

# A study of Acceptance and Commitment Therapy for older people with chronic worry who have not responded to treatment

<b>Submission date</b> 23/01/2017	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/01/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 23/05/2022	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## 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. It is associated with distress, difficulty in coping, poor quality of life and increased disability. Medication and talking therapy are usually offered to older people experiencing GAD, but for many this treatment is unsuccessful. Guidance as to how best manage this treatment-resistant GAD in older people is lacking. Acceptance and Commitment Therapy (ACT) is a type of talking therapy helps people to learn different ways of coping with distressing thoughts and feelings, and how to take part in more activities that are meaningful to them. It is helpful for reducing distress in other conditions including anxiety, depression, life-limiting illness and long-term pain. The aim of this study is to find out how acceptable and feasible it is to develop and deliver a new treatment program based on ACT to older adults with GAD.

### Who can participate?

Older adults aged 65 years and over who have been diagnosed with GAD that has not responded to treatment (either medication and/or conventional talking therapy).

### What does the study involve?

In the first part of the study, around 15 older people with GAD take part in an hour and a half long interview about their experiences of treatment. Information collected from these interviews is then discussed with healthcare professionals in order to create a treatment programme using ACT techniques. The participants are then interviewed again for their views on the programme.

In the second part of the study, around 40 older people with GAD receive around 16 face-to-face sessions of ACT over 20 weeks plus usual care. These sessions are delivered within the GP surgery, outpatient clinic or participant's home by therapists attached to talking therapy and specialist mental health services. All therapists will receive training in ACT, as well as regular supervision. The sessions involve working with therapists to learn new skills to help better manage their GAD. At the start of the study and then again after 20 weeks, participants are asked to complete a number of questionnaires to assess levels of anxiety, worry, depression and quality of life, and to see how satisfied they are with the therapy they have received.

What are the possible benefits and risks of participating?

The main possible benefits include that participants will be given access to a novel form of talking therapy that is not yet available in the NHS for this condition. They will also be given a more in-depth screening assessment than they might otherwise receive as part of their routine NHS care. The main possible risks include that participants may experience a deterioration in anxiety and/or depression symptoms during the intervention (as it may not be beneficial for them) or distress during the interviews (e.g. when discussing their current difficulties). Participants will remain under the care of their GP or mental health professional during the study, and will be monitored and referred for further support if necessary.

Where is the study run from?

The first part of the study is taking place in multiple sites in:

1. Camden and Islington NHS Foundation Trust (lead trust) (UK)
2. South London and Maudsley NHS Foundation Trust (UK)
3. Oxford Health NHS Foundation Trust (UK)
4. Barnet Enfield and Haringey Mental Health Trust (UK)
5. Thames Valley CRN (UK)
6. North East London NHS Foundation Trust (UK)

The second part of the study is taking place in multiple sites in:

1. Camden and Islington NHS Foundation Trust (lead trust) (UK)
2. South London and Maudsley NHS Foundation Trust (UK)
3. Oxford Health NHS Foundation Trust (UK)
4. Barnet Enfield and Haringey Mental Health Trust (UK)
5. Whittington Health NHS Trust (UK)

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

May 2017 to September 2019

Who is funding the study?

National Institute for Health Research, Health Technology Assessment Programme (UK)

Who is the main contact?

Dr Rebecca Gould  
r.gould@ucl.ac.uk

## Contact information

### Type(s)

Scientific

### Contact name

Dr Rebecca Gould

### Contact details

Division of Psychiatry  
University College London  
Wing A, 6th floor Maple House  
149 Tottenham Court Rd  
London  
United Kingdom

W1T 7NF  
+44 (0)20 7679 9225  
r.gould@ucl.ac.uk

## Additional identifiers

### Protocol serial number

3

## Study information

### Scientific Title

A Feasibility study of Acceptance and Commitment Therapy for Older people with treatment-resistant generalised anxiety Disorder

### Acronym

FACTOID

### Study objectives

The aim of this study is to investigate the feasibility of conducting a study to examine the clinical and cost effectiveness of Acceptance and Commitment Therapy (ACT) for older people with treatment-resistant generalised anxiety disorder.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

1. London – Camberwell St Giles, 09/05/2017, ref: 17/LO/0704
2. HRA, 12/05/2017

### Study design

Uncontrolled non-randomised feasibility study

### Primary study design

Interventional

### Study type(s)

Treatment

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

Treatment-resistant generalised anxiety disorder in older people

### Interventions

Phase 1:

