Mindfulness-based boxing therapy to treat depression and anxiety

Submission date Recruitment status 05/02/2024 No longer recruiting	Prospectively registered
No longer recruiting	☐ Protocol
Overall study status	Statistical analysis plan
Completed	[X] Results
Condition category	Individual participant data
	No longer recruiting Overall study status Completed

Plain English summary of protocol

Background and study aims

The purpose of this study is to explore the mental health benefits of an innovative approach combining non-contact boxing with mindfulness practices. There is a wealth of research suggesting that regular physical activity can greatly enhance mental well-being, with specific improvements noted in mood regulation, sleep quality, and stress reduction. Activities that engage both the body and mind, such as the focused breathing and deliberate movements in boxing, appear to be particularly effective. This study draws on previous findings that show how aerobic exercises, like boxing, can not only boost physical fitness but also provide mental health benefits by reducing symptoms of anxiety and depression.

Boxing, in particular, has garnered attention for its mental health benefits, such as lowering stress, bolstering self-confidence, and providing a healthy outlet for emotions like anger. This investigation is centered on Mindfulness-Based Boxing Therapy, which integrates the high-intensity workout of boxing with the calming, centering practice of mindfulness - a combination that may offer a unique therapeutic benefit.

While the primary aim is to conduct a feasibility study to determine whether such a program is practical and whether participants are receptive to this form of therapy, the secondary objectives are to assess mental health outcomes. The results of this feasibility study will guide future research and potential treatment options, particularly for those seeking non-pharmacological interventions.

Who can participate?

Adults (18-40 years old) enrolled within CAMH who are diagnosed with major depressive disorder and/or generalized anxiety disorder

What does the study involve?

Participants will attend a 90-minute, mindfulness-based non-contact boxing class twice a week for 10 weeks. These group classes include mindfulness and meditation, focusing on the connection between mind and body.

What are the possible benefits and risks of participating? Benefits could include those related to non-contact boxing exercises which may be improved mood, less anxiety, and learning new ways to handle stress. As with any physical activity, there's a risk of injury, but medical care will be available if needed.

Where is the study run from?
The Centre for Addiction and Mental Health (Canada)

When is the study starting and how long is it expected to run for? February 2022 to January 2023

Who is funding the study? Investigator initiated and funded

Who is the main contact?
Dr Johny Bozdarov, johny.bozdarov@camh.ca

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

Dr Johny Bozdarov

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Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Mindfulness-based (non-contact) boxing therapy for depression and anxiety: a feasibility study

Acronym

MBBT 1

Study objectives

Group non-contact boxing classes (mindfulness-based boxing therapy [MBBT]) added to standard care are feasible and acceptable for patients with major depressive disorder (MDD) and generalized anxiety disorder (GAD).

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 20/08/2022, Centre for Addiction and Mental Health Research Ethics Board (1001 Queen St West, Toronto ON, M6J 1H4, Canada; +1 (0)416 535 8501 x36113; research. ethics@camh.ca), ref: 153/2021

Study design

Open-label single-arm clinical trial (feasibility study)

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Fitness/sport facility, Hospital

Study type(s)

Treatment, Safety, Efficacy

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

Major depressive disorder (MDD) and generalized anxiety disorder (GAD)

Interventions

Mindfulness-Based (non-contact) Boxing Therapy (MBBT)

Patients will be asked to volunteer and commit to the 10-week MBBT program. Patients will be permitted to continue to take all medication during the intervention. Participants will not be permitted to start a psychosocial intervention or psychotherapy during the study but can continue with one if they were engaged with it prior to recruitment.

The non-contact boxing group exercise class will incorporate mindfulness and meditation into each session. There will be a general intake which will welcome patients to the concept, expectations, allow for baseline measurements, and obtain formal consent. The waiver is the consent form as per ICF. The first 2 weeks will focus on the fundamentals of boxing including stance, technique and basics of a boxing class. Thereafter, sessions will incorporate a standard framework. A large focus of the sessions will be on the recovery at the end of a "round" for one minute where patients will be learning breathing techniques. A HIIT circuit will be used for bag work and pad work. Guided meditation will be conducted at the end to conclude the session.

Duration of treatment and follow-up: Study participants will continue to consult with their regular psychiatrist, however the study team will maintain contact throughout the duration of the study to respond to any concerns or changes in circumstances or mental/physical state. Any study-related safety concerns will be the responsibility of the principal investigator, who can be contacted at any time through the research team.

