

Is mindfulness-based cognitive therapy a feasible additional treatment for young people who do not completely recover from depression after treatment at Child and Adolescent Mental Health Services or who rapidly get depressed again?

Submission date 26/08/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 04/09/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 16/08/2022	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Depression affects people in different ways and can cause a wide variety of symptoms. They range from lasting feelings of unhappiness and hopelessness to losing interest in the things you used to enjoy and feeling very tearful. Many people with depression also have symptoms of anxiety. There can be physical symptoms too, such as feeling constantly tired, sleeping badly, having no appetite or sex drive, and various aches and pains.

Depression in teenagers knocks normal development off course and disrupts family relationships. Even after treatment, many young people are left with depressive symptoms, so we need more treatments for this group who suffer greatly. We have developed a new treatment; Mindfulness for Adolescents and their Carers (MAC), which helps young people and their parents to learn to recognise unhelpful patterns of thoughts, feelings and behaviours, and to find alternative ways to cope with distress. Our earlier work shows that young people and their parents wanted to attend MAC sessions, which they found helpful. Young people's depressive symptoms reduced afterwards.

Aims

Before we can test whether MAC works and is value for money, we need to answer three questions.

1. Who should be trained to deliver MAC, and how should they be trained?
2. What does usual treatment look like for this group of young people?
3. What is the best way to recruit young people and their carers to trial of MAC?

Who can participate?

1. Young people aged 14-17 with a primary clinical diagnosis of depression who have had initial

treatment at Child and Adolescent Mental Health Services (CAMHS) and are not fully recovered or who have relapsed quickly following discharge, and their parent(s) / carer(s)

2. CAMHS practitioners at band 6 or above with a personal mindfulness practice and level 1 training in mindfulness-based intervention delivery, or equivalent experience

What does the study involve?

1. We will develop a training programme for potential group leaders who will attend 4 days of training prior to delivering MAC under supervision
2. We will interview key managers and practitioners in CAMHS about the depression treatment pathway and carry out a detail study of records to understand usual treatment for this group of young people.
3. We will run two groups of 10 young people (with a parallel group for their parents/ carers) to establish whether we can recruit and retain effectively and to study which questionnaires work best for a future randomised controlled trial. There are 9 weekly workshops, each lasting 1.5 hours. Workshops will be held using NHS approved video conferencing software that can be accessed securely from participants' homes using a laptop/computer or smart phone
4. We will ask both young people and their parent or carer to fill in a set of questionnaires at three different times, when they join the study at baseline and then 4 and 9 months later. The questions will help us to measure if there have been any changes in the way participants are feeling. These questions will be completed on a secure online website which participants can access via a computer or smart phone. These questionnaires are likely to take about 90 minutes to complete.

What are the possible benefits and risks of participating?

The young people and parents who participate will get access to a novel treatment that shows promise in young people and is established in adults.

The practitioners attending training will develop new skills and a deeper understanding of mindfulness.

All participants will need to complete questionnaires and some will discuss their experiences in person. This will demand their time, and some of the topics may be sensitive for some people. The researchers will do their utmost to avoid distress and anyone who becomes distressed will be signposted to support.

Mindfulness techniques can increase anxiety or lead to distress in some people. Group leaders will be trained to identify and support any young people or parents who experience such distress and support will be provided.

Where is the study run from?

University of Cambridge (UK)

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

May 202 to September 2021

Who is funding the study?

National Institute for Health Research Programme Development Grants (UK)

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

285257

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

IRAS 285257

Study information

Scientific Title

A combined mindfulness-based approach for adolescent non-responders to first-line treatments of depression and their carers: establishing feasibility of implementation and delivery

Acronym

ATTEND

Study objectives

This proposal addresses four important uncertainties and will:

