

What kind of self-help cognitive therapy is helpful for depression?

Submission date 28/10/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 22/01/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 24/07/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Depression is the most common mental health condition and is predicted by the World Health Organization to be the second leading cause of disability globally by 2020. The National Institute of Health and Care Excellence (NICE) recommends psychological interventions for depression including cognitive behavioural therapy (CBT) and mindfulness-based cognitive therapy (MBCT). However, demand exceeds supply, so NICE recommend that in most cases of mild or moderate depression CBT self-help materials should be offered along with brief support from a mental health worker. However, CBT self-help is only effective for some and, importantly, one third of people drop out.

MBCT is a group therapy for depression that adds mindfulness practice and principles to cognitive therapy. There is evidence MBCT is effective in preventing relapse for depression and reducing symptoms of depression. Self-help materials based on MBCT principles might be attractive to, and effective for some people experiencing mild or moderate depression. However, to date, high quality research has not evaluated the benefits of self-help MBCT. This study will evaluate whether MBCT works. Participants will also be interviewed about their experiences of the interventions. This is an initial study (called pilot study) that will tell us the approximate difference in outcome between MBCT self-help and CBT self-help, and how many people drop out from each intervention. This will allow us to know how many participants we need for a large scale study.

Who can participate?

Adult participants (18 years or older) will be recruited through primary care mental health services in Sussex Partnership NHS Foundation Trust (UK). To be included in the study participants will score in the sub-clinical, mild or moderate range on a self-report measure of depressive symptom severity. People currently undertaking another form of psychological intervention will not be included in the study.

What does the study involve?

Potential participants will meet with the study research assistant so that they can ask questions about the study and, if they would like to take part, to sign the study consent form. Following this participants will be asked to complete a number of self-report questionnaires about their current mental wellbeing. After completing the questionnaires, participants will be assigned at

random to either receive a guided self-help course based on cognitive-behaviour therapy (CBT) principles or a guided self-help course based on mindfulness-based cognitive therapy (MBCT) principles. They will have 10 weeks to complete the self-help course and during this time they will have four support telephone calls with a mental health worker. This will be an opportunity to discuss progress with the self-help course and to ask questions.

After completing the self-help course, participants will meet with a research assistant from the study team to complete the same set of questionnaires that were completed prior to the course starting. In addition, the research assistant will ask participants questions about their experiences of undertaking the self-help course. Six months after completing the self-help course participants will meet with a research assistant for a final time to complete the same questionnaires.

What are the possible benefits and risks of taking part?

Participants will have the opportunity to take part in a guided self-help course that they may find beneficial. Becoming more aware of thoughts and feelings and reflecting on experiences of depression can be helpful, although it can also sometimes feel difficult. The mental health practitioner who provides support will be experienced in helping people who have symptoms of depression. Participants will also be free to access help from their GP and to stop the self-help course and to drop out of the study without giving a reason.

Where is the study run from?

The study is running in Sussex Partnership NHS Foundation Trust in their primary care mental health service (UK).

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

The study is due to start in January 2014 and to run until April 2015.

Who is funding the study?

Grant from Sussex Partnership NHS Foundation Trust own-account funding panel (UK).

Who is the main contact?

Dr Clara Strauss

clara.strauss@nhs.net

Contact information

Type(s)

Scientific

Contact name

Dr Clara Strauss

Contact details

School of Psychology

University of Sussex

Brighton

United Kingdom

BN1 9QH

-

c.y.strauss@sussex.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

What kind of self-help cognitive therapy is helpful for depression? An internal pilot randomised controlled trial of mindfulness-based cognitive therapy supported self-help and cognitive behaviour therapy supported self-help for mild to moderate depression

Acronym

LightMind

Study objectives

This study is an internal pilot randomised controlled trial for a full trial. The hypotheses below are for the full trial. The aim of the internal pilot is to generate an effect size for the power calculation for the full trial.

