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Acceptance and commitment therapy for older people with treatment-resistant generalised anxiety disorder

Submission date
09/12/2022

Recruitment status
Recruiting

Registration date
04/01/2023

Overall study status
Ongoing

Last Edited
15/07/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Generalised anxiety disorder (GAD), characterised by a tendency to worry, is the most common anxiety disorder in older people. Medication and talking therapy are usually offered as forms of treatment, but many do not find them helpful. Guidance on how to help older people manage GAD when it does not respond to such treatments is lacking. In a previous study (the FACTOID study), we developed and tailored a talking therapy intervention to the psychological, physical and cognitive needs of older people with treatment-resistant GAD (TR GAD). This was based on Acceptance and Commitment Therapy (ACT); a form of talking therapy that helps people learn how best to live with distressing thoughts, feelings and sensations, while still doing things that really matter to them. This showed that tailored ACT was acceptable to older people with TR-GAD and it may help improve anxiety, depression and coping. The aim of CONTACT-GAD is to find out whether tailored ACT is helpful for older people with TR-GAD and whether it represents value for money in a larger clinical trial.

Who can participate?
People aged 60 years and over with TR-GAD that has failed to respond to a previous drug and/or talking treatments or those with TR-GAD who did not want to start or continue these treatments previously and still have symptoms of GAD

What does the study involve?
Participants will be allocated at random to either have tailored ACT plus usual care (intervention group) or usual care alone (control group). We will test whether ACT plus usual care leads to a greater reduction in anxiety than usual care alone at 6 months. We will follow people up at 12 months to see if any effects are maintained. We will also look at ACT's value for money, quality of life, depression, adverse effects, satisfaction with ACT and usual care, adherence and behaviour change.

What are the possible benefits and risks of participating?
The main possible benefit is that participants may receive a new type of psychological therapy that has been shown to benefit people with other mood disorders such as depression. The main

possible risk is that participants may experience distress when discussing their current situation in assessments and therapy sessions, or participants' mood may worsen after receiving ACT. Participants remain under the care of their clinical team during the study and will be monitored and referred for further support if necessary.

Where is the study run from?
University College London (UK)

When is the study starting and how long is it expected to run for?
August 2022 until July 2026

Who is funding the study?
1. National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) programme (UK)
2. National Health Medical Research Centre - National Institute for Health and Care Research (NHMRC-NIHR) Collaborative Research Grant Scheme (Australia)

Who is the main contact?
Prof. Rebecca Gould (r.gould@ucl.ac.uk) (UK)

Study website
https://www.ucl.ac.uk/psychiatry/contact-gad

Contact information

Type(s)
Principal Investigator

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
320523

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 54812, IRAS 320523

Study information

Scientific Title
A randomised CONtrolled trial of Tailored Acceptance and Commitment Therapy for older people with treatment-resistant generalised anxiety disorder (CONTACT-GAD)

Acronym
CONTACT-GAD

Study objectives
Tailored acceptance and commitment therapy plus usual care will be more clinically and cost-effective at reducing anxiety in older people with treatment-resistant generalised anxiety disorder in comparison to usual care alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/12/2022, West of Scotland REC 5 (West of Scotland Research Ethics Service, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, Scotland; +44 (0)141 314 0213; WoSREC5@ggc.scot.nhs.uk), ref: none provided

Study design
Randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice, Home, Hospital, Internet/virtual

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Treatment-resistant generalised anxiety disorder (TR-GAD)

Interventions
Treatment allocation:
Participants will be randomly allocated 1:1 to either the intervention group (Acceptance and Commitment Therapy [ACT] plus usual care) or the control group (usual care alone). Participants will not be blinded to allocation.

