Acceptance and Commitment Therapy for Young Brain Tumour Survivors: An Acceptability and Feasibility Trial

IRAS Reference: 266746

Participant Information Sheet (parents/carers of participants aged 11 to 15 years old)

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Contact details

Principle Investigator
[INSERT LOCAL PI DETAILS HERE]

1. What is the purpose of the study?

a) We want to find out if providing Acceptance and Commitment Therapy (ACT) via video-calling helps improve physical and mental health for young people who have had a brain tumour.

- Having a brain tumour can have a big impact on quality of life for young people and their families. One of the key difficulties is learning to cope with long-term problems that might not go away.
- ACT is a talking therapy that aims to help patients cope with difficulties in a healthy way and focus on what the individual really values in life.
- ACT has been used to help people with other long-term health problems, but has not yet been used to help young people who have had a brain tumour.
- Talking therapies like ACT can be delivered effectively over a video-calling system (like Skype or FaceTime), which can make the treatment more accessible and convenient.
- To find out whether ACT is helpful we will carry out a "randomised controlled trial" in which we make comparisons between two groups. Half of the people we interview will be offered ACT straight away and the other half will receive ACT after waiting 12 weeks. To try and make sure the groups are the same to start with, each patient is put into a group by chance (randomly). The results are then compared.
- This study aims to recruit 72 participants at 3-6 Children's Hospitals.
- Participants will be offered up to 12 ACT sessions each lasting an hour via video-calling.
- All participants will receive ACT either immediately or after a 12-week wait.

b) We want to understand the best way of offering ACT and what patients think about it.

- Young people who have had a brain tumour are not offered a talking therapy after treatment in usual care, so we do not know how many people would find it helpful.
- We also do not know what parts of ACT patients would find helpful or unhelpful.
- Therefore we will ask participants in this study to complete questionnaires about their experience of ACT and some participants will be invited to take part in an interview. Parents/carers can support this process if required.

2. Who has reviewed this study?

- Research in the NHS is usually looked at by an independent group called a Research Ethics Committee, to protect your child's safety, rights, well-being and dignity. This study has been reviewed and given a favourable opinion by the NHS, XXXXXX Research Ethics Committee.
- The study has also been reviewed and approved by the Health Research Authority and the Research & Innovation department of Nottingham University Hospitals NHS Trust. Nottingham University Hospitals NHS Trust will act as 'Sponsor' (i.e. the lead NHS hospital) for this research. The Brain Tumour Charity will fund this research.

3. Why has my child been asked to take part?

a) Why has my child been asked to take part?

- Your child is being invited to take part because they have had a brain tumour and have now completed their treatment. They are also aged 11 or older.

b) Do they have to take part in this study?

- No. It is up to you and your child to decide whether or not to take part. If you decide to take part you will be given this information sheet and be asked to sign a consent form to confirm that you understand what is involved when your child takes part in this study. If you decide to take part your child is free to leave the study at any time and without giving a reason.
- If your child withdraws, we will still keep records relating to the treatment given to them in the study, as this is valuable to the results. A decision to withdraw at any time, or a decision not to take part, will not affect the care your child receives.

4. What does my child have to do?

a) What will happen to my child if they take part in the study?

- One of our clinical psychologists will ask to meet with you and your child. If you are happy for them to meet you they will explain the study in more detail and ask you and your child some questions. Based on your answers, we may invite you to take part in the study. We will answer any questions you may have. We will ask for your written consent to allow your child to take

part in the study. We will ask your child for their written agreement to take part after they have had the study explained to them and we have answered all their questions. The clinical psychologist will then ask you and your child some questions about their physical health, mental health and use of health services. The interview is expected to last about an hour.

