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Is an adapted form of mindfulness-based cognitive therapy an effective treatment to support the recovery of 15-18-year-olds who, despite already receiving some treatment, are still experiencing symptoms of depression?

Submission date
01/08/2024

Recruitment status
Recruiting

Registration date
15/08/2024

Overall study status
Ongoing

Last Edited
15/08/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
In the UK about 140,000 15–19-year-olds experience depression. An estimated 35,000 young people access NHS treatment for depression, of which about 14,000 do not respond and a further 8,000 are likely to experience depression again after initial successful treatment. Teenagers who still have symptoms after treatment for low mood, depression or anxiety, or who relapse quickly, need more treatment options. These young people have a high risk of substance misuse, self-harm, school, or relationship difficulty, as well as poor adult mental and physical health. Parenting a teenager with depression is stressful and can damage family relationships. Teenagers whose parents have depression are more likely to develop mental health problems in adulthood.
Mindfulness-based cognitive therapy (MBCT) combines training in mindfulness meditation with principles from cognitive therapy. It teaches skills to recognise early warning signs of depression, avoid repetitive thinking patterns that make depression more likely, and respond in ways that protect mental health. Although MBCT is recommended for adults who have experienced three or more depressive episodes, MBCT for teenagers is relatively untested. Mindfulness for Adolescents and Carers (MAC) was developed as a version of MBCT adapted to be more engaging for teenagers. MAC aims to help teenagers recover from depression and the parallel parent/carer group aims to support parents and carers to cope better. The aim of this study is to see if MAC supports recovery and prevents relapse amongst 15-18-year-olds who risk developing recurrent depression as adults.

Who can participate?
Young people aged between 15 and 18 who have completed at least one evidence-based treatment for anxiety or depression but are still experiencing symptoms of low mood. If a young person is eligible to participate then their parent or carer will be invited to take part in a parallel parent mindfulness group.

What does the study involve?
This study is run across six different parts of England: London, Devon, Sussex, East of England, Oxford and Nottingham. People who agree to take part will either be randomly assigned to take part in the Mindfulness for Adolescents and Carers (MAC) group and continue to receive their current/usual treatment, or be assigned to continue with their current/usual treatment only. MAC is mindfulness-based cognitive therapy adapted for teenagers. MAC is delivered to a group of up to 12 young people. There are eight weekly sessions, each 1 hour 30 to 45 minutes. Between MAC sessions, people will be asked to record their Mindfulness at Homepractice on the MAC App. The App will have spaces where they can select what practices they have done and how they found them. This will be shared with their therapist. The App will also automatically record usage information such as how often they open the App, which audio recordings they listen to the most and how long they listen to them for. This automatically collected information will not be shared with their therapist, but it will be used in the study's final analysis.
The researchers will invite parents/carers to attend sessions as well as this can really help them to support their child. The young people and parent/carer sessions run separately, each in their own room. However, young people can still take part in this study even if their parent/carer doesn't want to take part themselves.
Mindfulness works by helping to learn skills that can prevent low mood or depression from coming back, helping people to become more aware of how their body is feeling and the impact this can have on their emotions, and trying to help pay attention to the present moment and think about the kind of things their internal voice is saying to you. Often our mind is thinking about what will happen (the future) or what has happened (the past) and sometimes we miss what is happening right now. The present is not always as bad as we think, but even when it is, then mindfulness practices and ideas can help us find new ways of responding to difficulties. The MAC programme aims to help the young person to 'train their mind' so that they can choose to respond rather than react to difficulties. To do this, first we need to learn to notice when we are doing something unhelpful, and then we need to let go of it and find a different way of working with our mind. In this programme we learn to be flexible, kind and understanding with ourselves in order to take the above steps.

What are the possible benefits and risks of participating?
Engaging in MAC involves a commitment to the workshops and the mindfulness practice. This typically involves experiencing the full range of positive, negative and neutral experiences that are an essential part of the treatment. This is done in a supportive and constructive therapeutic contact. Participants will complete some questionnaires and discuss with researchers how they are feeling. Some of these questions are personal and sometimes people can find it upsetting to discuss these issues. This is a new treatment and is only available through taking part in the study.