ACT plus usual care (intervention group):
Participants will be offered up to 14, 1:1 ACT sessions, with each session lasting up to 1 hour, over 6 months, plus a booster session at approximately 3-months post-intervention. There will be a phased ending to the sessions, such that they will be approximately weekly for the first 12 sessions and then approximately fortnightly thereafter, as some older people with generalised anxiety disorder (GAD) can experience difficulties when therapy ends abruptly. Sessions will be delivered in person in the outpatient clinic, GP surgery or participant's home, or via video call or telephone call (where videoconference facilities are not available), depending on participant preference, therapist availability and service restrictions. Therapists who will deliver ACT will be Band 7 or Band 8 clinical psychologists, counselling psychologists, psychotherapists or cognitive behavioural therapy (CBT) therapists who are based in primary or secondary care services, with ≥ 1 year experience of delivering psychotherapy interventions. Ideally, two or more therapists from each recruiting site will be identified, though this will vary across sites depending on therapist availability. All therapists will receive training in ACT and in the delivery of the intervention to older people with treatment-resistant (TR)-GAD. All therapists will attend a 4-day experiential ACT training workshop via video call, delivered by trained members of the research team with a minimum of five years of experience in delivering ACT, as well as experience in training therapists to deliver ACT in clinical trials. Training will be conducted via video call in order to accommodate therapists being located in geographically diverse regions across the UK. Participants in this group will receive usual care in addition to ACT, with the exception of formal psychological therapies such as CBT since this may lead to conflicts in therapeutic approaches and goals.

Usual care (control group):
Participants in this group will receive usual care, as outlined in NICE clinical guideline 113 for GAD.

Supervision of therapists delivering ACT:
Therapists will be invited to attend group supervision and consultation via video call on a fortnightly basis, though sessions will be provided weekly to make them as accessible as possible. Group supervision and consultation will be provided by trained members of the research team with a minimum of five years of experience in delivering ACT, as well as experience in supervising ACT, including within a clinical trial. Anonymised supervision notes will be recorded in each session and made available to both supervisors and therapists, and supervisors will observe some of each other's sessions to ensure that a consistent approach is used with therapists. In addition to group supervision and consultation via video call, therapists will be able to receive support through a secure, supervisor-moderated online forum. Therapists will be able to discuss anonymised issues arising in intervention delivery with supervisors and other therapists. The flexibility of this approach means that therapists will have the opportunity to receive supervisor and peer support between fortnightly group supervision and consultation sessions.

Intervention Type
Behavioural

Primary outcome measure
Generalised anxiety disorder measured using the Generalised Anxiety Disorder Assessment (GAD-7) at baseline (0 months), 6-months post-randomisation (the primary endpoint), and 12 months post-randomisation

Secondary outcome measures
Current secondary outcome measures as of 05/05/2023:
All secondary outcome measures are measured at baseline (0 months), 6-months post-randomisation, and 12 months post-randomisation, with three exceptions. The Client Satisfaction Questionnaire-8 will only be collected at the 6-month follow-up. Adverse events will be collected at 6- and 12-month follow-ups. Data on session attendance for those in the ACT arm will be collected after each session. Secondary outcome measures are as follows:
1. Quality of life measured using the McGill Quality of Life Questionnaire-Revised
2. Depression measured using the Geriatric Depression Scale-15
3. Psychological flexibility measured using the Comprehensive Assessment of ACT processes (CompACT)
4. Health and social care resource use measured using a modified version of the Client Service Receipt Inventory
5. Health-related quality of life measured using the EQ-5D-5L plus EQ-Visual Analogue Scale
6. Capability-adjusted life years measured using the ICECAP-O
7. Adverse events
8. Satisfaction with ACT and/or usual care measured using the Client Satisfaction Questionnaire-8
9. Personally meaningful behaviour change measured using the Goal-Based Outcomes tool
10. Cognitive and leisure activities measured using the Cognitive & Leisure Activity Scale
11. Adherence (i.e., session attendance for those in the ACT arm)

Previous secondary outcome measures:
All secondary outcome measures are measured at baseline (0 months), 6-months post-randomisation, and 12 months post-randomisation, with three exceptions. The Client

Satisfaction Questionnaire-8 will only be collected at the 6-month follow-up. Adverse events will be collected at 6- and 12-month follow-ups. Data on session attendance for those in the ACT arm will be collected after each session. Secondary outcome measures are as follows:
1. Quality of life measured using the McGill Quality of Life Questionnaire-Revised
2. Depression measured using the Geriatric Depression Scale-15
3. Psychological flexibility measured using the Comprehensive Assessment of ACT processes (CompACT)
4. Health and social care resource use measured using a modified version of the Client Service Receipt Inventory
5. Health-related quality of life measured using the EQ-5D-5L plus EQ-Visual Analogue Scale
6. Capability-adjusted life years measured using the ICECAP-O
7. Adverse events
8. Satisfaction with ACT and/or usual care measured using the Client Satisfaction Questionnaire-8
9. Personally meaningful behaviour change measured using the Goal-Based Outcomes tool
10. Adherence (i.e., session attendance for those in the ACT arm)

