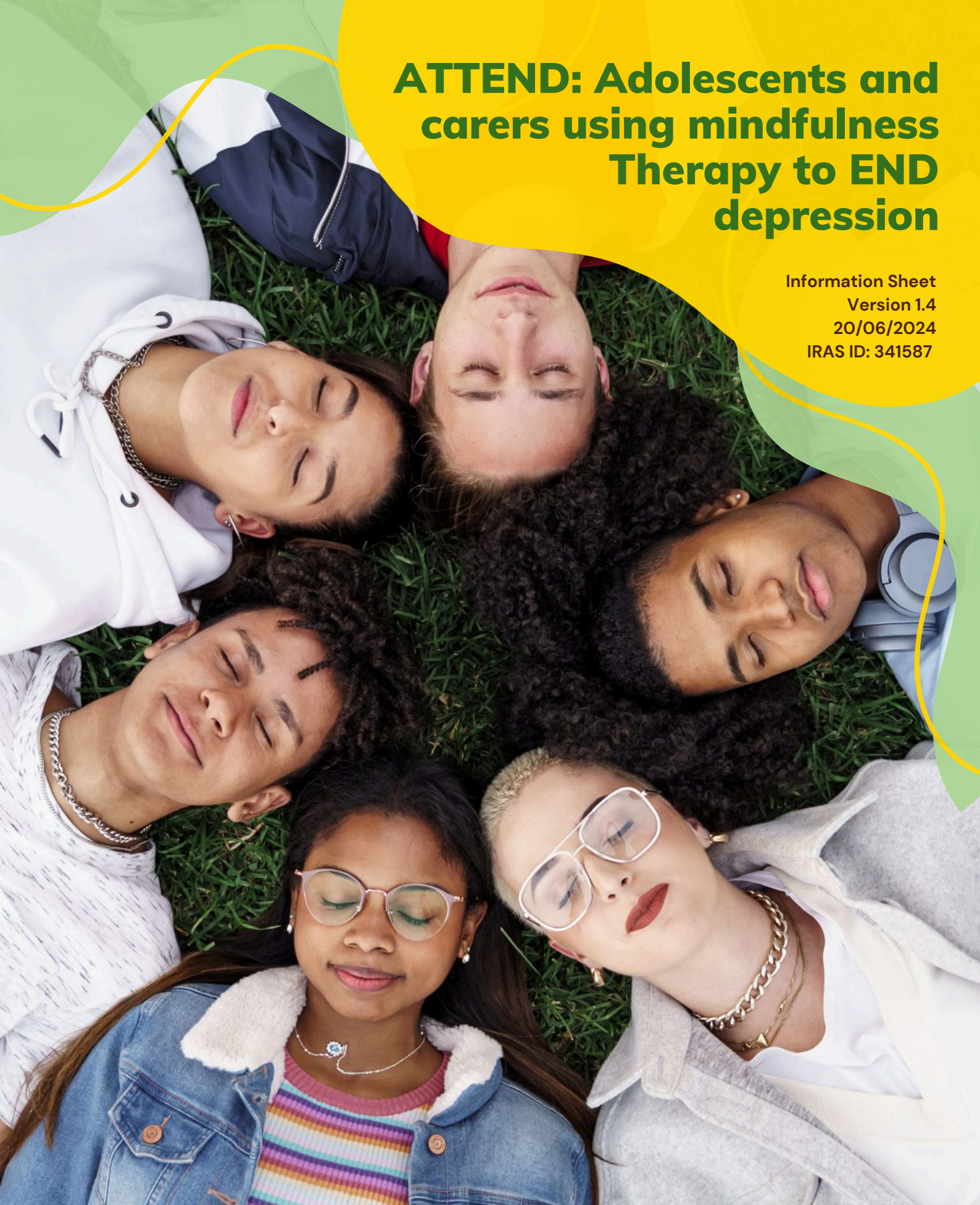


# ATTEND: Adolescents and carers using mindfulness Therapy to END depression

Information Sheet  
Version 1.4  
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UNIVERSITY OF  
CAMBRIDGE  
Department of Psychiatry



