

# 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?

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

Prof. Tamsin Ford, [tjf52@medschl.cam.ac.uk](mailto:tjf52@medschl.cam.ac.uk)

## Contact information

Type(s)

Scientific

**Contact name**

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

285257

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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

### **Secondary study design**

Mixed qualitative and quantitative study to evaluate the feasibility of training therapists and recruiting and retaining 20 young people and their carers including randomised allocation to MBCT or treatment as usual

### **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**

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 measure**

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

### **Secondary outcome measures**

There are no secondary outcome measures

### **Overall study start date**

01/05/2020

### **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

**Participant type(s)**

Mixed

**Age group**

Child

**Lower age limit**

14 Years

**Upper age limit**

17 Years

**Sex**

Both

**Target number of participants**

40 young people with one or both parents - 20 in each site

**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**

England

United Kingdom

**Study participating centre**

**University of Cambridge**

Department of Psychiatry

Douglas House, 18b Trumpington Road

Cambridge

United Kingdom

CB28AH

**Study participating centre****University of Exeter**

St Lukes Campus  
Magdelen Road  
Exeter  
United Kingdom  
EX12LU

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

Department of Psychology  
16 De Crespigny Park  
Camberwell  
London  
United Kingdom  
SE5 8AF

**Study participating centre****University of Surrey**

Department of Psychology  
4 Huxley Road  
The Surrey Research Park  
Guildford  
United Kingdom  
GU2 7RE

## **Sponsor information**

**Organisation**

Cambridgeshire and Peterborough NHS Foundation Trust

**Sponsor details**

Elizabeth House  
Fulbourn Hospital  
Cambridge  
England  
United Kingdom  
CB21 5EF  
+44 (0)1223 219400  
r&d@cpft.nhs.uk

**Sponsor type**

Hospital/treatment centre

**Website**

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

**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

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## **Results and Publications**

**Publication and dissemination plan**

We anticipate the following outputs from this study

- PGfAR application (all – TF lead)
- Protocol for RCT (all RH to lead drafting – draw in stats and health economics)
- Treatment Recording Scale / equivalent that is validated
- MAC manuals (as IP for the bid, with additions from this work is necessary)
- MAC training and delivery manuals finalised but to be published on completion of the main trial (TB, PS, JR, JF)

**Academic papers:-**

- Conceptual paper about how the manual has been modified in the light of the current literature in order to optimise response
- Intervention mapping paper
- Current state of provision for young people with depression

**Intention to publish date**

31/12/2021



## 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?
<a href="#">Plain English results</a>	version 1.3	01/11/2020	09/08/2022	No	Yes
<a href="#">Results article</a>		01/11/2020	09/08/2022	Yes	No
<a href="#">Protocol file</a>		06/04/2021	16/08/2022	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No