1. Develop the training programme for therapists, which may need to differ in emphasis depending on whether they come from child mental health or mindfulness backgrounds
2. Describe current care pathways (to aid recruitment) and develop an understanding of what Treatment As Usual (TAU; probable comparator) comprises for the young people we want to recruit
3. Test the process for identifying young people and their carers and see how many start and finish MAC, so we better understand how many clinics we need to work with to test MAC in a

definitive trial

4. Test the acceptability of asking for blood and saliva samples for the future study of how MAC works

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 10/12/2020, Cambridgeshire South REC (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8134; cambridgesouth.rec@hra.nhs.uk), ref: 20/EE/0246

Study design

Multi-centre mixed methods feasibility study

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Depression

Interventions

Potential therapists will attend 4 days of training to be delivered remotely to familiarise them with the manual – they will then contribute to the delivery of MBCT to two groups of 10 young people or the parallel groups for their carers

‘Mindfulness for Adolescents and Carers’ (MAC) is delivered to a group of up to 10 young people at a time, there are 9 weekly workshops, each lasting 1.5 hours. Workshops will be held using NHS approved video conferencing software that can be accessed securely from participants’ homes using a laptop/computer or smart phone. Their parent or carer are invited to attend a parallel but separate workshop with other carers to work through similar materials. Both young people and their parent or carer fill in a set of questionnaires at three different times, when they join the study at baseline and then 4 and 9 months later.

Intervention Type

Behavioural

Primary outcome(s)

All outcomes are measured at baseline and then 4 and 9 months later. The following constructs will be measured in young people using the following measures:

1. Depression using RCADS
2. Quality of Life using CHU-9D
3. Family dynamics using Score-15
4. Mindfulness using CAMM
5. Self-compassion using SCS-SF
6. Emotional Regulation using ERQ
7. Decentering using EQ (Decentering Scale)
8. Rumination using CRSQ

And in parents/carers:

9. Depression using GAD and PHQ-9
10. Quality of Life using EQ-5D
11. Family dynamics using Score-15
12. Mindfulness using FFMQ-SF
13. Self-compassion using SCS-SF
14. Emotional Regulation using ERQ
15. Decentering using EQ (Decentering Scale)
16. Rumination using RRS

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

30/09/2021

Eligibility

Key inclusion criteria

Young People:

1. CAMHS patients with a primary diagnosis of depression
2. Aged 14 - 17 years at the time of recruitment
3. Completed at least one NICE recommended treatment for depression or anxiety
4. Not recovered sufficiently to be discharged, or who have subsequently relapsed and been re-referred
5. Scoring 60 or more on the self-report RCADS

Carers:

6. A carer of a young person who has consented to take part in the study

Group leaders:

7. Band 6 and above with professional training meaning they can work therapeutically with depressed (and anxious) CYP
8. A named CAMHS service senior clinician to support clinician delivering the group with risk – Clinical responsibility rest with CAMHS
9. Own personal mindfulness practice following attendance at either 8-week MBCT or MBSR group
10. Some experience of leading or co-leading an MBI but ideally level 1 teacher training

Healthy volunteers allowed

No

Age group

Child

Lower age limit

14 years

Upper age limit

17 years

Sex

All

Key exclusion criteria

Young People:

1. A primary presenting problem of eating disorder, post-traumatic stress disorder or psychosis
2. Self-harming behaviour or substance misuse necessitating current active clinical management

Date of first enrolment

15/01/2021

Date of final enrolment

22/03/2021

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre**University of Cambridge**

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Study participating centre**University of Exeter**

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Study participating centre**Institute of Psychiatry, Psychology and Neuroscience, Kings College London**

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Study participating centre
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Sponsor information

Organisation
Cambridgeshire and Peterborough NHS Foundation Trust

ROR
<https://ror.org/040ch0e11>

Funder(s)

Funder type
Government

Funder Name
Programme Development Grants

Alternative Name(s)
NIHR Programme Development Grants, NIHR Programme Development Grants (PDG), NIHR – Programme Development Grants, PDG

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 and/or analysed during the current study are not expected to be made available due to confidentiality.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Participant information sheet	01/11/2020	09/08/2022	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet		11/11/2025	11/11/2025	No	Yes
Plain English results	version 1.3	01/11/2020	09/08/2022	No	Yes
Protocol file		06/04/2021	16/08/2022	No	No