural

Primary outcome(s)
Measured at T1: baseline; T2: 6 weeks post intervention; T3: 3 months post intervention:
1. Level of depression measured using the Beck Depression Inventory (BDI-II)
2. Level of anxiety measured using the State-Trait Anxiety Inventory (STAI)
3. Quality of life measured using the Functional Assessment of Cancer Therapy – Bone Marrow Transplant (FACT-BMT)
4. Level of psychological adjustment measured using the Mini-Mental Adjustment to Cancer Scale (Mini-MAC)

Key secondary outcome(s))
Measured at T1: baseline; T2: 6 weeks post intervention; T3: 3 months post intervention:
1. Mindfulness skills were assessed using the Five Facet Mindfulness Questionnaire (FFMQ)
2. Emotion regulation skills were measured with the Emotion Regulation Questionnaire (ERQ)
3. Decentring was measured with the Experiences Questionnaire (EQ)
4. Health domains affected by cancer measured using the Patient-Reported Outcome Measurement Information System (PROMIS) Cancer Scales, including fatigue, pain interference, physical functioning, and emotional distress
5. The tailored group mindfulness program's acceptability and feasibility measured using data collected during a treatment evaluation questionnaire and an optional 30-minute qualitative interview

Completion date
31/01/2019

Eligibility

Key inclusion criteria
1. 18 years of age and over
2. A diagnosis of haematologic cancer
3. Had undergone Hematopoietic stem cell transplant (HSCT) at least 30 days before enrolment in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
20

Key exclusion criteria
1. If they had comorbid medical issues
2. Significant cognitive impairment that interfered with their ability to attend the program
3. Were participating in other psychological treatments during the trial
4. Had a history of severe mental illness (e.g., schizophrenia or bipolar disorder)
5. Did not read, write, or understand English

Date of first enrolment
01/01/2016

Date of final enrolment
31/01/2019

Locations

Countries of recruitment
Australia

Study participating centre
Royal Melbourne Hospital
City Campus, Parkville
Melbourne
Australia
3010

Sponsor information

Organisation
University of Melbourne

ROR
https://ror.org/01ej9dk98

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Associate Prof. Litza Kiropoulos, litzak@unimelb.edu.au, upon reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/07/2025	16/07/2025	Yes	No