Approximately 15 older people with generalised anxiety disorder (GAD) will be invited to participate in individual qualitative interviews lasting 1.5 hours in order to develop and adapt the intervention for this population. These interviews will explore positive/negative experiences of previous psychotherapy, facilitators/barriers to engagement in therapy, and the perceived suitability and relevance of an intervention based on Acceptance and Commitment Therapy (ACT) for treatment-resistant GAD in older people. Data from these interviews, together with

discussions with experts in the field, will inform development of an intervention for this population. This will be based on the acceptance model of generalised anxiety disorder and existing ACT approaches. Once the intervention has been developed, the same set of participants from the initial interviews will be invited to participate in further individual qualitative interviews lasting 1.5 hours. These interviews will explore the acceptability and perceived value of the different components of the intervention, the practicalities of the intervention, and ways of optimising engagement. Modifications will be made to the intervention based on feedback from these interviews.

#### Phase 2:

Approximately 40 older people with treatment-resistant GAD will receive 16 1-hour face-to-face sessions of ACT over 20 weeks in addition to usual care. The intervention will involve helping participants to increase psychological flexibility through learning new skills, metaphors, experiential exercises and home practice tasks. These will aim to:

1. Reduce avoidance of difficult or uncomfortable experiences where such behaviour might be a barrier to life enriching activity
2. Reduce the amount of time people are "stuck in their head" ruminating about the past or worrying about the future
3. Reduce the degree to which people are caught up in negative or unhelpful thoughts about themselves, their situation or their identity and roles
4. Identify what really matters to them in their lives
5. Commit to doing personally meaningful activities that support what they value.

Sessions will be delivered within the GP surgery, outpatient clinic or participant's home by therapists attached to talking therapy and specialist mental health services. All therapists will receive training in ACT, as well as regular supervision. After 20 weeks, all participants will be followed up to assess how acceptable and feasible the intervention was. In addition, a sample of 15 participants and all therapists will also be invited to complete individual interviews lasting 1.5 hours to further assess acceptability and feasibility. These interviews will explore the perceived benefits and limitations of the intervention, together with any recommendations for revising it.

After 20 weeks, all participants will be followed up by an independent outcome assessor and the acceptability and feasibility of the intervention will be assessed.

#### **Intervention Type**

Other

#### **Primary outcome(s)**

Acceptability:

1. Engagement rate is recorded as the number of eligible participants who consent to participate in the study and attend 60% or more of sessions by 20 weeks (session attendance records will be kept by therapists)
2. Satisfaction rate is recorded as the number of eligible participants who consent to participate in the study and give 'satisfactory' ratings of therapy using the Satisfaction with Therapy and Therapist Scale-Revised (Oei et al., 2008) at 20 weeks. There is no set definition of what constitutes "satisfactory" and so this will be defined as a total score of 21 or more on the Satisfaction with Therapy subscale.

Feasibility:

1. Recruitment rate is recorded as the number of eligible participants who consent to participate

in the study by 10 months

2. Retention rate is recorded as the number of eligible participants who consent to participate that remain in the study until follow up at 20 weeks

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

Acceptability:

1. Failure to recruit rate due to lack of acceptability is recorded as the number of eligible participants who refuse to consent to participate in the study by 10 months due to lack of acceptability of the intervention

2. Attrition rate due to lack of acceptability is recorded as the number of eligible participants who consent to participate in the study that drop out due to lack of acceptability of the intervention by 20 weeks

3. Treatment credibility/expectancy is measured using the Credibility/Expectancy Questionnaire at 1 week

Feasibility:

1. Referral rate is recorded as the number of eligible referrals to the study overall and in each referral subgroup (self-referral, GPs, GP list searches, Improving Access to Psychological Therapies services, and Community Mental Health Teams) by 10 months

2. Failure to recruit rate for reasons other than lack of acceptability is recorded as the number of eligible participants who refuse to consent to participate in the study by 10 months for reasons other than dissatisfaction with therapy

3. Attrition rate for reasons other than lack of acceptability is recorded as the number of eligible participants who consent to participate in the study that drop out for reasons other than dissatisfaction with therapy by 20 weeks

4. Treatment integrity is measured using the ACT Treatment Integrity Coding Manual at 20 weeks

5. Treatment adherence is measured using the Adherence Checklist at 20 weeks

Patient-reported outcome measures:

1. Anxiety is measured using the Geriatric Anxiety Inventory at baseline and 20 weeks.

2. Worry is measured using the Penn State Worry Questionnaire at baseline and 20 weeks.

3. Depression is measured using the Geriatric Depression Scale-15 at baseline and 20 weeks.

4. Health-related quality of life is measured using the EQ-5D-5L at baseline and 20 weeks.

5. Service utilization is measured using a short modified version of the Client Service Receipt Inventory at baseline and 20 weeks.

6. Psychological flexibility is measured using the Acceptance and Action Questionnaire-II at baseline and 20 weeks.

### **Completion date**

30/09/2019

## **Eligibility**

### **Key inclusion criteria**

1. Aged 65 years and over

2. Primary diagnosis of GAD, as determined by the Structured Clinical Interview for DSM-IV Axis I and Axis II Disorders, that has failed to respond to treatment (medication or psychotherapy)

3. Living in the community

4. Able to provide informed, written consent

5. Sufficient understanding of English to enable engagement in ACT and completion of patient-

reported outcome measures

6. Added 31/08/2017: In Phase 2 only: Not previously participated in qualitative interviews in Phase 1 of the project

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Senior

### **Sex**

All

### **Total final enrolment**

37

### **Key exclusion criteria**

Currently inclusion criteria as of 31/08/2017:

1. Diagnosis of dementia
2. Standardised Mini-Mental State Examination score of <25
3. In Phase 2 only: Currently receiving ongoing psychotherapy or who are unwilling to refrain from engaging in other forms of psychotherapy during the receipt of ACT
4. Experiencing suicidal ideation with active intent for whom an inpatient admission would be more appropriate
5. Other medical or psychosocial factors that could compromise full study participation such as imminently life-limiting illness or severe sensory deficits (e.g. blindness)
6. Intellectual disabilities

Previous exclusion criteria:

1. Diagnosis of dementia
2. Standardised Mini-Mental State Examination score of <25
3. Currently receiving ongoing psychotherapy or who are unwilling to refrain from engaging in other forms of psychotherapy during the receipt of ACT
4. Experiencing suicidal ideation with active intent for whom an inpatient admission would be more appropriate
5. Other medical or psychosocial factors that could compromise full study participation such as imminently life-limiting illness or severe sensory deficits (e.g. blindness)

### **Date of first enrolment**

23/06/2017

### **Date of final enrolment**

31/10/2018

## **Locations**

### **Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Services for Ageing and Mental Health**

Camden Community Mental Health Team

The Peckwater Centre

1st floor

6 Peckwater Street

London

United Kingdom

NW5 2TX

**Study participating centre**

**Islington Services for Ageing and Mental Health**

Community Mental Health Team

Units 8-10 Blenheim Court

62 Brewery Road

London

United Kingdom

N7 9NY

**Study participating centre**

**Community Mental Health Team for Older Adults (Southwark)**

Marina House

63-65 Denmark Hill

Camberwell

London

United Kingdom

SE5 8RS

**Study participating centre**

**Community Mental Health Team for Older Adults (Lambeth)**

First Floor

Reay House

Lambeth Hospital

109 Landor Road

London

United Kingdom

SW9 9NT

**Study participating centre**

**Community Mental Health Team for Older Adults (Lewisham)**

91 Granville Park  
Lewisham  
London  
United Kingdom  
SE13 7DW

**Study participating centre**

**Community Mental Health Team for Older Adults (Croydon North)**

Heavers Resource Centre  
122 Selhurst Road  
London  
United Kingdom  
SE25 6LL

**Study participating centre**

**Community Mental Health Team for Older Adults (Croydon South)**

Purley Resource Centre  
50 Pampisford Road  
Purley  
United Kingdom  
CR8 2NE

**Study participating centre**

**Southwark Improving Access to Psychological Therapies**

Maudsley Psychology Centre  
Maudsley Hospital  
Denmark Hill  
London  
United Kingdom  
SE5 8AZ

**Study participating centre**

**Croydon Improving Access to Psychological Therapies**

Wickham Park House  
Bethlem Royal Hospital  
Monks Orchard Road  
Beckenham  
United Kingdom  
BR3 3BX

**Study participating centre**  
**Lambeth Talking Therapies Service (IAPT)**  
Adamson Centre  
South Wing  
St Thomas' Hospital  
Westminster Bridge Road  
London  
United Kingdom  
SE1 7EH

**Study participating centre**  
**Improving Access to Psychological Therapies Lewisham**  
Primary Care Psychological Therapies Service  
PO Box 61678  
London  
United Kingdom  
SE12 2AN

**Study participating centre**  
**Community Mental Health Team (Older Adult) - Central Oxfordshire**  
Manzil Resource Centre  
Manzil Way  
Oxford  
United Kingdom  
OX4 1XE

**Study participating centre**  
**Community Mental Health Team (Older Adult) - South Oxfordshire**  
Abingdon Hospital  
Marcham Road  
Abingdon  
United Kingdom  
OX14 1AG

**Study participating centre**  
**Community Mental Health Team (Older Adult) - North Oxfordshire**  
The Elms Centre  
Oxford Road  
Banbury  
United Kingdom  
OX16 9AL

**Study participating centre**

**Warneford Hospital**

Warneford Lane  
Headington  
Oxford  
United Kingdom  
OX3 7JX

**Study participating centre**

**The Whiteleaf Centre**

Bierton Road  
Aylesbury  
United Kingdom  
HP20 1EG

**Study participating centre**

**TalkingSpace Plus**

Oxbridge Court  
Osney Mead  
Oxford  
United Kingdom  
OX2 0ES

**Study participating centre**

**Healthy Minds Bucks**

Floor 2  
Prospect House  
Crendon Street  
High Wycombe  
United Kingdom  
HP13 6LA

**Study participating centre**

**Enfield Older People Community Mental Health Team**

Cumbria Villa  
Chase Farm Hospital  
The Ridgeway  
Enfield  
United Kingdom  
EN2 8JL

**Study participating centre**

**Haringey Mental Health Services for Older People**

Community Mental Health Team

Victoria Unit

St Ann's Hospital

St Ann's Road

London

United Kingdom

N15 3TH

**Study participating centre**

**Springwell Centre**

Barnet Hospital

Mental Health Services

Wellhouse Lane

Herts

United Kingdom

EN5 3DJ

**Study participating centre**

**Camden iCope (IAPT) Psychological Therapies & Wellbeing Service**

3rd floor

South Wing

St Pancras Hospital

4 St Pancras Way

London

United Kingdom

NW1 0PE

**Study participating centre**

**Islington iCope (IAPT) Psychological Therapies & Wellbeing Service**

Finsbury Health Centre

17 Pine St

London

United Kingdom

EC1R 0LP

**Study participating centre**

**Older People Community Services**

Refuge House

9-10 River Front

Enfield

United Kingdom  
EN1 3SZ

**Study participating centre**  
**IAPT, St Ann's General Hospital (Beh-Mht services)**  
St Ann's Road  
London  
United Kingdom  
N15 3TH

**Study participating centre**  
**Older Adults Mental Health Team**  
Broad St Health Centre  
Morland Road  
Dagenham  
United Kingdom  
RM10 9HU

**Study participating centre**  
**Havering Older Adults Mental Health Team**  
Yew Tree Resource Centre  
20 Yew Tree Gardens  
Romford  
United Kingdom  
RM7 9AA

**Study participating centre**  
**Older Adults Mental Health Team**  
Red Oak Lodge  
17 Thorne Close  
Langthorne Road  
Leytonstone  
United Kingdom  
E11 4HU

**Study participating centre**  
**IAPT**  
Goodmayes Hospital  
Barley Lane  
Goodmayes  
Essex

Ilford  
United Kingdom  
IG3 8XJ

## Sponsor information

**Organisation**  
UCLH/UCL

**ROR**  
<https://ror.org/042fqyp44>

## Funder(s)

**Funder type**  
Government

**Funder Name**  
Health Technology Assessment Programme

**Alternative Name(s)**  
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
National government

**Location**  
United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

The current 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

### Study outputs

<b>Output type</b>	<b>Details</b>	<b>Date created</b>	<b>Date added</b>	<b>Peer reviewed?</b>	<b>Patient-facing?</b>
<a href="#">Results article</a>	feasibility results	13/04/2021	26/04/2021	Yes	No
<a href="#">Results article</a>	qualitative results	01/09/2019	26/04/2021	Yes	No
<a href="#">Results article</a>	HTA report	01/09/2021	21/09/2021	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No