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LIGHTMind 2: Low-intensity guided help through mindfulness

Submission date
31/07/2017

Recruitment status
No longer recruiting

Registration date
31/08/2017

Overall study status
Completed

Last Edited
23/03/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Depression has serious personal, family and economic consequences. It is estimated that depression will cost £12.15 billion to the economy each year in England by 2026. Improving Access to Psychological Therapies (IAPT) is the NHS talking therapies service in England for adults experiencing anxiety or depression. Approximately 1 million people are referred to IAPT every year, over half experiencing depression. Where symptoms of depression are mild /moderate people are typically offered Cognitive Behaviour Therapy (CBT) self-help supported by a psychological wellbeing practitioner (PWP). The problem is that over half of people (58%) who complete treatment for depression in IAPT remain depressed despite receiving the NICE-recommended treatment. As well, less than half (40%) patients complete this treatment. This study seeks to investigate an alternative to CBT self-help. Mindfulness-based self-help, which differs from CBT in focus, approach and practice, could be more effective with lower dropout. The aim of this study is to comparing these two forms of self-help (CBT and Mindfulness).

Who can participate?
Adults aged 18 who have depression or anxiety

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive mindfulness cognitive behaviour therapy workbooks to complete for 16 weeks. Those in the second group complete cognitive behaviour therapy workbooks for 16 weeks. Participants attend six sessions psychological wellbeing practitioner (PWP) to answer questions and provide encouragement. Participants complete online questionnaires at the end of the programme and then again for a six months follow up.

What are the possible benefits and risks of participating?
Participants may benefit from a reduction in their depression symptoms. Participants may experience negative thoughts and feelings through using the exercises in self-help books, as both of the programmes increase awareness of current and past experiences. Participants are told by their Psychological Wellbeing Practitioners (PWP) that in MBCT/CBT it is common to become more aware of experiences and that this may include unpleasant, difficult experiences. Participants will have the opportunity to talk with the PWP about their experiences of their

allocated intervention and the PWP will be supervised by the study lead who is a clinical psychologist in working in mental health care settings. In the event of a participant experiencing a high degree of distress the research team would follow good practice and ensure that the participant is referred on to an appropriate source of support.

Where is the study run from?
This study is being run by the Sussex Partnership NHs Foundation Trust (UK) and takes place in four health centres in Sussex (UK).

When is the study starting and how long is it expected to run for?
September 2017 to January 2021

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Clara Strauss
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
33702

Study information

Scientific Title

Low-Intensity Guided Help Through MINDfulness: A randomised controlled trial comparing supported mindfulness-based cognitive therapy self-help to supported cognitive behaviour therapy self-help for adults experiencing depression

Acronym
LIGHTMind 2

Study objectives
Primary hypothesis:
Supported mindfulness-based cognitive therapy self-help (MBCT-SH), in comparison to supported cognitive behavioural therapy self-help (CBT-SH), will lead to greater reductions in depressive symptom severity (measured by the PHQ-9) from baseline to post-intervention.

Secondary hypotheses:
2. MBCT-SH in comparison to CBT-SH will lead to greater reduction in depressive symptom severity from baseline to six-months follow-up
3. A greater proportion of MBCT-SH participants will be in the non-clinical range for depressive symptoms than CBT-SH participants at post-intervention (i.e. remission) and six-months follow-up (i.e. recovery)
4. MBCT-SH in comparison to CBT-SH will lead to greater improvements in mindfulness, generalised anxiety, work and social adjustment and wellbeing from baseline to post-intervention and from baseline to six-months follow-up
5. Treatment completion rates will be higher for MBCT-SH than CBT-SH
6. Depressive symptom severity outcomes will be mediated by treatment completion
7. MBCT-SH will be cost-effective in comparison to CBT-SH at follow-up

A qualitative component is employed to close the evidence gap concerning reasons for treatment non-completion of the interventions by identifying facilitators and barriers to treatment completion in both study arms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Surrey Research Ethics Committee, 12/07/2017, 17/LO/0596

Study design
Randomised; Interventional; Design type: Treatment, Psychological & Behavioural

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Mental Health, Primary sub-specialty: Depression; UKCRC code/ Disease: Mental Health/ Mood [affective] disorders, Mental Health/ Neurotic, stress-related and somatoform disorders

Interventions

This is a parallel groups, superiority pragmatic RCT with 1:1 allocation to MBCT-SH or CBT-SH with blinded assessments at all time points. Participants are blind to the hypothesised direction of effects. The study includes qualitative evaluation of participants' experiences of both self-help interventions with a focus on better understanding barriers and facilitators to engaging in self-help interventions in IAPT. Four hundred and ten people meeting eligibility criteria for major depressive disorder or mixed anxiety and depression are randomly allocated to receive MBCT-SH or CBT-SH, along with six sessions of support from a psychological wellbeing practitioner. Participants complete measures at baseline, 16 weeks post-randomisation (post-intervention) and 42 weeks post randomisation (6-months follow-up). In addition, 32 participants are interviewed about their experiences.

All potential participants complete a standard IAPT initial assessment. This includes completion of the PHQ-9. Potential participants (i.e. those scoring 10-19 inclusive on the PHQ-9) are offered the study. Potential participants not meeting eligibility criteria are not be offered the study and are offered usual care by the IAPT service.

If eligible and interested in the study, potential participants are given a copy of the Participant Information Sheet.

Potential participants speak with a member of the research team to answer questions about the study and to complete the consent form (if appropriate). As assessment and intervention is typically offered by telephone at Step 2 in IAPT, participants are offered the choice of having the consent meeting by phone or in person. The consent form is presented online for participants to complete during the meeting (with hard copy option available). Potential participants not wanting to take part in the study are referred back to the person who conducted their initial IAPT assessment for usual care to be offered by the service.
Once the participant has consented to participate in the trial, the participant completes the full set of baseline measures with a research assistant present in person or by phone. Measures are completed online or on paper, depending on participant preference. Participants who do not meet eligibility criteria at the baseline assessment are referred back to the person who conducted their initial assessment for usual care to be offered by the service.

At the end of the baseline assessment, eligible participants are randomised to either the MBCT-SH or CBT-SH arm. Participants are then be given their allocated self-help workbook.

Participants are randomly allocated using the Sealed Envelope online service. The team statistician use Sealed Envelope to set up and test the randomisation procedure incorporating stratification by site and PHQ-9 severity category (mild or moderate) using random block length and 1:1 allocation. The research assistant randomise participants by completing the online form with participant's details. This immediately show whether the participant is assigned to the MBCT-SH or CBT-SH arm and participants are given their self-help workbook.

Mindfulness based congitive therapy (MBCT)-Self Help Arm
The MBCT-SH workbook 'The Mindful Way Workbook' (Teasdale, Williams & Segal, 2014), presents MBCT as a self-help course. MBCT-SH participants are given the workbook and are asked to guide themselves through the self-help course within a 16 week time period. As is routine at Step 2 in IAPT, participants are offered six support sessions with a psychological wellbeing practitioner (PWP) to answer questions and provide encouragement.

Cognitive Behaviour Therapy (CBT) -Self Help Arm
The CBT-SH workbook 'Overcoming Low Mood and Depression' (Williams, 2013) are given to

participants in the CBT-SH arm of the study and they are encouraged to guide themselves through within 16 weeks alongside six PWP sessions to answer questions and provide encouragement.

Participants complete measures online (with a postal option) at 16 weeks post-randomisation (post-intervention) and 42 weeks post-randomisation (6-month follow-up).

Participants are invited to take part in the qualitative Change Interview after their post-intervention quantitative assessment is completed. Participants are interviewed on a first come, first served basis with eight participants interviewed in each of four groups:
1. MBCT-SH intervention completers
2. MBCT-SH intervention non-completers
3. CBT-SH intervention completers
4. CBT-SH intervention non-completers

Payments by £20 gift vouchers will be made to participants for completing each assessment, including the qualitative interview.