Cambridgeshire and  
Peterborough  
NHS Foundation Trust

We are inviting young people who have previously had treatment for emotional difficulties, along with their parents/carers, to take part in the ATTEND study. **This Information Sheet will help you decide if you would like to be involved.**

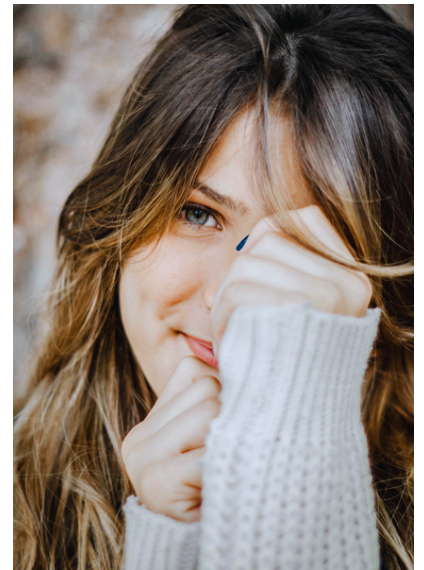
There is also a short section at the back for your **parent/carer** to read.



## Why are we doing this study?

Having depression or anxiety as a teenager is very hard and can have a big impact on friendships and family relationships as well as on education and employment. After their first treatment, many young people still have some symptoms, or could have another period of depression or anxiety in the future - it can seem like it's following you around.

We want to know if a new treatment, 'Mindfulness for Adolescents and parents or Carers' (MAC) can help young people and their families to learn to recognise unhelpful thoughts and feelings. We want to find new ways of dealing with stress, so that symptoms of low mood or depression improve and are less likely to come back in the future.



MAC is not usually offered in Children and Adolescent Mental Health Services (CAMHS). To see if the MAC treatment works well, and to understand how it works, we need to recruit about 480 young people across the country to the study. Our research has five parts that will:

**01** Finalise our therapist-training programme.

**02** Co-produce two Apps with young people and parents/carers to encourage and measure mindfulness practice.

**04** Find out how MAC works and who benefits the most by exploring **changes in how teenagers and parents/carers feel, think, and relate to each other.**

**03** a) Recruit 480 teenagers and their parents/carers. **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, anxiety and other outcomes.

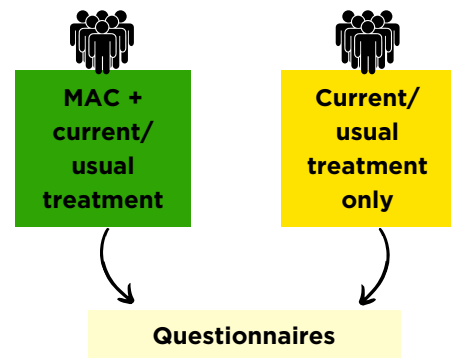
b) Compare the two groups' treatment costs, with their symptoms 10 months after treatment, to assess whether MAC is value for money.

**05** Understand how best we can make MAC available across the NHS.

## What does being part of the research involve?

This study is run across six different parts of England: **London, Devon, Sussex, East of England, Oxford, and Nottingham**. If you agree to take part in this study you will either:

1. **Be assigned to take part in the MAC treatment**, and still receive your current/usual treatment, or
2. You will continue with your current treatment and **not be assigned to take part in the MAC treatment**.



**Who gets MAC will be decided by a computer programme and will be random**, a bit like flipping a coin. **No one is able to alter this**, so the researchers, therapists, young people or parents/carers are **not able to choose which treatment anyone has**.

**Young people and their parents/carers from both groups** (assigned to the MAC treatment or not assigned to the MAC treatment) **will be interviewed and asked to fill in questionnaires for 12 months**. This will help us to compare MAC with other mental health treatments that are currently available.

