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

IRAS Reference: 266746

Participant Information Sheet (aged 16 years and over); Version 0.3, Dated 01-Sept-2020

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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 key difficulty is learning to cope with 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 Hospitals.
- Participants will be offered up to 12 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 be asking participants in this study to complete some questionnaires about their experience of ACT and some participants will be invited to take part in an interview.

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 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. The Nottingham University Hospitals NHS Trust will act as the 'Sponsor' (i.e., the lead NHS hospital) for this research. The Brain Tumour Charity will fund this research.

3. Why have I been asked to take part?

a) Why have I been asked to take part?

- You are being invited to take part because you have had a brain tumour and have now completed your treatment. You are also aged 16 to 24 years old.

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

- No. It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form to confirm that you understand what is involved when taking part in this study. If you decide to take part you are free to leave the study at any time and without giving a reason.
- If you withdraw, we will still keep records from your participation, as this is valuable to the study. A decision to withdraw at any time, or a decision not to take part, will not affect the quality of care you receive.

4. What do I have to do?

a) What will happen to me if I take part in the study?

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

then ask you some questions about your physical and mental health and your use of health services. The interview is expected to last about an hour.

- If you are assigned to receive immediate treatment the clinical psychologist will arrange for you 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.
- ACT sessions will typically be one-to-one with your clinical psychologist, but you may include a parent/carer at some points if you feel this might be helpful.
- If you are assigned to receive treatment after a 12-week wait the clinical psychologist will contact you when your treatment is due to start and for follow-up interviews.
- During ACT sessions, you and the clinical psychologist will work together to build skills that help to address responses to difficulties and move towards what you really value in life. Overall, this aims to help you 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 you.
- With your consent, meetings with the clinical psychologist may be audio/video recorded to help maintain the quality of the treatment and to better understand how treatment can be improved. You can also have a copy of each session recording and your therapist may suggest you review them between sessions to help you 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 you could not be identified. Transcripts will be typed by an approved transcription service with a confidentiality agreement in place. You are free to decide not to have the sessions recorded and this would not affect the care you 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 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 concerning ACT over video-calling. The interview will take place within 12 months of the first study interview. If

you agree 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, you will be asked about your experiences of Acceptance and Commitment Therapy, what you found helpful and what you did not find helpful. We will ask your views and opinions on how the treatment could be improved or parts that you found especially beneficial. With your 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 own name), places or services when we do this so that you remain anonymous.

- We may use anonymous quotes from interviews or ACT sessions in reports or materials arising from the study.
- Your responses to the research questions will be anonymised and stored safely according to clinical trial regulations (see below).
- If you decide to 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 rights to consult your usual doctors or seek treatment from other healthcare providers. If you have any concerns about your 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 medical notes. Your 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 you cannot be identified
- If you do decide to take part in the study, you must report any problems you have to the researchers. There is more information on this in section 10. In the unlikely event of an emergency during the conduct of the study, we may contact your nominated next of kin.

5. What are the possible benefits?

- By taking part you 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 you complete as part of the research will allow you to reflect on your experiences and emotions and how these have changed over the research period.

- We hope that this study will help you and the information we get may help 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 the treatment can improve your health. Many people find talking about concerns in a safe and confidential way can be helpful.
- Some people might not experience any improvement by attending ACT sessions. Information about this may help us to improve the treatment in future.

7. What will happen to my data?

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

- If you consent to take part in this study, the records obtained while you are in this study as well as related health records will remain strictly confidential at all times. The information will be held securely on paper, and electronically at your treating hospital (and Nottingham University Hospitals NHS Trust if this is not your treating hospital) under the provisions of the General Data Protection Regulation and the Data Protection Act. 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.

- The only time that confidentiality would change is if we felt we needed to share relevant information to protect your safety or the safety of others.

b) Use of your personal data in research

- We will need to use information from you for this research project. This information will include your 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 treatment, your data will remain on file and will be included in the final study analysis. We also 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.

- 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 you may also be shown to authorised people from the UK Regulatory Authority to ensure that the study is carried out to the highest possible scientific standards. All will have a duty of confidentiality to you 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 you took part in the study. 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.

- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

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

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

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

- at www.hra.nhs.uk/information-about-patients/
- our GDPR leaflet available on request from researchsponsor@nuh.nhs.uk; or by the following 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 I don't want to carry on with the study?

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

9. What happens when the study is finished?

- Your care will not change as a result of taking part in the study. 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 have a concern about any aspect of this study, you should 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 you are harmed during the research study there are no special compensation arrangements. If you are 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 treatment. If you have any questions about the study please speak to your study clinical psychologist who 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 end of this document).

- If you decide you would like 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 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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