Intervention Type
Other

Primary outcome(s)
Depression symptom severity at post-intervention. The PHQ-9 is a 9-item self-report measure of depression symptom severity used in all IAPT services. Items are rated on a four-point scale. The primary outcome for this study is change in PHQ-9 score from baseline to 16 weeks post-randomisation

Key secondary outcome(s))
1. Depression symptom severity is measured using the change in PHQ-9 score from baseline to follow-up (42 weeks post-randomisation) is a secondary outcome for the study at follow-up
2. Generalised anxiety is measured using the GAD-7 is a 7-item measure of generalised anxiety used in IAPT. Items are rated on a 4-point scale and the measure has excellent psychometric properties from baseline to post-intervention and from baseline to follow-up
3. Wellbeing is measured using the short version of the Warwick Edinburgh Mental Wellbeing Scale consists of 7 questions rated on a 5-point scale designed to measure wellbeing from baseline to post-intervention and from baseline to follow-up are secondary outcomes
4. Functioning is measured using the Work and Social Adjustment Scale (WSAS) is a 5-item measure of daily occupational and social functioning that is used routinely in IAPT from baseline to post-intervention and from baseline to follow-up are secondary outcomes
5. Mindfulness is measured using the 15-item version of the Five-Facet Mindfulness Questionnaire. from baseline to post-intervention and from baseline to follow-up are secondary outcomes
6. Service use is measured using the a self-report version of the Adult Service Use Schedule (ADSUS) will be used to collect data on resource used to estimate costs and will take the health and social services perspective at collected at baseline, post-intervention (16 weeks post-randomisation) and follow-up (42 weeks post-randomisation)
7. Health-related quality of life is measured using the EQ-5D is a five-dimension, generic, preference-based measure of health-related quality of life covering mobility, self-care, usual activities, pain/discomfort and anxiety/depression.at baseline, post-intervention (16 weeks post-randomisation) and follow-up (42 weeks post-randomisation).

Qualitative Evaluation:
The aim of the qualitative element of the study is to ascertain facilitators and barriers to treatment completion for each intervention given the well-established problem with drop-out from IAPT. Thirty-two telephone interviews will be conducted with eight participants interviewed from each of the following four groups; (1) MBCT-SH intervention completers, (2) MBCT-SH intervention drop-outs, (3) CBT-SH intervention completers, (4) CBT-SH intervention drop-outs. This strategy will ensure that participants are interviewed in equal numbers from each intervention arm and that an equal number of intervention drop-outs and completers are interviewed. Interviews will take place following the post-intervention assessment in order to accurately capture participants' experiences using the Change Interview.

Completion date
31/01/2021

Eligibility

Key inclusion criteria
1. Be aged 18 years or over
2. Meet diagnostic criteria on the revised Clinical Interview Schedule (CIS-R) for a primary diagnosis of a depressive episode, or mixed anxiety and depression
3. Score 10 or more on the PHQ-9 at their initial IAPT assessment (the cut-off for a major depressive episode); and
4. Have sufficient literacy skills to read and understand the self-help materials

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
410

Key exclusion criteria
1. Have severe symptoms of depression (a score 20 or more on the PHQ-9);
2. Score of 4 on the CIS-R suicidality scale
3. Express a strong preference (5/5) for one intervention over the other on the Treatment Preference 5. Question such that if randomised to the non-preferred intervention they would be likely to drop out of the intervention.

Date of first enrolment

11/09/2017

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Health in Mind in East Sussex
The Drive
Hellingly
East Sussex
Hailsham
United Kingdom
BN27 4ER

Study participating centre
Brighton and Hove Wellbeing Service
5th Floor
177 Preston Road
Brighton
United Kingdom
BN1 6AG

Study participating centre
Time to Talk
Brighton General Hospital
Elm Grove
Brighton
United Kingdom
BN2 3EW

Study participating centre
Talking Therapies Southwark
Munro Centre
66 Snowsfields

London
United Kingdom
SE1 3SS

Sponsor information

Organisation
Sussex Partnership NHS Foundation Trust

ROR
https://ror.org/05fmrjg27

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available upon request from Clara Strauss (clara.strauss@nhs.net) following publication of the main trial findings. Data will be shared with other research teams for the purpose of contributing to systematic reviews and meta-analyses. Participant consent has been sought for this. Shared data will be fully anonymised.

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	protocol	22/03/2022	23/03/2023	Yes	No
Protocol article		04/05/2020	06/05/2020	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes