

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

<b>Submission date</b> 04/09/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 03/10/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 16/07/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

### Contact name

Prof Litza Kiropoulos

### ORCID ID

<https://orcid.org/0000-0002-1921-5904>

### Contact details

Melbourne School of Psychological Sciences

Melbourne

Australia

3010

+61 3 9035 4063

litzak@unimelb.edu.au

## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

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

**Secondary study design**

Non randomised study

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details to request a participant information sheet

**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 measure**

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)

## **Secondary outcome measures**

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

## **Overall study start date**

01/07/2015

## **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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

12-35 participants

**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

## Sponsor details

Melbourne School of Psychological Sciences

The RMH Parkville

300 Grattan St

Parkville

Australia

3010

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ethics@mh.org.au

## Sponsor type

University/education

## Website

<https://www.unimelb.edu.au/>

## ROR

<https://ror.org/01ej9dk98>

# Funder(s)

## Funder type

Other

## Funder Name

Investigator initiated and funded

# Results and Publications

## Publication and dissemination plan

Planned publication in a peer-reviewed journal

## Intention to publish date

31/12/2024

## 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?
<a href="#">Results article</a>		14/07/2025	16/07/2025	Yes	No