ISRCTN12268776 https://doi.org/10.1186/ISRCTN12268776

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

Submission date
23/01/2017

Recruitment status
No longer recruiting

Registration date
23/01/2017

Overall study status
Completed

Last Edited
23/05/2022

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 taking 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
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Contact information

Type(s)
Scientific

Contact name
Dr Rebecca Gould

Contact details
Division of Psychiatry
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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

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	feasibility results	13/04/2021	26/04/2021	Yes	No
Results article	qualitative results	01/09/2019	26/04/2021	Yes	No
Results article	HTA report	01/09/2021	21/09/2021	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes