

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

<b>Submission date</b> 09/12/2022	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 04/01/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Protocol
<b>Last Edited</b> 28/01/2026	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> 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 December 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)

## Contact information

### Type(s)

Principal investigator

### Contact name

Prof Rebecca Gould

### ORCID ID

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Scientific

### Contact name

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### ORCID ID

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

320523

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

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

## **Study type(s)**

Treatment

## **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  $\geq 1$  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(s)**

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

## **Key secondary outcome(s)**

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)

**Completion date**

31/12/2026

## 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

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

60 years

**Upper age limit**

100 years

**Sex**

All

## **Total final enrolment**

0

## **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**

United Kingdom

England

Wales

Australia

**Study participating centre****Humber Teaching NHS Foundation Trust**

Trust Hq, Willerby Hill

Beverley Road

Willerby

Hull

England

HU10 6ED

**Study participating centre****Oxleas NHS Foundation Trust**

Pinewood House

Pinewood PLACE

Dartford

England

DA2 7WG

**Study participating centre****Sheffield Health & Social Care NHS Foundation Trust**

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S4 7QQ

**Study participating centre****Oxford Health NHS Foundation Trust**

Warneford Hospital

Warneford Lane

Headington

Oxford

England

OX3 7JX

**Study participating centre**

**Lincolnshire Partnership NHS Foundation Trust**

St George's  
Long Leys Road  
Lincoln  
England  
LN1 1FS

**Study participating centre**

**Midlands Partnership NHS Foundation Trust**

Trust Headquarters  
St Georges Hospital  
Corporation Street  
Stafford  
England  
ST16 3SR

**Study participating centre**

**Cardiff and Vale UHB**

Heath Park  
Cardiff  
Wales  
CF14 4XW

**Study participating centre**

**Cwm Taf Morgannwg Uhb**

Cds, Dental Department  
Treharris Health Centre  
Treharris  
Wales  
CF46 5HE

**Study participating centre**

**Derbyshire Healthcare NHS Foundation Trust**

Trust Headquarters  
Kingsway Hospital  
Kingsway  
Derby  
England  
DE22 3LZ

**Study participating centre**

**Norfolk and Suffolk NHS Foundation Trust**

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Drayton High Road  
Norwich  
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NR6 5BE

**Study participating centre**

**Tees, Esk and Wear Valleys NHS Foundation Trust**

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West Park Hospital  
Edward Pease Way  
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DL2 2TS

**Study participating centre**

**Barnet, Enfield and Haringey Mental Health NHS Trust**

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St Ann's Hospital  
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N15 3TH

**Study participating centre**

**Herefordshire and Worcestershire Health and Care NHS Trust**

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Charles Hastings Way  
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WR5 1JR

**Study participating centre**

**Greater Manchester Mental Health NHS Foundation Trust**

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**Study participating centre**  
**East London NHS Foundation Trust**  
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London  
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E1 8DE

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

**Study participating centre**  
**Essex Partnership University NHS Foundation Trust**  
The Lodge  
Lodge Approach  
Runwell  
Wickford  
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SS11 7XX

**Study participating centre**  
**North East London NHS Foundation Trust**  
West Wing  
C E M E Centre  
Marsh Way  
Rainham  
England  
RM13 8GQ

**Study participating centre**  
**Surrey and Borders Partnership NHS Foundation Trust**  
18 Mole Business Park  
Randalls Road

Leatherhead  
England  
KT22 7AD

**Study participating centre**  
**West London NHS Trust**  
1 Armstrong Way  
Southall  
London  
England  
UB2 4SD

## Sponsor information

**Organisation**  
Camden and Islington NHS Foundation Trust

**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

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Data sharing statement to be made available at a later date

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes