

# Acceptance and Commitment Therapy to improve Neuro-Oncology Wellbeing (ACT NOW)

<b>Submission date</b> 26/11/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 07/12/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 08/03/2023	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Survival rates for childhood brain tumours are improving, but quality of life after treatment is the worst of all cancer survivors. Research on psychological treatments after cancer treatment is the top priority for young people who have had cancer. This study aims to find out if a psychological therapy called Acceptance and Commitment Therapy (ACT) delivered remotely via video-conferencing is a feasible and acceptable treatment for young brain tumour survivors. The study also aims to find out how helpful ACT is for young brain tumour survivors' health and wellbeing.

### Who can participate?

Participants aged 11-to-24 years old who have been diagnosed with a brain tumour and completed treatment at least 6-months before starting the study.

### What does the study involve?

Participants will have a 50:50 chance of being placed into one of two groups: Half the study participants will be offered up to 12 weekly sessions of ACT straight away and the other half will be offered ACT after a 12-week wait. The effect of ACT straight away will be compared to those waiting. Every 3-months during this 12-week period participants will be asked to fill in some questionnaires about their health and experience of ACT.

### What are the possible benefits and risks of participating?

Acceptance and Commitment Therapy is an evidence-based psychological therapy shown to help improve the physical and mental wellbeing among people with long-term health problems. Therefore, it is expected that participants may experience improvements in their health as a result of taking part.

The intervention is expected to reduce not cause distress, but some participants may experience transitory increases in distress during treatment or find it distressing to be asked about emotions in questionnaires. Therefore, treatment procedures include standardised assessment of participant experience of therapy at every session to enable therapists to be responsive to participant distress. Furthermore, all assessment interviews with participants will be carried out by qualified clinical psychologists who are able to manage any distress related to questionnaires.

Where is the study run from?

Nottingham University Hospitals NHS Trust, University Hospitals Bristol NHS Foundation Trust, and Newcastle-Upon-Tyne Hospitals NHS Foundation Trust (UK).

When is the study starting and how long is it expected to run for?

From September 2018 to March 2023

Who is funding the study?

The Brain Tumour Charity (UK)

Who is the main contact?

Dr Sophie Thomas,  
sophie.thomas@nhs.net

## Contact information

### Type(s)

Principal Investigator

### Contact name

Dr Sophie Thomas

### Contact details

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United Kingdom  
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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

266746

### ClinicalTrials.gov number

NCT04722237

### Secondary identifying numbers

CPMS 47122, IRAS 266746

## Study information

**Scientific Title**

Acceptance and commitment therapy for young brain tumour survivors: an acceptability and feasibility trial

**Acronym**

ACT NOW

**Study objectives**

1. That ACT will be acceptable and feasible as a psychological treatment to improve quality of life among young brain tumour survivors aged 11-24
2. That ACT will be acceptable and feasible when delivered remotely via video-conferencing
3. That ACT will be clinically effective in improving secondary health and functioning outcomes

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 24/11/2020, East Midlands - Nottingham 1 Research Ethics Committee (HRA1 Meeting Room, The Old Chapel, Royal Standard Place, Nottingham NG1 6FS; +44 (0)207 104 8115; Nottingham1.rec@hra.nhs.uk), ref: 20/EM/0237

**Study design**

Multi-centre randomized waitlist controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

See additional files for parents (ISRCTN10903290\_PIS\_parent\_v4.0\_27Oct2020), for participants aged 11-15 years (ISRCTN10903290\_PIS\_11to15yrs\_v0.3\_27Oct2020), and for participants aged 16-24 years (ISRCTN10903290\_PIS\_16to24yrs\_v4.0\_27Oct2020)

**Health condition(s) or problem(s) studied**

Psychosocial oncology and survivorship, mental health, psychological wellbeing, young brain tumour survivors, malignant neoplasms of eye, brain and other parts of central nervous system

**Interventions**

The study aims to recruit 72 patients in total over a 12 month period. The researchers and clinical staff at each site will identify eligible participants according to the inclusion and exclusion criteria. Eligible participants will be provided with an age-appropriate information sheet by the clinical team and researcher who will invite the patient and parent (if desired in

over 16-year-olds) to participate during their clinical visit. They will also provide an overview of the study and what it entails. Adequate time will be given to families to read the information and decide whether they would like to participate. If those approached decide they would like to participate informed assent will be sought from participants under 16 years old and informed consent from their parents. Informed consent will directly be sought from participants aged 16 and over.

All of those recruited will be asked to express interest and consent to taking part in qualitative interviews after their treatment. Up to 15 of those consenting will be approached to take part in interviews where participants can describe their experience of the study and treatment they received.

Treatment within the study will involve up to 12 sessions of ACT, each lasting 1 h, delivered weekly over video-conferencing. Participants will then be randomly placed (1:1 ratio) into one of two groups, either ACT offered either straight away or after a 12-week wait. Randomisation will be conducted using established randomisation software (<https://www.sealedenvelope.com/>). Researchers and participants will not be blind to trial arm allocation. Treatment will begin with written and verbal guidance on the use of video-conferencing software, how to use it safely, and how to get the most out of the medium.

