

Community-based Behavioural Activation Training (ComBAT) for Depression in Adolescents: Randomised Controlled Trial (RCT)

Participant Information Sheet: Young Person (Detailed Version)

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

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

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

Why are you doing this research?

Lots of young people can struggle with low mood. Low mood can affect lots of parts of life and can make people feel sad and not want to take part in activities that they usually enjoy. One therapy that has been good at treating adults with low mood is called Behavioural Activation (BA). This is a type of therapy that aims to help people take part in activities to help them feel better. Even though BA has helped adults experiencing low mood, we know less about its use with young people. We are looking for some young people to take part in a study to compare a version of BA that we have made with treatments that are usually offered.

Why have I been approached to take part?

You have been approached to take part in this study as you are a young person aged between 12 and 18 years old who may be experiencing low mood. We are hoping that around 250 young people will take part in this research.

What is the BA like?

Our therapy is based on something called Behavioural Activation (BA). This is a therapy which aims to help people feel better by taking part in activities that they may have stopped doing because they have felt down. Our BA has 8 sessions which last around 30 to 40 minutes and take place each week. With support from a professional, sessions help young people to try and take part in some activities that they used to enjoy. The professional also shows young people how to set goals, how to deal with stress and what to do if they start to feel happier but then feel down again. Lots of people including other young people, parents/guardians and professionals have helped us to develop our BA.

What will the treatment I receive be like?

To see if our BA is helpful, we would like to compare this to other treatments that are usually offered to young people experiencing low mood. Therefore if you choose to take part in the research you will either receive BA or the support that the service you belong to usually offers (e.g. another type of talking therapy, signposting elsewhere, etc).

What will happen if I take part?

With this information sheet you will also have been given two questionnaires to fill in and a form called an expression of interest form. The questionnaires are called the Revised Child Anxiety and Depression Scale (RCADS) depression subscale and the Patient Health Questionnaire-9 modified for adolescents (PHQ-9A). Both questionnaires ask about your mood. You can fill them in in your own time. These will help us to decide whether we think taking part in the research is a good idea for you. If not, a member of the research team will contact you to tell you. Whether you enter the study or not, you will still be able to access other services as usual. If you would like to take part, it would be great if you could fill in the expression of interest form and the questionnaires and send them back to the research team. You can post these directly to the research team using the address on the expression of interest form or return them to the person who gave you this information.

When the research team has received your forms, they will decide whether they think the research is a good idea for you. If they think your mood is very low they might ask you to talk to another member of the research team about this. If they decide that the research might be a good idea for you, a researcher will contact you and arrange to meet with you. This meeting might be face-to-face, over the telephone or using video conferencing software. You can choose which you would prefer. If you are happy to take part in the research, the researcher will ask you to sign a form called a consent or an assent form. This shows that you understand and are happy to take part. Depending on your age (i.e. if you are aged 12-15 years), we will also ask your parent/guardian to join the meeting and will ask them to fill in a consent form too to say they are happy for you to take part.

You will then be asked to fill in some questionnaires with the researcher. These include some questions about you (e.g. your age, sex, ethnicity) and some more about how you have been feeling recently. Filling in the questionnaires should take around 60 minutes.

After this meeting a computer will decide randomly (like when you flip a coin) whether you receive BA or the support already being offered in the organisation that gave you this information (i.e. an NHS service like CAMHS, school or community-based setting). We will let you and your parent/guardian (if applicable) know which one it is. The research team will contact the person who will be supporting you during the research and will arrange for treatment sessions (if applicable) to take place. With your permission, some treatment sessions might be audio-recorded, or a researcher may ask to come along and sit in on the session. This helps us to see how different support is being delivered.

What happens next?

Six months after your first visit with the researcher, the research team will contact you to arrange a second visit. Again, this visit can be face-to-face, over the telephone or using video conferencing software; you can choose. The researcher will ask you to fill in the same questionnaires as you did during your baseline appointment.

A member of the research team will also arrange to meet with you 12-months after your first meeting with the researcher. This third meeting will ask you to fill in the same questionnaires as previously.

We will compare the questionnaires that you complete at 6 and 12 months with those completed at the beginning of the research to see if the support you have received has helped.

We are interested in finding out what young people thought of the support that they received when taking part in the research. Therefore, we will also ask some young people if they are happy to have an extra, short interview with a researcher about what they thought about the support they have received. This will take place 6-months after you have joined the research.

Do I have to take part?

No, it is up to you. We will ask for your consent or assent (agreement) and then ask if you would sign a form which means you agree to take part in the study. If you are aged between 12-15 years, we will also ask your parent/guardian to do this too. You are free to stop taking part at any time and do not have to give us a reason.

What do I do if I want to take part?

If you would like to take part in the study, please complete the expression of interest form, RCADS depression subscale and PHQ-9A questionnaires and return these to the research team. You can do this directly (the contact details of the research team can be found on the expression of interest form), or you can pass these back to the person who gave you this information sheet who will send this to us.

What are the risks of taking part?

We do not know of any risks of BA or of the usual care that you may be offered, but you might find that you feel down when taking part in the research or notice that your symptoms have got worse. If this happens it is important that you tell somebody straightaway like a parent, friend or professional. The professional who provides support during the research (e.g. the person who provides therapy or signposts you to alternative support) will be able to offer you some support if you need it. It might be that they think you need some extra help as well as BA or usual care, or they might decide that you should stop taking part in the study. If this happens, they will talk to you (and depending on your age, a parent/guardian as well). If the research team or the professional who provides support during the research (e.g. the person who provides therapy or signposts you to alternative support) felt that you no longer had capacity to take part in the study at any point, you would be withdrawn. However, any data already collected would be kept.

Are there any advantages or disadvantages of taking part?

If you choose to take part in the study, you will receive the support you have been randomised to. This might include attending treatment sessions with a professional. You will also need to complete the questionnaires with the researcher and possibly attend an interview if you are happy to do so. We cannot be sure that our BA or the usual care will work. However, we hope that the support that you receive is useful in helping with your low mood and in learning some skills that you can use in the future if you feel down. By taking part you will also be able to tell us what you think of the support you have received. This will be helpful in understanding more about the different support available to young people experiencing low mood and allowing us to make support better for young people in the future.

How will we use information about you?

- We will need to use information from yourself for this research project.
- This information will include your name and contact details. People 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 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 safe and secure.
- 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 took part in the study.
- All personal identifiable information will be destroyed at the end of the ComBAT 5-year programme of research 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?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If, during the research, a member of the research team or a participating professional identifies any safeguarding issues, confidentiality may be broken with the necessary professionals or supporting services notified of these issues.

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

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

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to Dr Lucy Tindall (lead researcher), email: lucy.tindall@york.ac.uk or the ComBAT research team, email: combat-project@york.ac.uk or
- by ringing us on 07385430934.

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: combat-project@york.ac.uk or call 07385430934]. If you remain unhappy and wish to complain formally, you can do this by contacting the sponsors' Data Protection Officer at TEAWVNT.AccessRequests@nhs.net or reporting your concerns to the Information Commissioner's Office at www.ico.org.uk/concerns.

In the event that something does go wrong, and you are harmed during the research, and this is due to someone's negligence then you may have grounds for a legal action for compensation against Tees Esk and Wear Valleys NHS Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Who is conducting the research?

Researchers based in the Department of Health Sciences at the University of York are conducting this work in partnership with Tees, Esk and Wear Valleys NHS Foundation Trust who are the sponsor for the study. Professionals based in both organisations will be responsible for running the study.

Who is organising and paying for the research?

This research is part of a 5-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 special research grant from the National Institute for Health Research (NIHR).

Who has checked the study?

Before any research goes ahead, it has to be checked by a research ethics committee. These are people who make sure the research is safe and fair. This study has been reviewed and approved by North East - Newcastle and North Tyneside 1 Research Ethics Committee (reference: 22/NE/0100).

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

If you have any questions about the study, you can talk to the person who gave you this form either a person in school, a community-based organisation or within an NHS service (e.g. CAMHS). You can also talk to this person if you are worried about the study. If you would like to talk to a member of the ComBAT study team please contact Dr Lucy Tindall (lead researcher), email: lucy.tindall@york.ac.uk or the ComBAT research team, email: combat-project@york.ac.uk.

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