Intervention Type

Behavioural

Primary outcome measure

The feasibility and acceptability of MBBT:

- 1. Recruitment assessed by measuring the number of eligible participants who consent to enroll in the study over a period
- 2. Retention assessed by tracking the percentage of participants who continue to engage with the study from start to finish
- 3. Adherence assessed by evaluating the consistency with which participants attend MBBT sessions
- 4. Acceptability assessed quantitatively by utilizing the Client Satisfaction Questionnaire (CSQ) and assessed qualitatively by informal interviews and utilizing an end User-Experience Questionnaire at the end of the study

Secondary outcome measures

Measurement-Based Care Scales completed at baseline, midway (week 5), and upon completion (week 10):

- 1. Current depression level, measured using The 9-item Patient Health Questionnaire (PHQ-9)
- 2. Current anxiety level, measured using the Generalized Anxiety Disorder-7 (GAD-7)
- 3. Current psychological distress level, measured using the Kessler Psychological Distress Scale (K10)
- 4. Overall symptom level severity, measured using the Clinical Global Impression of Severity (CGI-S)
- 5. Current mindfulness level, measured using using The Mindful Attention and Awareness Scale (MAAS)

There will also be an exploratory aim to measure the State Mindfulness Scale for Physical Activity (SMS-PA) of session 5 and the last session. Given that this is an exercise intervention, the researchers were also interested in exploring any changes in Body Mass Index (BMI) and qualitative changes related to fitness by measuring BMI at baseline, midway, and upon completion.

Overall study start date

01/02/2022

Completion date

13/01/2023

Eligibility

Key inclusion criteria

Patients are included if they:

- 1. Are outpatients
- 2. Are voluntary and competent to consent to treatment
- 3. Have a Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM–5) diagnosis of non-psychotic MDD, single or recurrent, or GAD
- 4. Are male or female between the ages of 18 40 years
- 5. Are able to adhere to the study schedule
- 6. Are currently taking psychiatric medication for at least 4 months but are not planning on initiating a new treatment regimen during the pilot study

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

40 Years

Sex

Both

Target number of participants

9

Total final enrolment

q

Key exclusion criteria

Patients are excluded if they:

- 1. Meet DSM-5 substance use disorder criteria within the past 3 months
- 2. Have a concomitant major unstable medical illness
- 3. Are pregnant or intend to get pregnant during the study (confirmed verbally)
- 4. Have a SCID-5 diagnosis of any psychotic disorder, bipolar disorder, obsessive-compulsive disorder, or post-traumatic stress disorder (current or within the last year)
- 5. Have a DSM-5 diagnosis of borderline personality disorder or previous documented borderline personality disorder (BPD) traits
- 6. Prior history of violence or sexual aggression

Date of first enrolment

29/09/2022

Date of final enrolment

06/11/2022

Locations

Countries of recruitment

Canada

Study participating centre Centre for Addiction and Mental Health (CAMH)

1001 Queen Street West Toronto Canada M6J 1H4

Sponsor information

Organisation

Centre for Addiction and Mental Health

Sponsor details

1001 Queen Street W Toronto Canada M6J 1H4 +1 (0)416 535 8501 x36113 research.ethics@camh.ca

Sponsor type

Hospital/treatment centre

Website

http://www.camh.ca/en/hospital/Pages/home.aspx

ROR

https://ror.org/03e71c577

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a open peer-review journal

Intention to publish date

31/03/2024

Individual participant data (IPD) sharing plan

Contact for Data Access:

To request access to the datasets, please contact Dr Johny Bozdarov via email at johny. bozdarov@camh.ca or Dr Ishrat Husain at the Centre for Addiction and Mental Health (CAMH).

Type of Data Shared:

The datasets that can be shared will include de-identified participant information, such as scores from mental health questionnaires (e.g., PHQ-9, GAD-7), attendance records, and any collected biometric data like BMI. Detailed intervention adherence metrics and post-intervention feedback may also be available.

Dates of Availability:

Data will become available after the study's completion and publication.

Consent for Data Sharing:

Participant consent for data sharing was obtained as part of the initial study consent process. Participants were informed that their de-identified data might be shared for research purposes, with strict adherence to privacy and confidentiality protocols.

Data Anonymization:

All participant data will be anonymized prior to sharing. Direct identifiers will be removed, and a unique code will be used to represent each dataset, ensuring that individual participants cannot be identified.

Ethical and Legal Restrictions:

Data sharing will comply with all applicable ethical guidelines and legal requirements, including those specific to CAMH. The sharing of data will be contingent upon ensuring that patient confidentiality is not compromised and that all legal and institutional policies regarding data privacy are strictly followed.

Additional Comments:

The researchers are committed to supporting further research while also upholding their participants' rights and privacy. Any data sharing will align with CAMH's policies on data access and the ethical conduct of research.

IPD sharing plan summary

Available on request

Study outputs

Output typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Results article06/02/202507/02/2025YesNo