Receiving treatment via video-conferencing will be the default modality for delivery. However, face-to-face treatment will be offered if internet access or appropriate device use is not possible for participants who are otherwise eligible and willing to meet in person. The reasons given for declining participation will be routinely sought, where patients are happy to give a reason, so that face-to-face inclusion can be offered. Any face-to-face meetings will be aligned with COVID-19 safety restrictions and guidelines at the time. Video-conferencing delivery will be supported with telephone contact to enable contingency management for any difficulties with internet connection that may be experienced.

At baseline, 3, 6, 9, and 12-month follow-up participants (and their parents for those under 16) will be asked to complete a series of health-related questionnaires to assess any changes over the course of their involvement. Those identified to take part in experiential interviews will be invited to conduct this interview after they have completed their final ACT session. Participants will be asked to complete the following questionnaires:

1. Strengths and Difficulties Questionnaire
2. Generalised Anxiety Disorder assessment
3. Patient Health Questionnaire for depression
4. Euroqol quality of life assessment
5. World Health Organisation wellbeing index
6. Patient-Reported Outcomes Measurement Information System- Satisfaction with Social Roles and Activities
7. Avoidance and Fusion Questionnaire for Youth (for participants aged 11 to 15 years)
8. Acceptance and Action Questionnaire (for participants aged 16 to 24 years)
9. Client Service Receipt Inventory (at 3 and 12 months only)
10. Experience of Service Questionnaire (at 3 and 6 months only)

The parent/carer of participants aged 11 to 15 years will be asked to complete appropriate versions of the Strengths and Difficulties Questionnaire and the Client Service Receipt Inventory.

A statistician will be consulted for advice on the analysis. Feasibility and acceptability will be assessed by comparing the number of participants approached with the number recruited and the proportion of participants completing treatment. Analysis of clinical change will compare 3-month outcomes of those receiving ACT straight away with those waiting for the same period.

Change in outcomes will also be measured over the 12-month follow-up period. Thematic analysis will be utilised for the interview data.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

Current primary outcome measures as of 14/05/2021:

1. Feasibility will be assessed by documenting the proportion of patients showing interest who then consent to the trial and complete the intervention. Completion is defined as attending five or more ACT sessions.
  2. Fidelity to the ACT therapeutic model will be assessed monthly and then bi-monthly using the ACT Fidelity Measure
  3. Acceptability will be assessed using the following assessments:
    - 3.1. Session attendance rate
    - 3.2. The credibility of the treatment assessed using the Credibility/Expectancy Questionnaire (CEQ) at baseline and at session 2 of treatment
    - 3.3. Patient evaluations of treatment assessed using the Evaluation of Service Questionnaire (ESQ) at 3 months (for those in the immediate treatment arm) or 6 months (for those in the waitlist arm).
  4. Participant experience assessed by inviting a purposive sample of participants to give a semi-structured qualitative interview about their experience of the treatment after it is completed. They will also be asked to keep a reflective diary of their experiences after each session.
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Previous primary outcome measures:

1. Psychological inflexibility measured using the Acceptance and Action Questionnaire II (AAQ-II) for 16-24-year-olds and the Avoidance and Fusion Questionnaire for Youth (AFQ-Y8) for 11-15-year-olds at baseline, 3, 6, 9, and 12 months
2. Wellbeing measured using the World Health Organisation wellbeing index (WHO-5) at baseline, 3, 6, 9, and 12 months; and the Outcome Rating Scale at baseline, each treatment session, then at 3, 6, 9, and 12 months
3. Generalised anxiety measured using the Generalised Anxiety Disorder assessment (GAD-7) at baseline, 3, 6, 9, and 12 months
4. Depression measured using the Patient Health Questionnaire (PHQ-9) at baseline, 3, 6, 9, and 12 months
5. Quality of life assessed using the Euroqol 5-dimensions 3-levels (EQ-5D-3L) for 16-24-year-olds and the Euroqol 5-dimensions youth version (EQ-5D-Y) at baseline, 3, 6, 9, and 12 months
6. Social engagement measured with the Patient-Reported Outcomes Measurement Information System, Satisfaction with Social Roles and Activities (PROMIS) at baseline, 3, 6, 9, and 12 months
7. Functioning assessed using the Strengths and Difficulties Questionnaire (SDQ) at baseline, 3, 6, 9, and 12 months
8. Health service usage measured using the Client Service Receipt Inventory (CSRI) at baseline 3 and 12 months
9. The credibility of the treatment assessed using the Credibility/Expectancy Questionnaire (CEQ) at baseline and at session 2 of treatment
10. Patient evaluations of treatment assessed using the Evaluation of Service Questionnaire (ESQ) at 3 months (for those in the immediate treatment arm) or 6 months (for those in the waitlist arm).

