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**Participant Information Sheet for Parent and Older Adolescent**

**Name of department:**

Clinical Education Development and Research (CEDAR)

**Title of the study:**

Evaluating Brief Behavioural Activation for depression in adolescents with acquired brain injury: A Single-case Experimental Design study

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**What is the aim of the study?**

The main aim of the study is to evaluate the effectiveness of Brief Behavioural Activation (BA) for treating symptoms of depression in adolescents with acquired brain injury (ABI). We are also looking to evaluate whether BA can improve:

* The participation levels of adolescents with ABI;
* The quality of life (QoL) of adolescents with ABI.

**How will this be measured?**

The study will try to see your if you respond well to BA by looking carefully at the scores of several questionnaires, known as routine outcome measures (ROMs). ROM scores before you receive BA will be compared with ROM scores after you have received BA. If you respond well to BA, we should notice a ‘significant’ difference in scores, and you should notice that you are feeling better than normal.

**What is BA?**

BA is a behavioural intervention that is shown to be effective for adults, adolescents and children in supporting them with their low mood. Research suggests that structured and meaningful activities can help with low mood. The main purpose of BA is to help the individual to start doing activities that are meaningful to them. The therapist will do this by identifying the individual’s current activity pattern, considering how this affects the individuals mood, encouraging the individual to introduce a more structured or new routine, and seeing the individual through to doing this independently in their own lives.

If you would like to learn more, please see the ‘Brief BA Study Information’ sheet.

**How long does the study last?**

The study will last for 9 weeks from the beginning to the end. There will be a one-off follow-up session 4 weeks after you have completed BA.

**What happens in the 9-week study period?**

At the beginning of the study, there is a minimum 2-week period where you will be asked to do some tasks without receiving any BA. You will meet with the researcher before this period starts in an introductory session, so he can talk about the tasks that you will be doing and answer any questions you might have.

During the 3rd week, you will be asked to begin BA at a random point. You will be told in advance when you will start BA. The reason why we start at random times is to make sure we know we are doing the study properly.

Once you have started BA, you will receive 8 sessions over 6 weeks. During the first 2 weeks, you will have 2 sessions per week. During the last 4 weeks, you will have 1 session per week.

**What happens at the end of the study?**

After you have completed your treatment, you will be left to continue with your life normally. I will set up a follow-up session, which we will do 4 weeks after you are finished. This is for me to check how you are and whether you have been feeling better. I will also give you some questionnaires to complete.

**What questionnaires will I have to do?**

There will be 1 main questionnaire, called the Mean Daily Achievement, Closeness and Enjoyment Scale (MACES), which you will complete on random days at least 4 times a week for the whole study. This can be done using a smartphone or a web browser to make it easier.

There will be 3 other questionnaires that you will be completing 4 times during the study. These are to help the researcher to learn a bit more about how BA helps. They are:

* Revised Children’s Anxiety and Depression Scale (RCADS)
  + Depression Subscale
* Child and Adolescent Scale of Participation (CASP)
* Paediatric Quality of Life Inventory (PedsQL)

Your parents will also need to complete these questionnaires. They will be asked slightly different questions from you but the reasons for the questionnaires are the same.

Information about all the questionnaires will be given to you in the introductory session. The researcher will call you during the week to check if you have had any problems with completing the MACES questionnaire.

At the end of the study, you will be given a Treatment Acceptability Questionnaire (TAQ), which gives you a chance to tell the researcher about anything you found helpful or not so helpful during BA.

**What will this study help to do?**

Most importantly, we are hoping that BA will help you to have less symptoms of depression, improve your QoL, and help you to feel more able to participate at home, school and in other situations.

This study will also help us to see if BA is a good enough therapy to be researched further. If we can research it further, we might be able to offer more adolescents with ABI some support for their symptoms of depression. Because BA is much easier and cheaper to do than other therapies, there is a chance that it could be used in the NHS in the future for more people. Your help in this study could mean that you help hundreds, maybe thousands of others like you!

**Will BA work for me?**

At the moment, we are not sure; that is why we are doing this study. Recent research has shown that BA has been effective for adolescents with depression in general. We are going to be using the same schedule and techniques as this study in the hope that it will be effective for adolescents with ABI too.

**How will my data be used and kept?**

The data the researcher collects from you must be kept by the researcher in order to do the study. Some of the information you give us will be ‘identifiable’, which means we can link it to you and we know whose data it is. This is important because the researcher needs to know how you are getting on and will need to contact you from time to time! This data will be kept safe on a computer with a strong password, which is kept in a safe place at the University of Exeter. This data will also be stored on a safe online storage facility and a memory stick, which also have passwords. The memory stick will be kept in a safe place at the researcher’s home. The researcher and their supervisor are the only people who can see this information and know the passwords. Any information that is given to the researcher on paper will be kept in a locked filing cabinet at the University of Exeter.