Overall study start date
01/08/2022

Completion date
31/07/2026

Eligibility

Key inclusion criteria
For older people with a treatment-resistant generalised anxiety disorder (TR-GAD):
1. People aged 60 years and over
2. Diagnosis of GAD using the Mini-International Neuropsychiatric Interview
3. GAD that is 'treatment resistant', defined as GAD that has failed to respond adequately to pharmacotherapy and/or psychotherapy treatment, as described in step 3 of the UK's stepped care model for GAD. GAD that has failed to respond adequately will be defined as continued symptoms of GAD that are still causing difficulties. Those who have been offered pharmacotherapy and/or psychotherapy treatment and did not want to start it or continue it and are still symptomatic will also be included in this definition. When determining whether GAD has failed to respond adequately to treatment, if a person has remitted and then relapsed in relation to GAD then any treatment received prior to remission will not be considered when deciding whether they meet the criteria for TR-GAD
4. Living in the community (i.e. those living in domestic residences or assisted living facilities, but not care homes)

The Mini-International Neuropsychiatric Interview has been modified for the purpose of this trial, with questions surrounding suicidality removed. The expression of suicidal ideation with active suicidal behaviours/plans and active intent is instead assessed via the Geriatric Suicide Ideation Scale, as detailed in the principal exclusion criteria.

For study therapists completing the qualitative satisfaction questionnaire:
1. Aged 18 years and over
2. Therapists involved in intervention delivery within the CONTACT-GAD trial

Participant type(s)
Patient

Age group
Adult

Lower age limit
60 Years

Sex
Both

Target number of participants
Planned Sample Size: 296; UK Sample Size: 296

Key exclusion criteria
Current participant exclusion criteria as of 05/05/2023:
For older people with TR-GAD:
1. Judged to lack the capacity to provide fully informed written consent to participate in the trial
2. A diagnosis of dementia or intellectual disability using standard diagnostic guidelines, or clinically judged to have moderate or severe cognitive impairment (e.g. due to probable dementia, traumatic brain injury, stroke, etc)
3. A diagnosis of an imminently life-limiting illness where they would not be expected to survive for the duration of the study
4. Expressing suicidal ideation with active suicidal behaviours/plans and active intent, as assessed using the Columbia-Suicide Severity Rating Scale Screener, for whom an inpatient admission would be more appropriate
5. Currently receiving a course of formal psychological therapy delivered by a formally trained psychologist or psychotherapist (e.g. cognitive behavioural therapy, psychodynamic psychotherapy, systemic therapy, counselling, etc), or those who are unwilling to refrain from engaging in such formal psychological therapy should they be randomly allocated to the ACT arm
6. Self-report having received ACT in the FACTOID feasibility study
7. Having already been randomised in the CONTACT-GAD trial or living with another person who has already been randomised in the CONTACT-GAD trial
8. Taking part in clinical trials of other interventions for GAD

Previous participant exclusion criteria:
For older people with TR-GAD:
1. Judged to lack the capacity to provide fully informed written consent to participate in the trial
2. A diagnosis of dementia or intellectual disability using standard diagnostic guidelines, or clinically judged to have moderate or severe cognitive impairment (e.g. due to probable dementia, traumatic brain injury, stroke, etc)
3. A diagnosis of an imminently life-limiting illness where they would not be expected to survive for the duration of the study
4. Expressing suicidal ideation with active suicidal behaviours/plans and active intent, as assessed using the Geriatric Suicide Ideation Scale, for whom an inpatient admission would be more appropriate
5. Currently receiving a course of formal psychological therapy delivered by a formally trained psychologist or psychotherapist (e.g. cognitive behavioural therapy, psychodynamic psychotherapy, systemic therapy, counselling, etc), or those who are unwilling to refrain from engaging in such formal psychological therapy should they be randomly allocated to the ACT arm
6. Self-report having received ACT in the FACTOID feasibility study
7. Having already been randomised in the CONTACT-GAD trial or living with another person who

has already been randomised in the CONTACT-GAD trial
8. Taking part in clinical trials of other interventions for GAD