## **Secondary outcome measures**

Current secondary outcome measures as of 14/05/2021:

Initial evidence of clinical efficacy will be assessed as secondary outcomes, using a range of health assessments:

1. Psychological inflexibility measured using the Acceptance and Action Questionnaire II (AAQ-II) for 16-24-year-olds and the Avoidance and Fusion Questionnaire for Youth (AFQ-Y8) for 11-15-year-olds at baseline, 3, 6, 9, and 12 months
2. Wellbeing measured using the World Health Organisation wellbeing index (WHO-5) at baseline, 3, 6, 9, and 12 months; and the Outcome Rating Scale at baseline, each treatment session, then at 3, 6, 9, and 12 months
3. Generalised anxiety measured using the Generalised Anxiety Disorder assessment (GAD-7) at baseline, 3, 6, 9, and 12 months
4. Depression measured using the Patient Health Questionnaire (PHQ-9) at baseline, 3, 6, 9, and 12 months
5. Quality of life assessed using the Euroqol 5-dimensions 3-levels (EQ-5D-3L) for 16-24-year-olds and the Euroqol 5-dimensions youth version (EQ-5D-Y) at baseline, 3, 6, 9, and 12 months
6. Social engagement measured with the Patient-Reported Outcomes Measurement Information System, Satisfaction with Social Roles and Activities (PROMIS) at baseline, 3, 6, 9, and 12 months
7. Functioning assessed using the Strengths and Difficulties Questionnaire (SDQ) at baseline, 3, 6, 9, and 12 months
8. Health service usage measured using the Client Service Receipt Inventory (CSRI) at baseline 3 and 12 months
9. The credibility of the treatment assessed using the Credibility/Expectancy Questionnaire (CEQ) at baseline and at session 2 of treatment
10. Patient evaluations of treatment assessed using the Evaluation of Service Questionnaire (ESQ) at 3 months (for those in the immediate treatment arm) or 6 months (for those in the waitlist arm)

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Previous secondary outcome measures:  
There are no secondary outcome measures.

### **Overall study start date**

01/09/2018

### **Completion date**

31/03/2023

## **Eligibility**

### **Key inclusion criteria**

1. Aged 11 to 24 years
2. Have had a historical primary diagnosis of brain tumour
3. Have stable disease and either off treatment or on low-intensity treatment
4. Sufficient understanding of English to engage with the intervention (spoken and written), as judged by the assessing clinician
5. Sufficient cognitive, sensory, and speech capabilities to take part in the intervention
6. Oral and written informed consent to participate in the study given by participants (or their parents if under 16)
7. Participants give written assent if under 16 years old

8. Access to the internet and appropriate devices to receive treatment over video-conferencing (the default modality for delivery). However, face-to-face treatment will be offered if internet access or appropriate device use is not possible for participants who are otherwise eligible.

**Participant type(s)**

Patient

**Age group**

Mixed

**Sex**

Both

**Target number of participants**

Planned Sample Size: 72; UK Sample Size: 72

**Key exclusion criteria**

1. Previous structured behavioural intervention within the last 6 months
2. Previous or current alcohol/substance dependence, psychosis, suicidality, or anorexia nervosa
3. Moderate/severe intellectual disability
4. Immediate risk to self or others
5. Parent or child not able to speak or read/write English

**Date of first enrolment**

04/01/2021

**Date of final enrolment**

31/03/2022

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Nottingham University Hospitals NHS Trust**

Trust Headquarters Queens Medical Centre

Derby Road

Nottingham

United Kingdom

NG7 2UH

**Study participating centre**

**University Hospitals Bristol NHS Foundation Trust**

Marlborough Street

Bristol  
United Kingdom  
BS1 3N

**Study participating centre**  
**Newcastle Upon Tyne Hospitals NHS Foundation Trust**  
Freeman Hospital  
Freeman Road  
High Heaton  
Newcastle upon Tyne  
United Kingdom  
NE7 7DN

## **Sponsor information**

**Organisation**  
Nottingham University Hospitals NHS Trust

**Sponsor details**  
Trust Headquarters  
R&I, Room 2600, C Floor, South Block, Queens Medical Centre  
Derby Road  
Nottingham  
England  
United Kingdom  
NG7 2UH  
+44(0)115 970 9049  
[researchsponsor@nuh.nhs.uk](mailto:researchsponsor@nuh.nhs.uk)

**Sponsor type**  
Hospital/treatment centre

**Website**  
<http://www.nuh.nhs.uk/>

**ROR**  
<https://ror.org/05y3qh794>

## **Funder(s)**

**Funder type**  
Charity



**Funder Name**

Brain Tumour Charity

**Alternative Name(s)**

The Brain Tumour Charity

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

Planned publication in a high-impact peer reviewed journal.

**Intention to publish date**

31/12/2023

**Individual participant data (IPD) sharing plan**

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

**IPD sharing plan summary**

Other

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	version v0.3	27/10/2020	07/12/2020	No	Yes
<a href="#">Participant information sheet</a>	version v4.0	27/10/2020	07/12/2020	No	Yes
<a href="#">Participant information sheet</a>	version v4.0	27/10/2020	07/12/2020	No	Yes
<a href="#">Protocol article</a>		01/06/2021	13/08/2021	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No