## What is Mindfulness for Adolescents and parents or Carers (MAC)?

- MAC is Mindfulness-Based Cognitive Therapy adapted for teenagers.
- MAC is delivered to a group of **up to 12 young people**.
- There are **8 weekly sessions**, each **1 hour 30–45 minutes**.
- Between MAC sessions, you will be asked to record your **Mindfulness at Home practice on the MAC App**. The App will have spaces where you can select what practices you have done and how you found them. This will be shared with your therapist. The App will also automatically record usage information such as how often you open the App, which audio recordings you listen to the most and how long you listen to them for. This automatically collected information will not be shared with your therapist, but it will be used in the study's final analysis.
- MAC sessions are usually held in the **late afternoon or early evening on a weekday**.
- Sessions will be held **in-person** at a central location, or **online**, using NHS approved video conferencing software—so you can attend securely from home using a laptop/computer or smart phone.
- To check the quality of the MAC teaching, some sessions may be recorded. The camera will be pointed at the therapist and we will not film you. However, your voice may be recorded. These recordings are not shared outside the research team.



Everyone in the group will be in a similar position to you, and may be worried about being part of a group or speaking in front of other people. The therapist will be there to support and guide you all, and **you will never be made to do or say anything you do not want to**.

**We invite parents/carers to attend sessions as well, as we know this can really help them to support you.**

Parents/carers of the young people assigned to the MAC treatment are invited to join separate parallel parent/carer MAC sessions, where they will work through similar MAC materials. This is **optional**. The young people and parent/carer sessions run **separately**, each in their own room. **However, you can still take part in this study even if your parent/carer doesn't want to take part themselves.**

## **Further information about mindfulness and MAC**

Mindfulness is about **noticing what is happening in the present moment**. 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. Mindfulness works by:

- helping to **learn skills** that can prevent low mood or depression coming back
- helping to become more aware of how your **body is feeling** and the impact this can have on your **emotions**
- trying to help pay attention to the **present moment** and think about the kind of things your **internal voice** is saying to you



The present is not always as bad as we think, but even when it is, then mindfulness practices and ideas can help us to 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.

Each session has a **theme** such as *'Thoughts are not facts'* or *'Looking after yourself'*. We think about the theme through questions, discussions, fun games and activities such as colouring or listening to music. We also learn together some **mindfulness practices** which might involve walking, stretching, or eating. There are also some that involve closing our eyes whilst sitting or lying down and focusing on our breath and different parts of our body.

This might be quite a new experience for many people and the great thing is **'there is no right way' and so you can't get it wrong!** You also only share what you feel comfortable in doing, and there is no pressure to speak. This approach is not religious but practical and skill based. It is grounded in science and has been used for many years in universities and in the NHS for adults. Science has shown that we can train our mind to learn new and better ways to respond when we are sad or anxious.

However, it is important to understand that this takes **time**. We will meet for 8 weeks and we will encourage you to **practice** the activities learnt in the workshop at home each week as this is the best way to see change.

## Who can take part?



Anyone who meets all the following criteria can take part:

Aged between 15 and 18

Already received some professional treatment for low mood, depression, or anxiety either in CAMHS or as part of a Mental Health Support Team

Still experiencing symptoms of low mood, depression or anxiety with low mood

Feel comfortable and able to take part in a group therapy programme

## Reasons the study may not be right for me?



MAC is designed to help you work with feelings of low mood. It is not suitable for all conditions, therefore anyone who is experiencing the following should not take part:

**Main difficulty** being an eating disorder or anxiety disorder **without experiencing current low mood**

Currently managing post-traumatic stress disorder (PTSD)

Hearing voices, seeing or feeling things that aren't there (psychosis)

Significant risky behaviour that you are regularly seeing a therapist about, such as hurting yourself on purpose, frequent suicidal thoughts or taking drugs

If you struggle to focus in group settings

## Do I have to take part?



***No. It is entirely up to you to decide.***

If you do not want to take part your decision will not affect the quality of the care you receive in any way. If you do decide to take part you are also free to change your mind at any time, without giving a reason.