Once we have collected all the information we need by the end of the study’s follow-up session, the data will be ‘anonymised’ within 1 month. Any identifiable data will be destroyed by this point. This means that the data will be disconnected from you because we do not need to know which information is yours anymore. The anonymised data will be kept in the same way that your identifiable data was kept. It will also be kept forever in an online ‘repository’, which is a place for others to see anonymous information if they need to learn more about the study. If we do not think the study is right for you and you do not take part, any information you have given to the researcher will be destroyed within a week of data collection.

It is likely that the study will be ‘published’. This means that the study will be written-up and shared online and in academic journals. The data will stay anonymous and cannot be linked to you in any way. This is so that other researchers can use this information to do more studies.

**Will anyone find out about things I’ve said?**

We will keep everything you tell us as confidential as possible. However, sometimes we might be concerned about your safety or the safety of others. If that is the case, we might have to share information to make sure you get the support you need. The researcher will try to make sure you know beforehand if he decides to share any confidential information.

**A notice for your parent(s)**

The University of Exeter processes personal data for the purposes of carrying out research in the public interest. The University will endeavour to be transparent about its processing of your personal data and this information sheet should provide a clear explanation of this. If you do have any queries about the University’s processing of your personal data that cannot be resolved by the research team, further information may be obtained from the University’s Data Protection Officer by emailing [dataprotection@exeter.ac.uk](mailto:dataprotection@exeter.ac.uk) or by visiting the data protection webpage at [www.exeter.ac.uk/dataprotection](http://www.exeter.ac.uk/dataprotection).

**I would like to take part in the study! What do I do?**

If you would like to take part in the study, you will first need to go through ‘screening’. Screening is where we check if you are suitable for the study. Before you go through screening, you or your parents must give consent using the Informed Consent for Screening Form.

For the screening procedure, you will be asked for evidence of your ABI. You will then be given the full RCADS questionnaire to complete. If you have an ABI and your RCADS score is above 65, you will be able to take part in the study. If your score is too low, then you cannot take part.

If you are invited to take part, you or your parents will be asked for consent to receive BA using the Participant Consent form if you are over 16, or the Child Assent and Parental Consent Form if you are under 16. The relevant form must be signed before you can receive BA.

If you would like some more information about the ‘screening procedure’, please ask the researcher.

**What if I do not want to do the study or carry on with BA anymore?**

If you do not want to do the study, you do not have to. If you start the study and do not want to do BA anymore at any point, you also do not have to continue. You can either tell your parent(s)/guardian to tell the researcher or the supervisor, or you can tell the researcher yourself. You will not be punished nor stopped from having any other treatment again. You can tell the researcher or the supervisor by e-mailing them at the e-mail addresses below.

If you want, you can also remove your data from the study. You will only be able to do this for up to a month after your final follow-up session is completed. This is because your data will be anonymised after this point and the researcher will not know what data is yours.

The researcher is ‘bound’ by ethical guidelines outlined by the University of Exeter, which means they have to follow a very strict policy to make sure you are being treated fairly.

**I have questions about this study – who do I contact?**

You can contact the main researcher, Conor O’Brien (Trainee Clinical Psychologist) at any time before, during, and after the study by e-mailing: [co359@exeter.ac.uk](mailto:co359@exeter.ac.uk)

If you have any concerns or complaints about the researcher, or wish to withdraw without speaking to the researcher, you may contact the main researcher’s supervisor, Dr Anna Adlam (Chartered Clinical Psychologist & Deputy Director of Research for Clinical Psychology training), by e-mailing: [a.r.adlam@exeter.ac.uk](mailto:a.r.adlam@exeter.ac.uk)

For any further information about the university’s ethical procedures and policies, or to raise any concerns or complaints about the research, please contact Dr Nick Moberly, the Chair of Psychology Ethics, by e-mailing: [n.j.moberly@ex.ac.uk](mailto:n.j.moberly@ex.ac.uk)

Thank you for your time and for considering taking part in this study.

A close up of a device

Description automatically generated

Conor O’Brien

Trainee Clinical Psychologist, University of Exeter, under the supervision of:

Dr Anna Adlam

Chartered Clinical Psychologist/Associate Professor

Deputy Director of Research, DClinPsy, University of Exeter