

PARENT/GUARDIAN INFORMATION SHEET

Version 1.4, 28/03/2023

Title of Project: Behavioural activation for depression (Beat-D) in adolescents with mild to moderate learning disabilities: A feasibility randomised controlled study of Beat-D versus support as usual alone

Chief investigator: Professor Kylie Gray

Centre for Educational Development, Appraisal and Research (CEDAR), University of Warwick, UK

Co-investigators:

Professor Richard Hastings, Andreas Paris, Dr Ashley Liew, Dr Paul Thompson (University of Warwick), and Professor Andrew Jahoda (University of Glasgow),

If you need help to read this information sheet, please contact a member of the project team using the contact details at the end of this information sheet.

Introduction

This study is aiming to find out whether behavioural activation helps adolescents with learning disability who have depression, using an intervention called Beat-D. Behavioural activation intervention involves increasing people's behaviours and engagement in things they enjoy doing, aiming to improve their mood, thoughts, and overall wellbeing.

You and your child are invited to take part in this study. Please take the time to read the following information carefully before deciding whether or not to participate in this research.

Please ask us if there is anything that is not clear, or if you would like more information.

Who can take part?

We will be recruiting adolescents aged between 12 and 17 years old who have a learning disability (mild to moderate) and who are currently experiencing clinically significant depression (depression that requires treatment through medication or therapy). To take part in the study, adolescents must have the support of a parent or carer who can support them throughout the study.

What does taking part in the study involve for my child?

Whether adolescents will receive the behavioural activation intervention for depression for adolescents with intellectual disability (Beat-D) or continue to receive their usual support from their school (and not receive Beat-D) will be decided at random (like tossing a coin). Half of the adolescents will receive Beat-D, and the other half will be in the control group (receiving their usual support from your school). This is so that we can compare the results between the groups. It is the best way to show whether there are any differences between the groups.

Before your child can be part of the study, we will need your consent for them to take part. The form is attached to this information sheet and needs to be completed and returned to the research team to let us know if you are happy for your child to take part.

If you are happy for your child to take part, you and your child will be asked to complete a questionnaire and an interview with a researcher to determine whether your child is eligible to participate. This will take approximately one hour. If your child is eligible, they will be

randomly allocated to receive either the behavioural activation intervention for approximately 3 months, or to continue with their usual support. If your child is not receiving any services for depression, your school will be supporting you in the usual way.

At the end of 3 months, you and your child will meet with the researchers again for one hour, and will be asked to complete questionnaires and an interview about your child's activities, mental health and behaviour, and your thoughts about the intervention (if applicable).

What does Beat-D involve?

If your child is allocated to receive the behavioural activation intervention, you will be required to accompany them to 12 therapy sessions (one session per week for approximately 1-2 hours) for approximately 3 months, at the [insert school name here]. The intervention involves working with you and your child to increase their activities and the things they enjoy doing.

Are there any other parts to the study?

We will also ask some adolescents who received Beat-D, and their parents, to have an interview with a researcher to tell us more about their experiences of Beat-D A. The interviews with adolescents will be undertaken using Talking Mats® to ensure that children with different levels of communication abilities are able to share their experiences with the evaluation team. We will send you further information about the interviews at the time, so that you can decide whether or not you would want to take part in this additional part of the research.

How will information about my child be handled?

All information about you and your child will be handled in confidence and only members of the research team will have access to identifiable data. Study data stored at the University of Warwick will be kept separate from personal information (e.g., names). Study data will be kept securely for 10 years in line with the University of Warwick's policies.

Research data will be pseudonymised as quickly as possible after data collection. This means all direct and indirect identifiers will be removed from the research data and will be replaced with a participant number. The key to identification will be stored separately and securely to the research data to safeguard your identity.

You may also, should you wish, refer to the University of Warwick Research Privacy Notice which is available here:

<https://warwick.ac.uk/services/idc/dataprotection/privacynotices/researchprivacynotice>
or by contacting the Information and Data Compliance Team at GDPR@warwick.ac.uk

Are there any negative side-effects or risks from participating?

We do not expect any side-effects or risks from participating. There is a chance your child might feel some discomfort as a result of talking about how they feel or completing the questions, either during or after completion of the survey. If at any point your child feels any discomfort, you can both talk to their classroom teacher and/or their school's wellbeing lead.

Does my child have to take part in this study?

No, you are free to choose whether or not you want your child to take part in the study. You can ask questions about the study using the contact details below.

If you decide to participate in this research study, you will be asked to read and sign the consent form. We will also provide your child with an information sheet and consent form, which you can read with them to decide together if you would like to take part.

Your child can stop taking part in the study at any time, without giving a reason, and without affecting you/them in any way. If you, or your child, decide to withdraw from the study, you will be able to choose to have their data removed as well, provided that this is before data analysis takes place (scheduled for July 2023). If the study is stopped for any other reason, we will inform you.

What will happen to the results of this study?

Results will be published in scientific journals and presented at scientific meetings. Neither you nor your child will not be identified in any report, publication or presentation. Once the research study is complete, we will send you a summary of the results.

What are the potential benefits?

We believe that participating in the behavioural activation intervention will be beneficial for your child and help to improve their mood and overall wellbeing. However, behavioural activation does not always work for everyone.

Who has funded this study?

This research is being funded by the Monash Warwick Alliance Research Accelerator Fund.

Who has reviewed the study?

This study has been reviewed and given favourable opinion by the University of Warwick's Humanities and Social Science Research Ethics Committee (HSSREC Reference Number: 192/21-22).

Research Team contact details

Chief Investigator: Professor Kylie Gray	Beat-D@warwick.ac.uk
Research Assistant: Andreas Paris	07824 541 182

Who should I contact if I wish to make a complaint?

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a senior University of Warwick official entirely independent of this study:

Head of Research Governance

Research & Impact Services
University House
University of Warwick
Coventry
CV4 8UW

Email: researchgovernance@warwick.ac.uk

Tel: 024 7657 5733

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer, who will investigate the matter: DPO@warwick.ac.uk

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

Thank you for taking the time to read this Participant Information Leaflet