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

Submission date	**Recruitment status**	[X] Prospectively registered
26/11/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/12/2020	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
08/03/2023	Cancer	[_] 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,
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Contact information

Type(s)
Principal Investigator

Contact name
Dr Sophie Thomas

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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 (at3 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 qualitativeinterview 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
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Derby Road
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United Kingdom
NG7 2UH
+44(0)115 970 9049
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?
Participant information sheet	version v0.3	27/10/2020	07/12/2020	No	Yes
Participant information sheet	version v4.0	27/10/2020	07/12/2020	No	Yes
Participant information sheet	version v4.0	27/10/2020	07/12/2020	No	Yes
Protocol article		01/06/2021	13/08/2021	Yes	No
HRA research summary			28/06/2023	No	No