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Behavioural Activation for Young people with depression in specialist child and adolescent mental health services (BAY)

Participant Information Sheet: Carer Version

We would like to invite your child to take part in the above trial. Before you decide if you are happy to support them with this, please read the following information.

Can our Behavioural Activation (BA) help young people with low mood?

We are asking if your child would like to join in a research study examining different therapies to help young people with low mood.

Before you decide if you want your child to join in, it is important to understand why the research is being done and what happens if they take part. Please read this leaflet carefully.

Why is this study important?

Depression is a common problem in young people, and around one in 5 teenagers will have depression at least once by the age of 18. Symptoms can include sadness, irritability, loss of interest and pleasure in activities, tiredness, loss of confidence, trouble with concentration and sleep, and changes in appetite. Low mood can affect young people's lives including their relationships with others, education, and physical health. Emotional disorders in young people have been increasing, with more need for support since the covid-19 pandemic. However even before the pandemic, only a quarter of children and young people with mental health disorders could get help; even when young people are seen by specialist Child and Adolescent Mental Health Services (CAMHS), they often have to wait a long time for specialist therapy.

Behavioural activation (BA) is a type of therapy that works for depressed adults, but we don't know how it works in young people. This study uses a new version of BA which is an online 8 session workbook, that can be used by therapists in CAMHS.

We want to find out if BA works for young people with low mood. There are a lot of keen therapists in CAMHS who would like to give better help to young people but need more training. We would like to give these therapists training in our BA. We also want to find out if our BA is good value for money, how easy it is to use for young people, carers and clinicians, and if it can reduce long waits for other therapy.

What do we want to find out?

We want to look at the difference between 2 types of support for young people with depression, who have just been referred to CAMHS. If you agree to take part in the study your child will get one of these treatments:

1. BA plus psychoeducation (PE, which is information about depression), and CAMHS usual care.

OR:

2.PE and CAMHS usual care.

We will offer ‘blended’ BA, that is, after the first BA session in the clinic, young people will choose whether they would prefer to have other sessions online, by phone, or in the clinic. However, there may be times when the therapist may ask that the young person attend the clinic, for example, if their mood has become worse.

Why have I been approached?

We are asking young people aged 11 to 17 years with low mood, who have recently been referred to CAMHS, to take part in the research. You have been approached as the carer of a young person who may be suitable for the study. We hope to find around 528 young people across England to take part.

What is BA?

Our treatment is based on Behavioural Activation (BA) which aims to improve people’s mood by encouraging them to take part in activities they may have stopped doing that they previously enjoyed, or which gave them a sense of achievement, or closeness to other people. Our BA therapy lasts for up to 8 sessions; each session is around 40 minutes long and delivered weekly, either in the clinic or online. The sessions help young people to identify activities that are meaningful and enjoyable and they are encouraged to take part in these activities, with the support of carers; young people aged 16 and over may prefer to choose another adult for support. Young people will be shown how to set goals, use problem solving, and learn ways of dealing with stress. Their therapist will also help them if they are avoiding activities and how to overcome this. They will be taught what to do if they start to get better but find that they are starting to feel low again. All our sessions have been developed with professionals, carers and young people.

What is psychoeducation?

Psychoeducation (PE) for this study will be an online leaflet to help young people understand what depression is, what they and others can do to help, and give information about other services. This will be given to every young person in the study.

Does my child have to take part?

Your child does not have to take part. If they do choose to take part they are free to leave the study at any time, without giving a reason. If you and your child decide not to take part, the researcher may ask you to give a reason why. This will help with how we do our research processes in the future, but you do not have to give a reason if you don’t want to.

What will happen if my child takes part?

You will be asked some questions to see if your child is suitable for the study , and they will also be asked to complete a short questionnaire. If they are suitable for the study and, if you and your child choose to take part, you will be asked to sign a consent form (if your child is aged 11-15). Your child's GP will be informed that they are taking part in the study.

You will then book in your first appointment with the researcher who will check again to make sure your child is still suitable for the study; if they are, they will then complete some other questionnaires. If we don't feel your child is suitable at this stage or they do not wish to continue, they will then receive treatment as usual from CAMHS. The questionnaires will be done in-person at your local CAMHS or somewhere similar or at home. If needed, it can be over the telephone or using a videocall. You will complete a set of questionnaires, and your child will complete a separate set of questionnaires. This first assessment will take place in 2 parts. First, they will complete questionnaires about their mental and physical health, mood, anxiety, moods, use of health services, and your strengths and difficulties. This will take about 60-90 minutes with breaks as needed. As part of this, their date of birth will be collected to check that they are part of CAMHS for therapy delivery and follow-up assessments, and also to check when they might transition to adult services.

The second part will include more questions around different symptoms and wellbeing which can take up to 90 minutes. You and your child will be given the option to complete the first assessment in one appointment , or book a second appointment to complete this.

To see if our BA is helpful, we would like to compare this to other forms of support that are usually offered to young people with low mood. Therefore, if your child chooses to take part in the study they will EITHER receive BA + PE , as well as CAMHS usual care if they need it (e.g. crisis support, other talking therapies, etc), OR only PE and CAMHS usual care. This is decided through a process called 'randomisation', which is done by a computer and it is like flipping a coin. You and your child will then be informed which treatment they will receive. If your child receives BA, with their permission the sessions will be audio recorded. This is so we can check to ensure the therapy is being delivered the way that it was meant to be.

What happens next?

After your child's first appointment the research team will contact you again after 12 weeks and then after six months for more assessments. These assessments will be much shorter than the first appointment. You and your child can choose if this will be face-to-face, over the telephone or a video call. Your researcher will ask your child to fill in some of the same questionnaires that they did during your first appointment, but they will be a lot shorter (60-90 minutes in one appointment).

Most young people in the study will also be contacted 12-months after their first meeting with the researcher. Your researcher will let you know if your child will need to be assessed at this time. At this meeting we will ask your child to fill in the same questionnaires as before and this will be the last assessment with the researcher.

The research team will compare the questionnaires that have been completed by all the young people during the study to see how BA compares to other support from CAMHS.

We are interested in finding out what young people thought of the support that they received when taking part in the research. We will also ask some young people if they are happy to have a short interview to talk about this (even if you finish therapy earlier than planned). This will take place 6-months after they have joined the study.

What is my role if my child wants to take part?

If your child wants to take part, we would ask that you support them during their time in the research. This might involve helping them to attend treatment sessions, discussing what they have done as part of the support they have received, and supporting them with tasks they have been asked to do.

You will also be asked to complete your own set of questionnaires at each appointment with the researcher at each timepoint and will follow the same process as detailed above.

A summary of the process

You will speak with a researcher about the study and be asked some questions to check your child is eligible. This helps us to decide whether the study is right for them.

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If we think the study is appropriate for your child, the researcher will confirm this with you and allow you 24 hours to read this information and decide whether you and your child would like to take part.

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You will then be asked to complete a consent form and book in your first appointment. Your child will complete an assent form to indicate they are happy to take part too.

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You and your child will meet with a researcher for your first research appointment. You will both be asked to complete some questionnaires. This could take up to 90 minutes.

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A computer will decide randomly which treatment your child will receive. The researcher will contact you to let you know. This will either be BA/PE/usual care or PE/usual care.

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Your child will receive either BA/PE/usual care or PE/usual care to help them with their low mood.

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12 weeks after you start the study, and then at 6 months , you and your child will meet with the researcher again to see how things have been and answer some of the same questions. You and your child may also be invited to take part in a short interview (if you are happy to do so).

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12 months after your first visit with the researcher most participants will also be invited to meet with them again to see how things have been and answer the same questions once more.

What do I do now if my child wants to take part?

If your child is interested in taking part in the study, you will be asked to confirm this by texting or emailing the researcher and then your child will be asked to complete the Mood and Feelings questionnaire (MFQ).If your child is suitable , you will be asked to complete a consent form and book your appointment with the researcher. The researcher will contact you again to discuss this.

You will be given a copy of your consent form to keep. A copy will be retained at your NHS site, and then securely sent to the University of York where it will be stored during the study. Online consent will be stored on the electronic database (REDCap), held at the York Trials Unit, University of York.

Are there any advantages and disadvantages of taking part?

We hope that BA helps your child to feel better, and that taking part in the research is meaningful for them. The research also provides an opportunity to try a therapy that your child might not be able to access in CAMHS. We cannot be sure how well BA or usual care will work, but we hope that BA will be useful in helping young people with their low mood. By taking part you and your child will also be able to tell us what you think of the support they have received. This will be useful in understanding how we can better help young people with low mood in the future.

We do not know of any risks of BA, but in the study it will be important to notice if your child starts to feel worse. If this happens, we ask that you seek additional support if you need it. This may include contacting your CAMHS professional or GP. If the research team or your CAMHS professional feels that your child no longer has capacity (ability) to take part in the study, they will advise that they should no longer carry on with the research. They will still get the care that you need from CAMHS. Any data already collected would be kept.

Will I get compensation for my time?

Your child will receive £30 for the first appointment, which will be the longest assessment. They will then receive:

- £15 at 12 weeks
- £20 at 6 months
- £15 at 12 months.

How will we use information about you?

- We will keep your name and contact details. We will use this information to do the research or to check your records to make sure that the research is being done properly.

- People who do not need to know who you and your child are will not be able to see your name or contact details. Your data will have a code number instead.

- We will keep all information about you and your child safe and secure.

- If randomised to receive BA and use our website for sessions, we will capture data on your child's usage of the website including pages visited, links downloaded and number of visits to the website. This is to see whether the website is user friendly and if young people are engaging with it.

- Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you and your child took part in the study.

- Any information that could identify you and your child will be destroyed at the end of the 4-year BAY study and the rest of the information from the study will be destroyed after 10 years. We will keep this information for longer in case we need to check the results of the study.

What are your choices about how your information is used?

- Your child can stop being part of the study at any time, without giving a reason, but we will keep information about them that we already have.

- When we do research we need to manage your child's records in a certain way, this means that we won't be able to let you or your child see or change the data we hold about them.

- With your permission, you and your child's contact details will be saved if you'd like to be contacted about future research opportunities.

- With your permission, your information will be stored in a research repository for future research and learning.

What will happen if someone is worried about my safety?

- If, during the research, a member of the research team or supporting professional has concerns for your child's safety, they may have to talk to other professionals or services. They will discuss this with them first. What happens next will depend on whether your child is still being seen by CAMHS.
    - If your child is no longer in services and is under 16 at follow up, you will be informed if there is an immediate risk and advice given regarding signposting.
    - If your child is over 16, agreement will be sought to inform you of any immediate risk, or, if they don't want you to know, another adult or professional such as a GP will be contacted. Information about other support will be given. Additional signposting will be offered, such as the NHS 24/7 crisis helpline.
    - In an emergency, the researcher may need to call emergency services and inform you

Where can you find out more about how your childs information is used?

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

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to the BAY research team, email: bay-project@york.ac.uk

Who is doing the research?

Researchers in the Department of Health Sciences at the University of York are doing this work with the Greater Manchester Mental Health NHS Foundation Trust (study sponsor). The Trial Managers at the University of York are responsible for running the study. Professor Bernadka Dubicka is the chief investigator and has overall responsibility for the study.

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions [email: bay-project@york.ac.uk].

If you still have concerns, you may wish to contact your local Patient Advice and Liaison Service (PALS - Telephone number: <<insert local number>>), or, if you wish to make a formal complaint, or if you are not happy with our response, please contact Greater Manchester Mental Health NHS Trust Customer Care Team Manager customercare@gmmh.nhs.uk; Telephone 0161 358 0600 or 0800 587 4793.

If you have a complaint about how we use your personal information, you can also contact the Information Commissioners Office: https://ico.org.uk/make-a complaint; Telephone: 0303 123 1113

If you have any questions about data protection, you can contact the Sponsors Data Protection Officer:Sponsors Data Protection Officer: grace.birch@gmmh.nhs.uk.

In the unlikely event that something does go wrong, you and/or your child are harmed during the research, and you feel this is the research team’s fault, then you may be able to take legal action against Greater Manchester Mental Health NHS Foundation Trust. You may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you (if appropriate).

Who is organising and funding the research?

This research is part of a 4-year research project that has been organised by The Department of Health Sciences at the University of York and the NHS. It has been paid for by a research grant from the National Institute for Health Research (NIHR).

Who has reviewed the study?

All research must be checked by a research ethics committee before it can go ahead. This makes sure the research is safe and fair. This research has been reviewed and approved by (reference: xxx).

What will happen to the results of the study?

The results will be published in a study report and scientific journals. If you tell us that you would like to know what we find in the research, we will send you information about what we have found when the study has finished.

Who can I contact if I want to learn more about the study?

If you would like more information about the study please contact Rachel Ellison or Emma Standley (Trial Managers), via email: bay-project@york.ac.uk. You can also visit the website [add link/name].

[TO ADD: LOCAL TEAM CONTACT DETAILS]

Thank you for reading this. If you have any questions, please ask.