Where is the study run from?
Cambridge and Peterborough NHS Foundation Trust and University of Cambridge (UK)

When is the study starting and how long is it expected to run for?
September 2021 to September 2027

Who is funding the study?
National Institute for Health Research, Programme Grant for Applied Research (NIHR PGfAR) (UK)

Who is the main contact?
Gemma Giove-Hunt, gg434@cam.ac.uk

Study website
https://attendstudy.org

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
341587

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 62119, NIHR204413, IRAS 341587

Study information

Scientific Title
Is Mindfulness for Adolescents and Carers plus treatment as usual more effective and cost-effective compared to treatment as usual alone; how does it work and for whom does it work best? A randomised controlled trial with embedded economic evaluation and study of mechanisms

Acronym
ATTEND

Study objectives
The research aims to answer the following questions:

PGfAR WP3 RCT:
1. Is Mindfulness for Adolescents and Carers (MAC) plus treatment as usual (TAU) more effective at producing a sustained reduction of symptoms of depression in adolescents compared to TAU?
2. Is MAC plus TAU cost-effective compared to TAU?
3. Does MAC plus TAU impact the following secondary outcomes:
3.1. For young people:
3.1.1. Anxiety
3.1.2. Quality of life
3.1.3. Ability to cope
3.1.4. Perceived quality of family relationship
3.2. For parents/carers:
3.2.1. Depression

3.2.2. Anxiety
3.2.3. Quality of life
3.2.4. Ability to cope
3.2.5. Perceived quality of family relationship

PGfAR WP4 mechanisms:
4. What characteristics moderate the effect of MAC?
5. Does MAC work through its intended psychological mechanisms (such as increases in the ability to decentre and mindfulness skills)? And if yes, what are the exact pathways?
6. Do changes in process variables (such as decentring and mindfulness) transfer to influence outcomes across the young person-carer dyad? If yes, what are the exact pathways?
7. Are outcomes of the MAC intervention related to the amount of mindfulness practice that participants engage in?
8. How is the learning from the trial intervention reflected in participants' actual responses to negative mood (as assessed using second-person methods to analyse subjective reports)?
9. What are the experiences of young people and their carers with the intervention?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/05/2024, East of England – Cambridge South Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 (0)207 104 8084, +44 (0)207 104 8258, +44 (0) 207 104 8208; cambridgesouth.rec@hra.nhs.uk), ref: 24/EE/0091

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Mental health

Interventions
The programme grant has work packages as follows:
1. Finalise the therapist-training programme.
2. Co-produce two Apps to encourage and measure mindfulness practice.
3.1. Recruit 480 teenagers, and their parents/carers will be invited too. Half will access MAC and

half will access the standard NHS treatment currently available. This will allow us to compare the differences between the two groups on depression and other outcomes.
3.2. Compare the two group's treatment costs, with their symptoms 9 months after treatment, to assess whether MAC is value for money.
4. Find out how MAC works and who benefits the most by exploring changes in how teenagers and parents feel, think, and relate to each other.
5. Understand how best we can make MAC available across the NHS.

Work packages 3 and 4 form part of an individually randomised two-arm controlled trial. The researchers will be recruiting 15–18-year-olds who, even after having a previous evidence-based treatment for depression or anxiety, continue to experience significant symptoms or have relapsed. The focus is to test the effectiveness of MAC as an intervention. This does not include the therapist training (WP1), the App for home practice (WP2), or the different care pathways or implementation (WP5 IRAS number 333973), which have their own protocols and ethics where applicable.

The economic analysis will evaluate the cost and cost-effectiveness of MAC plus TAU compared to TAU alone from NHS/personal social services, education, and societal perspectives.