## What will I need to do if I take part?

Everyone, regardless of whether you are assigned to the MAC treatment group or not:

Will be asked to fill in **a set of questionnaires three times** (takes around 90 minutes to complete):

- When you first join the study
- 4 months later
- 12 months later



**Every two weeks, we ask you to complete 1 questionnaire** made up of 13 questions (takes about 5 minutes to complete).

These questions will be completed on a **secure online app** which you can access via a computer, tablet, or smart phone.



We will give you **£15 for each set of questionnaires** you complete (**totalling £60** if all are completed). These can be via bank transfer (therefore the University of Cambridge will need your bank details), or via a shopping voucher.

The questions will help us to measure if there have been any changes in the way you are feeling. They are about you and some of the questions are personal, sometimes people can find it upsetting to think about these issues. **If anything upsets you, you can talk to a member of the research team or your clinical case manager. Please see the contact list at the back of this leaflet.**

## You may be invited to complete some interviews



We would like to complete some interviews with young people and parents/carers about their **experience of the MAC treatment**. We will only be asking about 30 young people with their parents/carers to take part in these. In order to make sure that we can get a wide and balanced range of views, we will reach out to young people who have completed the course as well as young people who have not completed the course. We will also make sure to include young people who (according to our questionnaire measures) have benefited from the course as well as those for whom there has been little or no change.

These interviews will take about 60 minutes, are **separate from the rest of the study**, and we would pay you £10. We would want to video record these interviews. **You can choose not to take part in these interviews. If you do want to take part in these interviews**, please let a member of the research team know and we will give you more information about what this involves.

## What are the risks and benefits in taking part?



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**. In normal clinical practice this is the same commitment that patients would make before being offered any psychological therapy.

You will complete some questionnaires and discuss with the researchers how you are feeling. Some of the questions are personal and sometimes people can find it upsetting to discuss these issues. **You do not have to discuss anything you don't want to.** Please see the contact details at the back of this leaflet if you need to talk to a member of the research team.

**We won't know if there are any benefits by taking part in MAC until the results of the study. Your participation is crucial in helping us evaluate its effectiveness.**

## What will happen to information collected about me during the study?

All information collected will be confidential and stored in accordance with University regulations and requirements (General Data Protection Regulation (GDPR) 2016 and the UK Data Protection Act 2018). **All information is held in an electronic file on secure servers which can only be accessed by members of the ATTEND research team.**

The information you provide, for example your responses to the questionnaires or interviews, is considered "**research data**". Everyone will be assigned a **unique code number** which we will use when we save the answers. This means that your answers are stored **anonymously**. Only those that need information that identifies you will have access to the codes. More information about this is further down.

Once we have finished the study, we will keep some of the research data so we can check the results. The information gathered from all young people will be grouped together to summarise the different treatment groups. A report will be written describing the study and what we found out. Direct anonymised quotes may be used when sharing study results. **Your name will not be written anywhere in any of our reports and we will write our reports in a way that no-one can work out that you took part in the study.**

We will write to all participants at the end of the study with a summary of our findings. Other researchers may have access to the answers you give us, but we will always remove any information that might indicate who you are, for example your name or the mental health service you attend.

If you take part in the **optional interview** asking about your thoughts of MAC and taking part in the study, we will make a **video recording** of this interview. This will be securely shared with an external transcription service who will type up word for word what was said during the interview. This company has a **confidentiality agreement with us**, meaning they cannot share anything they hear with anyone else. Anything that identifies you will be removed, for example if your name is mentioned or the area of the country you live in. This transcription of the interview will be stored securely with the other information you have given us and the video recording will be destroyed as soon as it has been transcribed, which will be by the end of the study.

