ISRCTN17823155 https://doi.org/10.1186/ISRCTN17823155

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

Registration date
04/09/2020

Last Edited
16/08/2022

Recruitment status
No longer recruiting

Overall study status
Completed

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 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

Contact information

Type(s)

Scientific

Contact name
Prof Tamsin Jane Ford

ORCID ID
http://orcid.org/0000-0001-5295-4904

Contact details
Department of Psychiatry
Douglas House
18b Trumpington Road
Cambridge
United Kingdom
CB2 2AH
+44 (0)7891 409229
tjf52@medschl.cam.ac.uk

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