WP4 Mechanisms: In line with guidelines on the evaluation of complex interventions (Skivington et al., 2021), the researchers will investigate treatment moderators and mediators. This WP aims to provide a more nuanced understanding of:
1. Who is likely to benefit
2. How change is achieved
3. How mechanisms of change are best facilitated

Participant journey:
Recruitment + eligibility:
1. The Clinical Team and the Clinical Research Network will identify potential young participants by active screening of caseloads. Research Assistants in each site will provide support by answering any eligibility queries but will not have access to identifiable information. Participants will also be recruited via practitioner referrals.
Any participants who contact the study email address directly via word-of-mouth or from seeing promotional materials will be asked to provide their name, date of birth, and the city/town they live in. The relevant site's Research Assistant with the local Clinical Team and Clinical Research Network will then screen their case notes for eligibility. One method of recruitment will be via NHS Trust research databases, each approved and operated by the relevant NHS Trust. The database will be queried to find patients who are likely to meet the study's eligibility criteria. For patients that have specifically consented to the following (either in advance or having been approached by their primary clinical team), the Trust will provide the patient's details to the research team and authorize the research team to view the patient's records and to contact the patient to discuss participation in the study. Researchers will not be given identifiable information without the patient's specific consent. Study participation itself would require the patient's further consent.
2. Potential eligible young participants that have been identified will be provided with a short, written summary (Appendix b) in the format of a printable or email leaflet from the referring clinician, local CRN support, or clinical care team which have recruited them.
3. If a young person expresses an interest in the study, the young person (aged 16 to 18 years) or parent/carer (for a young person aged 15 years) will be asked to return a Permission to Contact Form (Appendix e) either directly to the study team or provide permission for the person who referred them to return it.
4. When a permission to contact form is received by the study team, a Research Assistant will

contact the young person and parent/carer to explain more about the study and answer any questions.
5. If the young person is still interested, they will be sent the full Participant Information Sheet (PIS) and the Privacy Notice, and a time will be arranged to complete an intake assessment.
6. During the intake assessment the study will be fully explained to the young person and their parent/carer before written informed consent is obtained by the Research Assistant via REDCap. The Research Assistant will also ask the young person to complete an eligibility questionnaire. Parents/carers of eligible young participants that have consented to join will be invited to take part in the parent/carer group of the trial.

Trial:
The next stage is participants complete the baseline questionnaires online and they will be randomised. They then start the fortnightly completion of a short questionnaire online for 12 months. Those assigned to MAC will complete the 8-week intervention. Those assigned to TAU will continue their standard care as normal.
They will all complete a set of online questionnaires at 14 weeks post-randomisation and 12 months randomisation. The researchers will thank them for their involvement and pay both the young people and parent/carers a small incentive at set stages.

Intervention Type
Behavioural

Primary outcome measure
Young people's levels of depression measured using the Short Moods and Feelings Questionnaire (SMFQ) over the 12-month follow-up period using an Area Under the difference Curve (AUC) analysis of the fortnightly

Secondary outcome measures
For young people:
Measured at baseline, 3.5 months post-randomisation and 12 months post-randomisation:
1. Anxiety measured using the Revised Children's Anxiety and Depression Scale-25 (RCADS-25)
2. Quality of life measured using the EQ-5D-5L
3. Ability to cope with life measured using a single bespoke question
4. Parent – young people relationship quality measured using the Parent-Adolescent Relationship Scale (PARS)

For parents or carers:
Measured at baseline, 3.5 months post-randomisation and 12 months post-randomisation:
1. Depression measured using the Patient Health Questionnaire eight-item depression scale (PHQ-8) over the 12-month follow-up period using an Area Under the difference Curve (AUC) analysis of the fortnightly
2. Anxiety measured measured using Generalized Anxiety Disorder 7 (GAD-7)
3. Quality of Life measured using the EQ-5D-5L
4. Ability to cope with life using a single bespoke question
5. Parent – young people relationship quality measured using the PARS