## What about information that identifies me?

We need to keep information that identifies who you are during the course of the study. This is so we can contact you to arrange you completing the questionnaires and also to give you any important information.

**We will keep a record of your name, address, phone number, email, GP name and who your CAMHS or mental health service case worker is.**

We will keep all information about you on a secure server, only accessible by certain members of the ATTEND research team. Your identifiable information will be kept separate to the anonymous research data. People who do not need to know who you are will not be able to see your name or contact details.

## Will you use my information beyond the study?

We would also like to keep **your name, address, and date of birth beyond the study**. This is to combine information from the trial with information that is normally held in government records, such as information about schools, apprenticeships, universities, Hospital Episode Statistics, and the Mental Health Dataset. We plan to do this at the end of the trial, and again 5 and 10 years later.

By connecting these different sets of data, we want to see **how participating in the study might affect your education and future interactions with health services**. This could help us understand how various things impact someone's education and health later on.

The government departments which hold this information have usual strict and detailed processes, including requesting ethical permission, which we will need to follow to access these government records. We will not be contacting your past, current, or future educational institutions or employers.

Your information will be **combined securely and privately** to keep your personal details safe. **Any identifying information will be deleted** after this linkage. **You can still take part in the study if you choose not to have your data linked in this way.**

## Will my taking part in this study be kept confidential, will my parent or carers be told what I've said?

Usually all information collected about you during the course of the research will be kept confidential in line with the normal NHS and clinical research policies, we would not tell your parent or carer or anyone else what you tell us.

**The only exceptions are if you tell us that:**

- (a) someone is hurting you,
- (b) you know of someone else who is in danger of being hurt, or
- (c) you are doing something that hurts yourself or others.

In these cases we have a duty to inform your CAMHS, mental health team and GP, but we will always try and speak to you first to discuss sharing this information.



## What are my choices about how my information is used?

You can stop being part of the study at any time, without giving a reason.

If you do stop taking part:

- We would like to keep the information about you that we already have.
- We would like to continue collecting information about your health from your clinical care case worker. If you do not want this to happen, you can tell us and we will stop.

We need to manage your records in specific ways for the research to be reliable. In line with GDPR, you may:

- Request to access and change the information you have given us.
- However, once this information has been analysed we will be unable to make any changes.
- This means that we won't be able to let you see or change the information we hold about you after it has been analysed.

If you agree to take part in this study, **you will have the option to take part in future research using your data saved from this study.** These data will be stored in the University of Cambridge Clinical School secure data storage facility, and indexed by the CAM:IDE database at the University of Cambridge Department of Psychiatry.

## Where can I find out more about how my information is used?

You can find out more about how we use your information:

- at [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)
- in our leaflet available from [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch)
- by asking one of the research team
- by sending an email to [attend@medschl.ac.uk](mailto:attend@medschl.ac.uk), or by ringing us on XXXX
- by contacting the relevant Data Protection Officer at [informationgovernance@cpft.nhs.uk](mailto:informationgovernance@cpft.nhs.uk)



## Who is organising and funding the research?

This study is being carried out by the University of Cambridge, Cambridge and Peterborough Foundation Trust, University of Exeter Medical School, Kings College London, South London and Maudsley NHS Trust, University of Surrey, Nottingham Healthcare NHSFT, Bradford NHSFT, Sussex Healthcare NHSFT, University of Oxford.

It is funded by the National Institute for Health and Care Research, Programme Grant for Applied Research (NIHR204413) and sponsored by the University of Cambridge and Cambridge and Peterborough NHS Foundation Trust. The research has been approved by East of England - Cambridge South Research Ethics Committee (ref: 24/EE/0091).