- If your child is allocated to receive immediate treatment the clinical psychologist will arrange for them to receive up to 12 sessions of ACT via video-calling. If you do not have internet access or a device available for video-calling then face-to-face sessions can be offered instead.
- Although ACT will include some joint session-time with you and your child (e.g. at the beginning middle and end of treatment), most of the time your child will meet one-to-one with the clinical psychologist.
- If your child is allocated to receive treatment after a 12-week wait the clinical psychologist will contact you when their treatment is due to start and for follow-up interviews.
- During ACT sessions, your child and their clinical psychologist will work together to build key skills that help to address their responses to difficulties that cannot be changed and move towards what they really value in life. Overall, this aims to help your child cope with the long-term problems that can come after brain tumour treatment in a way that aims to keep life focused on what is most important to them.
- With your consent and your child's agreement, meetings with the clinical psychologist may be audio/video recorded to help maintain the quality of the treatment, to better understand how treatment can be improved. Your child can also have a copy of each session recording and their therapist may suggest that they review recordings between sessions to help them remember what happened. All session recordings will be destroyed once the study in finished and published. Any use of recordings for research will only be from written transcripts with all names, places and dates removed so your child could not be identified. Transcripts will be typed by an approved transcription service with a confidentiality agreement in place. You and/or your child are free to decide not to have the sessions recorded and this would not affect the care they receive in any way.
- We will ask all participants to complete a set of questionnaires three, six, nine and twelve months after they joined the study. These can be completed over the telephone, over video-calling or sent to you by post or email, whichever is most convenient to you. The questions will

again ask about your child's physical health, mental health and use of health services so that we can compare any changes. These questionnaires will take around 45 minutes to complete.

- We will ask some people who take part in the study whether they would like to be interviewed again. This interview will allow them to talk in more detail about their thoughts on ACT over video-calling. The interview will take place within 12 months of the first study interview. If you agree for your child to take part, the researcher will set the interview date and time with you. The interview will last up to 60 minutes. During the interview, your child will be asked about their experiences of Acceptance and Commitment Therapy, what they found helpful and what they did not find helpful. We will ask their views and opinions on how the treatment could be improved or parts that they found especially beneficial. With yours and your child's permission, we will be audio-video recording the interview so that we do not miss any important points. The recordings will be transcribed and we will remove any names of people (including your child's name), places or services when we do this so that your child remains anonymous.
- We may use anonymous quotes from interviews or ACT sessions in reports or materials arising from the study.
- Your child's responses to the research questions will be stored safely and anonymously according to clinical trial regulations (see section 7).
- If you and your child decide they will take part in this study you will be given a copy of this information sheet to keep and a copy of the signed consent form.
- Participation in this research does not affect your child's rights to consult your usual doctors or seek treatment from other healthcare providers. If you have any concerns about your child's symptoms you should continue to see your usual doctors and/or other healthcare providers.
- By taking part you agree for a member of the research team to examine your child's medical notes. Your child's notes will not be taken from where they are usually kept and any information taken from them will remain confidential and will be anonymised so that your child cannot be identified
- If you and your child decide to take part in the study, you must report any problems to the study researchers. There is more information on this in section 10.

5. What are the possible benefits?

- By taking part your child will be offered treatment which has been shown to improve physical and mental health for people who have had long-term health conditions. The questionnaires and interview they complete as part of the research will allow you and your child to reflect on their experiences and emotions and how these have changed over the research period.
- We hope that the study will help your child and the information we get from this study may help similar patients in the future to get treatment that helps them manage their difficulties, and cope better.

6. What are the disadvantages?

- Some of the questions we will ask are about emotions such as feeling anxious or low. Whilst most people do not mind answering these questions, some people may feel upset. It is important that we ask these questions and find out if treatment can improve your child's health. Many people find talking about or sharing concerns in a safe and confidential way can be helpful.
- Some people might not experience any improvement by attending ACT sessions. Information about this can help us to improve the treatment in future.

7. What will happen to my data?

a) Will my child's taking part in this study be kept confidential?