Overall study start date
30/09/2021

Completion date
30/09/2027

Eligibility

Key inclusion criteria
Young people:
1. Aged 15 to 18 years old at the time of recruitment
2. Completed at least one evidence-based treatment for anxiety or depression
3. Primary problem of unresolved or relapsed depression or anxiety: not recovered sufficiently to be discharged, or who have subsequently relapsed and been re-referred for treatment of depression or anxiety
4. Readiness to engage in a group-based mindfulness-based intervention, which would include the ability to focus and participate in a group for up to 1 hour 45 minutes; capacity to think flexibly and reflect on one's own experiences; and the willingness to practice everyday mindfulness and learn formal meditation for up to 15 minutes per day.

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

Participant type(s)
Patient, Carer

Age group
Child

Lower age limit
15 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 480; UK Sample Size: 480

Key exclusion criteria
Young people:
1. Current active management required for suicidal risk, self-harm or eating disorder
2. Current psychosis or PTSD

Carers:
1. A carer of a young person who has not consented to take part in the study

Date of first enrolment
21/08/2024

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
CAMHS Croydon London Road
78 London Road
Croydon
United Kingdom
CR0 2TB

Study participating centre
Lambeth CAMHS (clamhs)
393 Brixton Road
London
United Kingdom
SW9 7AW

Study participating centre
CAMHS Lewisham Park
78 Lewisham Park
London
United Kingdom
SE13 6QJ

Study participating centre
CAMHS Southwark Adolescent Team
Bloomfield Clinic
St. Thomas Street
London
United Kingdom
SE1 9RT

Study participating centre
South London and Maudsley NHS Foundation Trust
Bethlem Royal Hospital
Monks Orchard Road

Beckenham
United Kingdom
BR3 3BX

Study participating centre
Children and Family Health Devon
Single Point of Access Team
1a Capital Court
Bittern Road
Sowton Industrial Estate
Barnstaple
United Kingdom
EX2 7FW

Study participating centre
Livewell Southwest
Local Care Centre
200 Mount Gould Road
Plymouth
United Kingdom
PL4 7PY

Study participating centre
Devon Partnership NHS Trust
Wonford House Hospital
Dryden Road
Exeter
United Kingdom
EX2 5AF

Study participating centre
Cambridge Child and Adolescent Mental Health Services
18a Trumpington Road
Cambridge
United Kingdom
CB2 8AH

Study participating centre
Peterborough Child and Adolescent Mental Health Services
City Care Centre
Thorpe Road

Peterborough
United Kingdom
PE3 6DB

Study participating centre
Huntingdon Child and Adolescent Mental Health Services
Newtown Centre
Nursery Road
Huntingdon
United Kingdom
PE29 3RJ

Study participating centre
Sussex Partnership NHS Foundation Trust
Trust Hq
Swandean
Arundel Road
Worthing
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BN13 3EP

Sponsor information

Organisation
Cambridgeshire and Peterborough NHS Foundation Trust

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CB21 5EF
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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
NIHR Central Commissioning Facility (CCF)

Results and Publications

Publication and dissemination plan
The researchers will mobilise knowledge from all WPs via social media, podcasts, blogs, and brief written summaries modified to suit the needs and interests of different stakeholders, including young people, parents, the public, practitioners in mental health and other services working with young people. The researchers plan to discuss how best to present their findings with the Science Media Centre, and to provide policy briefings for service providers, commissioners, and policymakers. Lived experience leads will support the young people and parent advisers who express an interest to actively contribute or lead the development of dissemination materials. Likewise, dissemination will be co-delivered with the young people and carer advisers and will leverage professional networks, such as the Association of Child and Adolescent Health, a multidisciplinary organisation devoted to evidence-based mental health care with a national network of branches and a widely disseminated newsletter.

The researchers anticipate publishing the protocol in 2024 with the final outcome papers being submitted for publication in 2027 or early 2028.

Intention to publish date
30/09/2028

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.4	17/07/2024	14/08/2024	No	Yes
Protocol file	version 1.3	20/06/2024	14/08/2024	No	No