If you want to make a complaint about the way this study is being carried out you can contact the Chief Investigator Prof Tamsin Ford [tjf52@medschl.cam.ac.uk](mailto:tjf52@medschl.cam.ac.uk). The normal National Health Service complaints mechanism is also available to you (Patient Advice & Liaison Service <https://www.nhs.uk/service-search/other-health-services/patient-advice-and-liaison-services-pals>).

## What happens next?

Thank you for reading. If you are interested in finding out more ***please give this information sheet to your parent/carer and ask them to fill out the 'Permission to Contact' form or the sign-up form on our website at [attendstudy.org](https://attendstudy.org)***



To help you decide if the ATTEND study is something your family would like to get involved in please read all of this information sheet. **All of the information above also applies to you as the parent/carer.** However, we know there are likely to be some specific questions about your personal involvement.

### Why are you asking parents/carers to have therapy too?

Whilst mindfulness can feel a bit ‘trendy’ it actually involves learning a very different way of going about our lives. These new skills can take time to learn, and we think that **if you understand more about what we are teaching your children it will help you to support their learning.**

Having a child that has an emotional disorder can be very distressing and isolating. We hope that meeting with other parents/carers who are experiencing the same things may support you.



Depression and anxiety can often run in families. Therefore, you might have experienced similar feelings to your child. We hope that MAC may be able to help you too. Some questions are about how well you think the family is getting along with one another.

### What does being part of the research involve?

This trial is run across six different parts of England: London, Devon, Sussex, East of England, Oxford, and Nottingham.

**Who gets MAC will be decided by a computer program and will be random,** a bit like flipping a coin. No one is able to alter this, so the researchers, therapists, young people or parents/carers are not able to choose which treatment anyone has.

**Young people and their parents/carers from both groups** (assigned to the MAC treatment or not assigned to the MAC treatment) **will be interviewed and asked to fill in questionnaires for 12 months.** This will help us to compare MAC with other mental health treatments that are currently available. We ask your child these questions too, but we also want to know your experiences about this.

Some of the questions are about how you have been feeling. The work we have done in the past suggests that MAC could be helpful for parents’ and carers’ own mental health as well as supporting their child’s. We want to explore this further, and that is why we ask about your own emotional wellbeing.

### What will I need to do if I take part?

**Everyone, regardless of whether you are assigned to the MAC treatment group or not:**

Will be asked to fill in **a set of questionnaires three times** (takes around 90 minutes to complete):

- When you first join the study
- 4 months later
- 12 months later



**Every two weeks, we ask you to complete 1 questionnaire** made up of 8 questions (takes about 5 minutes to complete).

These questions will be completed on a **secure online app** which you can access via a computer, tablet, or smart phone.



We will give you **£15 for each set of questionnaires** you complete (**totalling £60** if all are completed). These can be via bank transfer (therefore the University of Cambridge will need your bank details), or via a shopping voucher.

The questions will help us to measure if there have been any changes in the way you are feeling. They are about you and some of the questions are personal, sometimes people can find it upsetting to think about these issues. **If anything upsets you, you can talk to a member of the research team or your GP. Please see the contact list at the back of this leaflet.**

### Will you share what I say with my child or anyone else?

All information collected will be confidential and stored in accordance with University regulations and requirements (General Data Protection Regulation (GDPR) 2016 and the UK Data Protection Act 2018).

Usually all information collected about you and your child during the research will be kept confidential in line with the normal NHS and clinical research policies. The only exceptions are if you tell us that:

- a) someone is hurting you,
- b) you know of someone else who is in danger of being hurt, or
- c) you are doing something that hurts yourself or others.

In these cases we have a duty to inform your GP, but we will always try to speak to you first to discuss sharing this information.

### What about information that identifies me?

We need to keep information that identifies who you are during the course of the study. This is so we can contact you to arrange you completing the questionnaires and also to give you any important information. We will keep a record of **your name, address, phone number, email and who your GP is. This will be deleted after the study is complete.**

### What if I don't want to attend MAC sessions?

If your child is randomly assigned to the MAC treatment, we hope that you attend the parent/carer MAC sessions, but **you don't need to attend for your child to take part in the study.** You can also start coming to the parent/carer MAC and then leave if you decide it's not for you.