- If you consent for your child to take part in this study, the records obtained while they are in this study as well as related health records will remain strictly confidential at all times. The information will be held securely at your child's treating hospital (and Nottingham University Hospitals NHS Trust if this is not your hospital) under the provisions of the General Data Protection Regulation and the Data Protection Act. People who do not need to know who your child is will not be able to see their name or contact details. Your child's data will have a code number instead.
- The only time that confidentiality would change is if we felt we needed to share relevant information to protect your child's safety or the safety of others.

b) Use of your child's personal data in research

- We will need to use information from your child for this research project. This information will include your child's name, date of birth and contact details. People will use this information to do the research or to check your child's records to make sure that the research is being done properly.
- If you withdraw consent from further study involvement, your child's data will remain on file and will be included in the final study analysis. We also need to manage your child's 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 your child.
- In line with Good Clinical Practice guidelines, at the end of the study, your data will be securely archived for a minimum of 5 years. After this period arrangements for confidential destruction will be made. After the study is complete, in line with current research best practice, the anonymous data from questionnaires will be published on Figshare – a research data repository so it may be used in future by other researchers. Other anonymous study data may also be used in future research by other researchers. Such usage would have to be approved by the sponsor and investigators at the Nottingham University Hospitals NHS Trust and the Research Ethics Committee, before anonymous data is released.
- The information collected about your child may also be shown to authorised people from the UK Regulatory Authority to ensure the study is carried out to the highest possible scientific standards. All will have a duty of confidentiality to your child as a research participant.
- Once we have finished the study, we will use the data to analyse the results. We will write our reports in a way that no-one can work out that your child took part in the study. 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 have already collected.
- If you agree for your child to take part in this study, they will have the option to be invited to take part in future research related to this study.

c) Informing your General Practitioner (GP) or other healthcare professionals

- Your child's GP and other doctors treating your child may be notified that you are taking part in this study. This will include your child's cancer care team.

d) You can find out more about how we use your child's information:

- at www.hra.nhs.uk/information-about-patients/
- our GDPR leaflet available at the link www.nuh.nhs.uk/gdpr
- by asking one of the research team
- by emailing the Data Protection Officer for NUH at dpo@nuh.nhs.uk
- by ringing the Data Protection Officer for NUH on 0115 924 9924 (extension 63975)

8. What will happen if my child doesn't want to carry on with the study?

- Your child can decide to withdraw at any time without giving a reason. This would not affect any other healthcare they receive. If your child would like to withdraw from the study completely we will use the information collected up until they withdraw. If your child would like to withdraw from receiving ACT sessions, but not the whole study we would still like them to complete follow-up interviews if they are willing to do so.

9. What happens when the study is finished?

- Your child's care will not change as a result of taking part in the study. So after the study you can continue to access your child's usual healthcare providers in the same way. If you are interested in finding out the results of the study we can keep your contact details and inform you of results when the study is completed.

10. What if there is a problem?

- If you or your child has a concern about any aspect of this study, ask to speak with the researchers who will do their best to answer your questions.
- If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital or you can contact the Patient Advice and Liaison Service (PALS) telephone 0800 183 0204.
- In the event that something does go wrong and your child is harmed during the research study there are no special compensation arrangements. If your child is harmed and this is due to

someone's negligence then you may have grounds for a legal action for compensation but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you.

11. Further Information

- You are encouraged to ask any questions you wish before, during or after your child's treatment. If you have any questions about the study please speak to a member of the study team using the contact details at the top of this information sheet. They will be able to provide you with up to date information about the therapy involved. If you require any further information or have any concerns while taking part in the study please contact the chief investigator (listed at the top of this document).
- If you decide you would like your child to take part then please read and sign the consent form. You will be given a copy of this information sheet and the consent form to keep. A copy of the consent form will be filed in your child's medical notes, and one will be filed with the study records.
- You can have more time to think this over if you are at all unsure.

Chief Investigator Contact Details

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