ISRCTN16944868 https://doi.org/10.1186/ISRCTN16944868

LiveMind: Living well through mindfulness

Submission date 10/02/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 10/02/2016	**Overall study status** Completed	
Last Edited 31/03/2016	**Condition category** Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Mindfulness is a widely-used technique which helps people to become more aware of their own thoughts and feelings, and the world around them. Many studies have shown that mindfulness-based cognitive therapy (MBCT), a structured therapy programme involving mindfulness exercises and techniques from cognitive behavioural therapy (a talking therapy helping to teach people how to change the way they think and behave) can help to improve mental wellbeing, and is regularly offered to people suffering from mental health conditions such as depression. Traditional MCBT requires a significant commitment from participants, in terms of both attending sessions and practicing mindfulness techniques at home every day. Living Well Through Mindfulness (LiveMind) is a new mindfulness programme which is much shorter than traditional MCBT. It has been developed specifically for people suffering from a mental health condition who are being treated by specialists (secondary care mental health care). The aim of this study is to find out whether the LiveMind programme is an acceptable and beneficial treatment for people suffering from mental health problems.

Who can participate?
Adults with a mental health problem who are being treated by the mental health services in Sussex Partnership NHS Foundation Trust.

What does the study involve?
At the start of the study, all participants complete a set of questionnaires asking them about their experiences, mental health and wellbeing. Following this, participants are then randomly to one of two groups. Those in the first group attend the LiveMind group immediately, which involves four weekly sessions lasting from about 90 minutes given by two trained therapists. The sessions include short (less than 15 minutes) sessions of mindfulness practice, as well as a discussion about what they noticed during the mindfulness practice. Those in the second group are placed on a waiting list, and attend the LiveMind group eight weeks later. Participants are asked to complete the questionnaires again after the first LiveMind group has ended (the immediate-start group) and again after the second LiveMind group has ended (delayed-start). At the end of the study, participants are interviewed about their experiences to help develop the methods used further.

What are the possible benefits and risks of participating?
Benefits include contributing to a research study that will further understanding of the effects

of learning mindfulness. Some participants may value the opportunity to find out more about mindfulness. Risks include the fact that practicing mindfulness can raise awareness of current difficulties. The groups are led by two therapists who will monitor risk to participants and will ensure that the NHS trust procedure formanaging risk is followed if necessary.

Where is the study run from?
Brighton and Hove Assessment and Treatment Service, , Nevill View Hospital (UK)

When is the study starting and how long is it expected to run for?
February 2016 to December 2016

Who is funding the study?
Economic and Social Research Council (UK)

Who is the main contact?
Dr Clara Strauss

Contact information

Type(s)
Public

Contact name
Dr Clara Strauss

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18273

Study information

Scientific Title
A feasibility randomised controlled trial of a brief mindfulness-based intervention in a mental health secondary care setting

Acronym
LiveMind

Study objectives
Feasibility questions about the LiveMind intervention are:
1.Is it possible to recruit secondary care service users to the LiveMind intervention?
2. Are participants willing to engage in the LiveMind intervention?
3. o participants find the LiveMind intervention acceptable?

Feasibility questions about the planned programme of research are:
1. Are participants willing to be randomised to a wait-list condition?
2. Are participants willing to complete the study questionnaires?
3. What are participant experiences of taking part in the study?

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South East Coast – Surrey, 02.12.2014, ref: 14/LO/1964

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: Mental Health; Subtopic: All Diagnoses; Disease: Not Applicable

Interventions
Participants are randomly allocated to one of two groups.

Intervention group: Participants receive the Live Mind intervention immediately. The LiveMind intervention consists of four weekly group sessions with each session being 90 minutes duration. There will be up to 10 participants per LiveMind group and the intervention will be delivered by two therapists, at least one of whom will be a trained MBCT teacher. The LiveMind intervention draws on the MBCT course protocol but is designed for people experiencing more severe and enduring forms of distress. Each of the four sessions provides the opportunity to engage in brief

mindfulness practices (<15 minutes) including mindfulness of the breath, body, sounds, movement and thoughts. Mindfulness practice is followed by discussion ('inquiry') of what participants noticed during the mindfulness practice and the mindfulness practices are also provided as audio recordings so that participants can practice at home, between group sessions.

Control group: Participants are placed on a waiting list to receive the intervention after an 8-week delay.

All participants will continue to receive their usual care from their secondary care mental health team during the course of the study.

Intervention Type
Other

Primary outcome measure
Feasibility of the intervention is determined at 1 month.

Secondary outcome measures
All outcomes are measured at baseline (pre-randomisation), time 1 (following the end of the immediate-start mindfulness groups) and time 2 (following the end of the delayed-start mindfulness groups).

1. Generalised Anxiety symptom severity. Measured using the Generalised Anxiety Disorder Questionnaire
2. Depression symptom severity. Measured using the Patient Health Questionnaire (PHQ-9)
3. Trait Mindfulness. Measured using the Five Factor Mindfulness Questionnaire Short Form (FFMQ-SF)
4. Self-compassion. Measured using the Self-compassion Scale Short Form (SCS-SF)
5. Wellbeing. Measured using the Short Warwick-Edinburgh Mental Well-being Scale (SWEMEBS)5.

Overall study start date
01/07/2014

Completion date
31/03/2017

Eligibility

Key inclusion criteria
1. Aged 18 years old or older
2. Currently in receipt of care from secondary care mental health services in Sussex Partnership NHS Foundation Trust
3. Meet diagnostic criteria for a current DSM IV Axis 1 disorder as assessed by the Mini International Neuropsychiatric Interview (version 6.0)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 40; UK Sample Size: 40; Description: A trial with 40 participants will allow us to run four therapy groups

Key exclusion criteria
1. Misusing substances to the extent that this is likely to adversely influence other members of the mindfulness course (as judged by the person's psychiatrist or care coordinator)
2. Risk of current or recent (past month) active suicidal attempt or intent
3. Have experienced a recent (past month) serious life event/crisis, which would make an MBI inappropriate at the time of referral.
4. Current or planned participation in another form of psychological therapy
5. Taking part in research investigating new medicinal products

Date of first enrolment
12/02/2016

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nevill View Hospital
Brighton and Hove Assessment and Treatment Service
Nevill Avenue
Hove
United Kingdom
BN3 7HZ

Sponsor information

Organisation
Sussex Partnership NHS Foundation Trust

Sponsor details
Sussex Education Centre
Nevill View Hospital
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England
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BN3 7HZ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05fmrjg27

Funder(s)

Funder type
Research council

Funder Name
Economic and Social Research Council

Alternative Name(s)
ESRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication of findings in a peer reviewed journal.

Intention to publish date
31/03/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No