### What if I want to do the study but my child doesn't?

**ATTEND's main aim is to support your child**, therefore if your child does not want to take part you cannot take part alone. If you would like to try mindfulness, we can give you details of other places you can access mindfulness for adults. However, if you and your child take part, but your child decides to withdraw from the study, you may continue to take part.

### What Consent Forms do I need to sign?

**Permission to Contact Form:** Every parent/carer or young person over the age of 16 will have to sign this initial form. This form gives permission for CAMHS or your mental health service to pass your name onto the research team.

**Informed Consent Forms:** After you've spoken to the research team you would like to take part, we will ask you to fill out a formal written consent form before taking part:

- **Parents/Carers** for your own involvement.
- **15 year olds** will need a parent/carer to sign a consent form for their child to be able to take part in the study. We also ask the young person to sign an additional assent form because it's important that it's their choice to be involved. They will be asked to sign their own consent form when they reach 16 years of age during the study.
- **16 to 18 year olds** will need to sign their own consent form to be able to take part in the study—you do not need to also complete a consent form for your child.

**We will talk you through this form in detail as it's really important to us that you fully understand what we are asking you to do.**

### What happens next?

If you or your child would like to take part **please complete the 'Permission to Contact' form** and return it to a member of the CAMHS or mental health team, or contact your local research team directly using the details below.

Someone from the research team will then arrange a time to **talk with both you and your child**, this is most likely to be via a video call but if you would prefer a face-to-face meeting we can arrange this. During this meeting **we will explain exactly what will happen if your child and you choose to be involved in this study.**



We will also ask you some questions about symptoms your child may have that would mean being part of this study would not be appropriate for them. We will give you and your child a chance to **ask any questions about the study**. If at the end of the meeting your child would like to take part we will ask both of you to sign formal consent forms confirming this. We will email or post these forms to you and ask that you sign them and send them back to us. We would then email you a link to the online questionnaires that we ask you to complete.

### Insurance details

Cambridgeshire and Peterborough NHS Foundation Trust, as a member of the NHS Clinical Negligence Scheme for Trusts, will accept full financial liability for harm caused to participants in the study caused through the negligence of its employees and honorary contract holders. There are no specific arrangements for compensation should a participant be harmed through participation in the study, but no-one has acted negligently.

The University of Cambridge will arrange insurance for negligent harm caused as a result of protocol design and for non-negligent harm arising through participation in the study.

*If you have any questions about the research, or you would like more information, you can contact the research team or scan the QR code to visit our website:*



[attendstudy.org](http://attendstudy.org)

**ATTEND Research Team email:**

[attend@medschl.cam.ac.uk](mailto:attend@medschl.cam.ac.uk)

Tel: XXXX



(QR Code subject to change)

**Search for “ATTEND Mindfulness Study”**



You could also speak to someone from the Patient Advice and Liaison Service (PALS) to talk about your options. Your local PALS contact details can be found at: <https://www.nhs.uk/service-search/other-health-services/patient-advice-and-liaison-services-pals>

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**CAMBRIDGE**  
Department of Psychiatry



## Research Team Contact Details

If you need to speak to a member of the research team, please see the contact details below:

| Site            | Name           | Email                   |
|-----------------|----------------|-------------------------|
| East of England | Katie Buttriss | kb860@cam.ac.uk         |
| Devon           | Helene Bonnici | h.bonnici@exeter.ac.uk  |
| London          | Ching-Yin Lee  | ching-yin.lee@kcl.ac.uk |
| Sussex          | Harry Ellis    | Harrison.Ellis@nhs.net  |
| Nottingham      | TBC            | TBC                     |
| Oxford          | TBC            | TBC                     |