Date of first enrolment
24/05/2023

Date of final enrolment
31/01/2026

Locations

Countries of recruitment
Australia

England

United Kingdom

Wales

Study participating centre
Humber Teaching NHS Foundation Trust
Trust Hq, Willerby Hill
Beverley Road
Willerby
Hull
United Kingdom
HU10 6ED

Study participating centre
Oxleas NHS Foundation Trust
Pinewood House
Pinewood PLACE
Dartford
United Kingdom
DA2 7WG

Study participating centre
Sheffield Health & Social Care NHS Foundation Trust
Centre Court
Atlas Way
Sheffield
United Kingdom
S4 7QQ

Study participating centre
Oxford Health NHS Foundation Trust
Warneford Hospital
Warneford Lane
Headington
Oxford
United Kingdom
OX3 7JX

Study participating centre
Lincolnshire Partnership NHS Foundation Trust
St George's
Long Leys Road
Lincoln
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LN1 1FS

Study participating centre
Midlands Partnership NHS Foundation Trust
Trust Headquarters
St Georges Hospital
Corporation Street
Stafford
United Kingdom
ST16 3SR

Study participating centre
Cardiff and Vale UHB
United Kingdom
CF14 4XW

Study participating centre
Cwm Taf Morgannwg Uhb
Cds, Dental Department
Treharris Health Centre
Treharris
United Kingdom
CF46 5HE

Study participating centre
Derbyshire Healthcare NHS Foundation Trust
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Kingsway Hospital
Kingsway
Derby
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DE22 3LZ

Study participating centre
Norfolk and Suffolk NHS Foundation Trust
Hellesdon Hospital
Drayton High Road
Norwich
United Kingdom
NR6 5BE

Study participating centre
Tees, Esk and Wear Valleys NHS Foundation Trust
Trust Headquarters
West Park Hospital
Edward Pease Way
Darlington
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DL2 2TS

Study participating centre
Barnet, Enfield and Haringey Mental Health NHS Trust
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N15 3TH

Study participating centre
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Study participating centre
Greater Manchester Mental Health NHS Foundation Trust
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Study participating centre
East London NHS Foundation Trust
Robert Dolan House
9 Alie Street
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E1 8DE

Study participating centre
Whittington Health NHS Trust
The Whittington Hospital
Magdala Avenue
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N19 5NF

Study participating centre
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The Lodge
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United Kingdom
SS11 7XX

Study participating centre
North East London NHS Foundation Trust
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C E M E Centre
Marsh Way

Rainham
United Kingdom
RM13 8GQ

Study participating centre
Surrey and Borders Partnership NHS Foundation Trust
18 Mole Business Park
Randalls Road
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United Kingdom
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Study participating centre
Macquarie University
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NSW 2113

Study participating centre
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1 Armstrong Way
Southall
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Sponsor information

Organisation
Camden and Islington NHS Foundation Trust

Sponsor details
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JML House
8 Regis Road
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England
United Kingdom
NW5 3EG

+44 (0)207 850 8507
sponsor.noclor@nhs.ne

Sponsor type
Hospital/treatment centre

Website
http://www.candi.nhs.uk/

ROR
https://ror.org/03ekq2173

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
National Health Medical Research Centre - National Institute for Health and Care Research (NHMRC-NIHR) Collaborative Research Grant Scheme (Australia)

Results and Publications

Publication and dissemination plan
Findings will be disseminated to the academic and clinical community, service users and the broader public through:
1. Planned publication in a high-impact peer-reviewed journal

2. Blogs about key findings
3. National and international academic conferences
4. Local clinical conferences and meetings
5. Talks to local groups, Primary Care Research Network, MIND and other organisations
6. University media releases, Twitter feeds and the University website
7. Training and seminars delivered via ACT special interest groups and professional bodies
8. Participants will have the option to receive a summary of findings once the trial has concluded

Intention to publish date
31/07/2027

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date