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A tailored mindfulness-based intervention for people in mental health recovery: an exploratory study

Submission date
14/07/2022

Recruitment status
No longer recruiting

Registration date
19/07/2022

Overall study status
Completed

Last Edited
18/07/2022

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
A novel, tailored mindfulness-based intervention (MBI, the REMIND 2.0 programme) to facilitate personal recovery for Hong Kong mental health service users was developed based on the qualitative and quantitative results from the previous pre-pilot randomised controlled trial (RCT) (ISRCTN90791918), literature and opinions from mental health professionals and mindfulness and meditation teachers.

The current study was the final stage of the development process of the tailored MBI for people in mental health recovery before conducting larger-scale, fully statistically powered, definitive RCTs. Therefore, the current study examined the feasibility, acceptability and potential effectiveness of the tailored MBI (REMIND 2.0) for facilitating personal recovery, improving mindfulness, self-compassion, resilience, moods, quality of life and general health while alleviating psychological distress among mental health service users.

As the pre-pilot trial results and literature pointed out that mindfulness practices have been misused as relaxation practices, participants in the MBI were compared to their counterparts in the relaxation training (RT) active control group. RT included empirical techniques designed to mirror the MBI closely, without any instructions on mindfulness and self-compassion.

Who can participate?
Patients aged 18 years and above, diagnosed with mental illness.

What does the study involve?
Participants were randomly assigned to either the MBI or RT group. Both groups consisted of 8 weekly 2.5-hour sessions, while both groups also continue to receive treatment that was deemed necessary by health professionals/themselves.

Participants from the MBI and RT were assessed before and after the intervention and one month after the intervention. The assessment tasks included quantitative measures to evaluate personal recovery, mindfulness, self-compassion, resilience, depression, anxiety, stress, mood,

quality of life and general health. Qualitative interviews were conducted further to explore the experiences and views of the MBI participants. The current exploratory pilot study ran for 6 months, which excluded 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 the practices were intended to increase mindful awareness, just like other psychological interventions. Participants were recommended to notify the facilitator of any concerns or difficulties as soon as possible, and referral services would be provided if necessary. All participants had to attend at least 70% of the MBI or RT and complete the baseline and post-assessments to receive HK$50 supermarket cash coupons and the 1-month follow-up assessment to receive another HK$100 supermarket cash coupons.

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 January 2021

Who is funding the study?
Hong Kong Baptist University

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

Contact information

Type(s)
Principal investigator

Contact name
Dr Daphne Cheng

ORCID ID
https://orcid.org/0000-0001-5358-6867

Contact details
AAB1013, Department of Social Work
Hong Kong Baptist University
Kowloon Tong
Hong Kong
-
+852 3411 2005
daphnecheng@hkbu.edu.hk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Development and implementation of a mindfulness-based intervention (REMIND2.0) for people in recovery in Hong Kong: the exploratory pilot randomised controlled trial

Study objectives
This pilot study aimed to examine the feasibility, acceptability and potential effectiveness of a tailored Mindfulness-based Intervention (MBI, known as the REMIND 2.0 programme) for facilitating recovery among Hong Kong mental health service users. Hypotheses were not postulated due to the pilot nature of this study.

Ethics approval required
Old ethics approval format

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

Study design
Single-centre single blinded parallel groups mixed-methods pilot randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Facilitation of personal recovery among people with mental illness

Interventions
After screening and giving informed consent, participants were randomly assigned to either the mindfulness-based intervention (MBI) or the relaxation training (RT). RT was designed the closely mirror the MBI. The concept and practice of mindfulness and self-compassion were not covered in the RT. Both the MBI and RT consisted of 8 weekly 2.5 hours sessions, with weekly home assignments taught by the same facilitator and follow-up calls from the same facilitator between sessions to keep track of all participants' progress.

The randomisation process was conducted with SPSS Syntax, stratified by gender and age. The process was done by a third party who was not involved in data collection or analysis.

Intervention Type

Behavioural

Primary outcome(s)
1. Personal recovery: Recovery Assessment Scale (RAS-C) at pre-, post-intervention and 1-month follow-up
Trait mindfulness: Kentucky Inventory of Mindfulness Skills (KIMS-17-C), Mindful Attention Awareness Scale (MAAS) at pre-, post-intervention and 1-month follow-up
2. Self-compassion: Self-compassion Scale (SCS) at pre-, post-intervention and 1-month follow-up
3. Resilience: Connor-Davidson Resilience Scale (CD-RISC) at pre-, post-intervention and 1-month follow-up
4. Mindfulness-based intervention participants' experiences and views: Qualitative Interviews at post-intervention and 1-month follow-up

Key secondary outcome(s))
1. Depression, Stress and Anxiety: The Depression Anxiety Stress Scales (DASS-21) at pre-, post-intervention and 1-month follow-up
2. Positive and negative affect: Positive and Negative Affect Schedule (PANAS) at pre-, post-intervention and 1-month follow-up
3. Quality of life and general health: The World Health Organization Quality of Life – BREF (WHOQOL-BREF) at pre-, post-intervention and 1-month follow-up

Completion date
31/01/2021

Eligibility

Key inclusion criteria
1. Aged 18 years or above
2. Permanent Hong Kong residents
3. Diagnosed with mental illness with standardised diagnostic criteria, such as the Classification of Diseases (11th ed.; ICD-11; World Health Organization, 2018) or Diagnostic and Statistical Manual of Mental Disorders (5th ed.; DSM-5; American Psychiatric Association, 2013), for any length of illness
4. Capable of providing informed consent to participate in the trial; (v) able to understand Chinese languages to engage in the intervention or to complete written assessment in Chinese; and
5. A service user from 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
28

Key exclusion criteria
1. Established 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, as substance use may increase and/or trigger symptoms of mental illnesses, and hence it has different trajectories from other mental illnesses
3. Mental state that precludes the possibility of engaging in the intervention (e.g. significant thought disorder)
4. Engagement in concurrent mindfulness intervention
5. Do not provide informed consent
6. Refused to be randomised

Date of first enrolment
01/07/2020

Date of final enrolment
01/08/2020

Locations

Countries of recruitment
Hong Kong

Study participating centre
Caritas Wellness Link (Tsuen Wan)
1313, Grand City Plaza
1-17, Sai Lau Kok Road
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
University/education

Funder Name
Hong Kong Baptist University

Alternative Name(s)
, , HKBU, BaptistU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Hong Kong

Results and Publications

Individual participant data (IPD) sharing plan
Not expected to be made available due to the sensitive nature of the data and confidentiality.

IPD sharing plan summary
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