1. Mindfulness-based supported self-help will be more effective than cognitive behavioural therapy (CBT)-based supported self-help at reducing the severity of symptoms of depression and this will remain true at the six-months follow-up.
2. Mindfulness-based supported self-help will have higher rates of therapy engagement than CBT supported self-help and this will remain true at the six-months follow-up.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration - pending (application for ethical approval will be made through the UK NHS Research Ethics Committee before starting the study).

Study design

Internal pilot randomised controlled trial

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

Major depressive disorder (sub-clinical, mild or moderate severity)

Interventions

The participants will be randomly allocated to receive one of the following interventions:

1. Mindfulness-based cognitive therapy (MBCT) supported self-help

The MBCT self-help intervention will be guided self-help using the book 'Mindfulness: A practical guide to finding peace in a frantic world' (Williams & Penman, 2011). The first author of the book, Mark Williams, is one of the leading figures who developed and evaluated MBCT groups.

The book is based on the MBCT course and guides the reader through mindfulness principles with an accompanying CD of mindfulness practices. It is structured as an 8-week course with one chapter per week. The book starts with an introduction and rationale for the intervention followed by eight chapters, with each chapter based on the equivalent session in the face-to-face MBCT course. Participants randomised to the MBCT self-help condition will be given a copy of the book after randomisation. They will be guided through the book over 8 weeks via weekly phone support from the Psychological Well-being Practitioner (PWP).

2. Cognitive behaviour therapy (CBT) supported self-help

The CBT self-help intervention will be guided self-help using the book 'Overcoming depression and low mood: a 5 areas approach' (Williams, 2013). This is the CBT self-help book routinely used by primary care mental health services in the UK for depression.

Participants randomised to the CBT-help condition will be given a copy of the book after randomisation. They will be guided through the book over 8 weeks via weekly phone support from the Psychological Well-being Practitioner (PWP).

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Patient Health Questionnaire for depression (PHQ-9)
2. Engagement with the intervention (defined as completing at least 50% of the intervention)

Measures will be completed at baseline, immediately following the 10-week intervention (10 weeks after baseline) and then again six months after the end of the intervention (36 weeks after baseline).

Secondary outcome measures

1. Short form of Warwick Edinburgh Mental Wellbeing scale (SWEMWS)
2. Five facet mindfulness questionnaire (FFMQ)
3. Self-compassion scale (SCS)
4. General self-efficacy scale (GSES)

Measures will be completed at baseline, immediately following the 10-week intervention (10 weeks after baseline) and then again six months after the end of the intervention (36 weeks after baseline).

Overall study start date

01/01/2014

Completion date

31/03/2015

Eligibility

Key inclusion criteria

1. Adults (18 years or older)
2. Scoring between 5 and 19 on the Patient Health Questionnaire for depression (PHQ-9)
3. Sufficient English language reading ability to read the self-help books

Participants will be recruited through UK primary care mental health services.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

40

Key exclusion criteria

1. Meet diagnostic criteria based on the Mini International Neuropsychiatric Interview (MINI version 6.0.0, Sheehan et al., 2010) for any of the following: a psychotic disorder, anorexia nervosa, post-traumatic stress disorder, substance misuse or obsessive-compulsive disorder.
2. Be currently receiving or have plans to receive another form of psychological therapy during the course of the study.

Date of first enrolment

01/01/2014

Date of final enrolment

31/03/2015

Locations

Countries of recruitment

England

United Kingdom

Study participating centre**School of Psychology**

Brighton

United Kingdom

BN1 9QH

Sponsor information

Organisation

Sussex Partnership NHS Foundation Trust (UK)

Sponsor details

c/o Tanya Telling

Sussex Education Centre

Mill View Hospital

Nevill Avenue

Hove

England

United Kingdom

BN1 6ED

-

tanya.telling@sussexpartnership.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<http://www.sussexpartnership.nhs.uk>

ROR

<https://ror.org/05fmrjg27>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Sussex Partnership NHS Foundation Trust (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration