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Can we use a mindfulness-based intervention for people in mental health recovery?

Submission date
06/05/2022

Recruitment status
No longer recruiting

Registration date
09/05/2022

Overall study status
Completed

Last Edited
10/05/2022

Condition category
Mental and Behavioural Disorders

[ ] 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 the mental health recovery journey, people encounter challenges every day. Mindfulness and self-compassion training has been shown to enhance holistic well-being. Mindfulness-based interventions (MBIs) consist of secular trainings in mindfulness and self-compassion. The current study aimed to apply the concept and practice of mindfulness and self-compassion to mental health recovery in Hong Kong. Based on this aim, a pre-pilot mixed-methods randomised controlled trial (RCT) was adopted, before the pilot and the main RCTs, to provide detailed information for subsequent development of a tailored MBI to facilitate personal recovery among people with mental illness. The MBI (Remind 1.0) in the current pre-pilot RCT is one of the MBI in the MBI series known as the Remind Programme.

Who can participate?
Adults over 18 years, diagnosed with mental illness

What does the study involve?
Participants were randomly allocated into either the MBI or treatment-as-usual group. MBI consisted of 8 weekly 2.5 hour sessions, while treatment-as-usual consisted of treatment that was deemed as necessary by health professionals/themselves.

Participants from both groups were assessed before and after the intervention, as well as one month after the intervention. The assessment included quantitative approach to evaluate personal recovery, mindfulness, self-compassion, resilience, mood and quality of life, and qualitative approach was used to explore the experiences and perceptions of MBI participants. The pre-pilot study ran for 6 months, excluding publication and dissemination of study results.

What are the possible benefits and risks of participating?
Before giving informed consent, participants were informed that emotional discomfort might arise in MBI practices as those practices could increase emotional awareness. Participants were encouraged to notify the facilitator of any concerns or difficulties, and referral services would be provided when necessary. All participants had to complete all the assessments to receive HK$50 supermarket cash coupon and the 1-month follow-up assessment to receive another HK$100 supermarket cash coupon.

Where is the study run from?
Hong Kong Baptist University

When is the study starting and how long is it expected to run for?
December 2019 to June 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Daphne Cheng, daphnecheng@hkbu.edu.hk

Contact information

Type(s)
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
A randomised controlled pre-pilot trial of a mindfulness-based intervention (The Remind programme 1.0) improving personal recovery outcomes among people with mental illness compared to inactive treatment-as-usual controls

Study objectives
The current pre-pilot study was a preliminary mixed-methods, exploratory study for the subsequent development and implementation of a novel, tailored mindfulness-based intervention (MBI) to facilitate personal recovery among people with mental illness, for further examination of the feasibility and acceptability in the pilot and main trial. As there was limited detailed information regarding the application of MBI to facilitate personal recovery among people with mental illness, the current pre-pilot study was set out to initially assess an MBI with combined components from contemporary MBI protocols (i.e., MBCT and MSC) that were most relevant to the mental health settings.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/12/2019, Hong Kong Baptist University Research Ethics Committee (Research Office, Hong Kong Baptist University, Kowloon Tong, Kowloon, Hong Kong; +852 3411 7400; hkbu_rec@hkbu.edu.hk), ref: none available

Study design
Single centre interventional single-blinded randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Intervention to facilitate personal recovery in people with mental illness

Interventions
Eligible participants were randomly allocated (1:1) into either the mindfulness-based intervention (MBI) or the treatment-as-usual (TAU) control group. The MBI consisted of 8-weekly 2.5 hours sessions, with weekly home assignments and follow-up calls from the facilitator between sessions to keep track of each participant's progress. The concept and practice of mindfulness and self-compassion were covered in the MBI, with a slightly stronger focus on mindfulness in the first four sessions of the MBI.

The randomisation process was conducted with SPSS Syntax, stratified by age and gender. The randomisation process was administered by a third party (a research assistant) who was not involved in either the data collection or data analysis process.

Intervention Type
Behavioural

Primary outcome(s)
1. Personal recovery: Recovery Assessment Scale (RAS) at baseline (pre-intervention), post-intervention, 1-month follow-up.
2. Trait mindfulness: the Kentucky Inventory of Mindfulness Skills (KIMS-17) at baseline (pre-intervention), post-intervention, 1-month follow-up.
3. Self-compassion: Self-compassion Scale (SCS) at at baseline (pre-intervention), post-

intervention, 1-month follow-up.
4. Resilience: Connor-Davidson Resilience Scale (CD-RISC) at baseline (pre-intervention), post-intervention, 1-month follow-up.
5. Qualitative semi-structured interviews were conducted at baseline (pre-intervention), post-intervention, 1-month follow-up.

Key secondary outcome(s))
1. Positive and negative mood: Positive and Negative Affect Schedule (PANAS) at baseline (pre-intervention), post-intervention, 1-month follow-up.
2. Quality of life: The World Health Organization Quality of Life – BREF (WHOQOL-BREF) at baseline (pre-intervention), post-intervention, 1-month follow-up.

Completion date
06/06/2020

Eligibility

Key inclusion criteria
1. Aged 18 or above
2. Permanent Hong Kong residents
3. Diagnosed with mental illness with standardised diagnostic criteria (e.g. ICD-11 or DSM-5), for any length of illness
4. Capable of providing informed consent to participate in the trial
5. Able to understand Chinese languages
6. Recipient the community-based mental health service

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. A diagnosis of learning disability or major cognitive impairment arising from any underlying medical condition resulting in significant functional impairment
2. Primary diagnosis of substance abuse
3. In a mental state that precludes the possibility of engaging in the intervention (e.g. significant thought disorder)

4. Engagement in concurrent mindfulness training/intervention
5. Do not provide informed consent
6. Refused to be randomised

Date of first enrolment
28/02/2020

Date of final enrolment
28/03/2020

Locations

Countries of recruitment
Hong Kong

Study participating centre
Caritas Wellness Link
1313, 1-17 Sai Lau Kok Rd
Grand City Plaza
Tsuen Wan
New territories
Hong Kong
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Sponsor information

Organisation
Hong Kong Baptist University

ROR
https://ror.org/0145fw131

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

Due to the sensitive and personal nature of this study, participants were assured that any research raw data would remain confidential and would not be openly accessed.

IPD sharing plan summary

Stored in non-publicly available repository, Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes