Age and Ageing 2021; **50:** 1751–1761
https://doi.org/10.1093/ageing/afab059
Published electronically 13 April 2021

RESEARCH PAPER

Acceptance and commitment therapy for late-life treatment-resistant generalised anxiety disorder: a feasibility study

Rebecca L. Gould[1], Julie Loebach Wetherell[2,3], Kate Kimona[1], Marc A. Serfaty[1,4], Rebecca Jones[1], Christopher D. Graham[5], Vanessa Lawrence[6], Gill Livingston[1], Philip Wilkinson[7], Kate Walters[8], Marie Le Novere[8], Iracema Leroi[9], Robert Barber[10], Ellen Lee[11], Jo Cook[12], Viviana M. Wuthrich[13,14], Robert J. Howard[1], on behalf of the FACTOID group[†]

[1]Division of Psychiatry, Faculty of Brain Sciences, University College London, London, UK
[2]Mental Health Service, VA San Diego Healthcare System, San Diego, CA, USA
[3]Department of Psychiatry, University of California, San Diego, CA, USA
[4]Priory Hospital North London, London, UK
[5]School of Psychology, Queen's University Belfast, Belfast, Northern Ireland
[6]Health Services and Population Research Department, Institute of Psychiatry, Psychology & Neuroscience, King's College London, London, UK
[7]Department of Psychiatry, University of Oxford, Oxford, UK
[8]Department of Primary Care and Population Health, University College London, London, UK
[9]Global Brain Health Institute, School of Medicine, Trinity College Dublin, Dublin, Ireland
[10]Centre for Health of the Elderly, Campus for Ageing and Vitality, Newcastle University, Newcastle upon Tyne, UK
[11]Clinical Trials Research Unit, School of Health and Related Research, University of Sheffield, Sheffield, UK
[12]The Bexleyheath Centre, Oxleas NHS Foundation Trust, Bexleyheath, UK
[13]Department of Psychology, Centre for Emotional Health, Macquarie University, Sydney, Australia
[14]Department of Psychology, Centre for Ageing, Cognition and Wellbeing, Macquarie University, Sydney, Australia

Address correspondence to: Rebecca L. Gould, Tel: +44 (0) 20 7679 9225. Email: r.gould@ucl.ac.uk

[†]The following are members of the FACTOID group: Steve Boddington, Julia Brownlie, Rachel Butterfield, Lisa Carmody, Georgina Charlesworth, Charlotte Gardner, Danielle Gaynor, Rachel Holliss, Debbie Hunt, Joana Johnson, Maitri Khurana, Eva Klamerus, Gemma Knight, Victoria Lawson, Ruth Lukeman, Monique Maroney, Eleanor Martin, Aska Matsunaga, Alison Milton, Harry O'Hayon, Meenaxi Patel, Dhriti Ratra, Catherine Simpson, Nicola Stanhope, Debbie Walker, Janet Wingrove and Grace Wong.

Abstract

Background: Generalised anxiety disorder (GAD) is the most common anxiety disorder in older people. First-line management includes pharmacological and psychological therapies, but many do not find these effective or acceptable. Little is known about how to manage treatment-resistant generalised anxiety disorder (TR-GAD) in older people.

Objectives: To examine the acceptability, feasibility and preliminary estimates of the effectiveness of acceptance and commitment therapy (ACT) for older people with TR-GAD.

Participants: People aged ≥65 years with TR-GAD (defined as not responding to GAD treatment, tolerate it or refused treatment) recruited from primary and secondary care services and the community.

Intervention: Participants received up to 16 one-to-one sessions of ACT, developed specifically for older people with TR-GAD, in addition to usual care.

Measurements: Co-primary outcomes were feasibility (defined as recruitment of ≥32 participants and retention of ≥60% at follow-up) and acceptability (defined as participants attending ≥10 sessions and scoring ≥21/30 on the satisfaction with therapy subscale). Secondary outcomes included measures of anxiety, worry, depression and psychological flexibility (assessed at 0 and 20 weeks).

Results: Thirty-seven participants were recruited, 30 (81%) were retained and 26 (70%) attended ≥10 sessions. A total of 18/30 (60%) participants scored ≥21/30 on the satisfaction with therapy subscale. There was preliminary evidence suggesting that ACT may improve anxiety, depression and psychological flexibility.
Conclusions: There was evidence of good feasibility and acceptability, although satisfaction with therapy scores suggested that further refinement of the intervention may be necessary. Results indicate that a larger-scale randomised controlled trial of ACT for TR-GAD is feasible and warranted.

Keywords: older people, generalised anxiety disorder, treatment-resistant, acceptance and commitment therapy, feasibility

Key Points

- There is a lack of evidence to guide the management of treatment-resistant GAD (TR-GAD) in older people.
- A psychological intervention based on acceptance and commitment therapy (ACT) was developed for older people with TR-GAD.
- ACT was feasible and acceptable to older people with TR-GAD, but further refinement of the intervention may be necessary.
- There was preliminary evidence of improvements in anxiety, depression and psychological flexibility, which is promising.
- Further research is needed to establish the clinical and cost-effectiveness of ACT for older people with TR-GAD.

Introduction

Generalised anxiety disorder (GAD) is the most common anxiety disorder in older people, with an estimated prevalence of 1.2–11.2% [1]. It is characterised by excessive anxiety and worry, including feelings of fear, dread and uneasiness, experienced as being difficult to control, on more days than not for at least 6 months [2]. Other symptoms include restlessness or feeling on edge, fatigue, irritability, muscle tension and difficulties with concentrating and sleeping. It may persist for decades, with a mean symptom duration of 20–30 years [3]. It is associated with numerous negative outcomes in older people, including poorer health-related quality of life, increased disability and greater healthcare utilisation in comparison to non-anxious older people [4]. Comorbidity with other mood and personality disorders is common and is associated with poorer outcomes [5].

First-line management of GAD includes pharmacotherapy (e.g. selective serotonin reuptake inhibitors) and psychotherapy (e.g. cognitive behavioural therapy (CBT) and applied relaxation). However, many older people with GAD find these treatments ineffective, lacking acceptability (e.g. due to side effects) or unable to produce a sustained benefit [6], leaving clinicians uncertain as to how best to manage this condition. At present, there is a lack of evidence to guide the management of GAD that has not responded adequately to first-line pharmacological and psychological interventions (i.e. treatment-resistant GAD [TR-GAD] [7]). For example, a previous systematic review was unable to identify any randomised controlled trial (RCT) or prospective comparative observational study of pharmacotherapy or psychotherapy for treatment-resistant anxiety in older people [8].

Meta-analytic evidence of lower efficacy of CBT for GAD in older people compared to working-age adults [9] suggests that an alternative form of psychological intervention may be required for managing TR-GAD in older people. One such alternative is acceptance and commitment therapy (ACT), an acceptance-based behaviour therapy [10] with a strong evidence base in chronic pain [11], and a growing evidence base in mental health conditions [12]. It aims to help people (i) deal with uncomfortable thoughts, emotions and sensations; (ii) clarify what is important and meaningful to them in their lives (i.e. their values); and (iii) identify ways to best live their lives in accordance with their values, alongside their uncomfortable experiences. With its focus on increasing adaptive functioning and how best to live with uncomfortable thoughts, emotions and sensations (as opposed to challenging, changing or trying to eliminate them), ACT may be particularly appropriate for older people with TR-GAD who have not derived benefit from interventions focused directly on controlling such experiences [6]. Evidence that control-orientated strategies (e.g. trying to eliminate problems that cannot be solved) are detrimental to older people's well-being further supports this notion [13]. Another alternative is interpersonal psychotherapy, which focuses on reducing problematic mood by addressing interpersonal relationship issues [14]. Although such issues may be particularly relevant to older people, interpersonal psychotherapy may be less applicable to those with TR-GAD as it is subject to the arguments noted above.

To date, only one small study of ACT has been conducted in older people with GAD [15]. This preliminary RCT of ACT vs. CBT reported improvements in worry or anxiety and depression with both interventions, but higher treatment completion rates with ACT compared to CBT. Although results were promising, this study was limited by a small sample size ($n = 16$) and did not focus specifically on those with TR-GAD. Therefore, it is not known whether an approach that focuses on 'living with' rather than 'getting rid of' uncomfortable experiences is acceptable to older people with TR-GAD. Consequently, the aims of this study were to examine the acceptability and feasibility of ACT for older people with TR-GAD and to obtain preliminary estimates of potential effectiveness.

Methods

All reporting is in accordance with the Consolidated Standards of Reporting Trials and Template for Intervention

Description and Replication guidelines (checklists are presented in Appendices 1 and 2, available in *Age and Ageing* online). Additional details about study methods are provided in Appendix 3, available in *Age and Ageing* online. Ethical approval was granted by the London-Camberwell St Giles Research Ethics Committee (17/LO/1314).

Design

A pre-registered, uncontrolled, feasibility study (ISRCTN Registry ISRCTN12268776). An uncontrolled study rather than pilot RCT was conducted as specified by the commissioning funder.

Participants

Participants were recruited from general practitioner (GP) practices, primary and secondary care services within London, UK, and the community. Eligible participants:

(1) Were aged ≥65 years with a primary diagnosis of GAD as determined by the MINI International Neuropsychiatric Interview [16] and the Structured Clinical Interview for diagnostic and statistical manual of mental disorders (DSM)-IV Axis II Disorders [17];
(2) Had failed to respond to first-line treatment (i.e. still experiencing moderate-to-severe GAD after 6 weeks of an age-appropriate dose of antidepressant medication or a course of individual psychotherapy [7]), failed to tolerate this treatment, or previously refused it and remained symptomatic;
(3) Were community living;
(4) Had capacity to provide informed consent for participation;
(5) Had sufficient English to understand study materials;
(6) Had not participated in previous qualitative interviews [6];
(7) Had at least a 1 month interval between previous psychotherapy and engagement in ACT.

Procedure

Potential participants were identified and approached about the study through local clinicians and research databases, list searches of GP electronic medical records and community leaflets and advertisements. Service users were pre-screened using the Generalised Anxiety Disorder-7 (GAD-7) [18], and verbal consent for contact was sought from those scoring ≥11 on this scale (i.e. at least moderate GAD). Participants who provided written informed consent and met eligibility criteria were invited to participate.

Intervention

We used systematic, qualitative methods to develop and optimise the relevance, acceptability and feasibility of a manualised intervention for older people with TR-GAD [6]. The intervention comprised up to 16 one-to-one, face-to-face sessions of ACT, with each session lasting up to 1 hour. Sessions were delivered in person within the GP practice, outpatient clinic or participant's home, as soon as a therapist became available. The first 14 sessions were weekly, while the subsequent sessions were fortnightly in order to facilitate ending of the intervention. Each session was associated with a specific set of skills, metaphors, experiential exercises and home practice tasks. All participants received usual care in addition to ACT, comprising assessment, medication review and management within primary or secondary care. Therapists were qualified clinical psychologists, CBT therapists or counselling psychologists, with a minimum of 1 year's experience in delivering psychotherapy interventions. Therapists were provided with weekly telephone group supervision and consultation.

Treatment fidelity

All therapy sessions were recorded using encrypted digital voice recorders. Ten percent of sessions were randomly selected (stratified by therapist, phase of intervention and phase of study recruitment) and assessed for treatment fidelity by independent ACT therapists using an adapted form of the ACT Treatment Integrity Coding Manual [19].

Data collection

A range of socio-demographic and clinical data were collected face-to-face at screening and baseline. Data collection was conducted face-to-face or via telephone at 20-week follow-up. Baseline assessments were completed in the 2 weeks prior to starting ACT.

Outcomes

The primary outcomes were

(i) Acceptability:
   (a) Participants attending ≥60% sessions (i.e. ≥10 sessions);
   (b) 'Satisfactory' ratings of therapy on the satisfaction with therapy subscale of the Satisfaction with Therapy and Therapist Scale-Revised [20] at 20-week follow-up. There is no set definition of what constitutes 'satisfactory' and so we defined this as a total score of ≥21/30.

(ii) Feasibility:
   (a) Recruitment of ≥80% of the target sample size (n = 40) in a 10-month recruitment period;
   (b) Retention rate of ≥60% as measured by attendance at the follow-up assessment.

Three out of four of these *a priori* indicators of success needed to be met in order to demonstrate feasibility of the study.

Secondary acceptability and feasibility outcomes are listed in Table 1. Mental health outcomes were Geriatric Anxiety Inventory (GAI) [21], Penn State Worry Questionnaire (PSWQ) [22], Geriatric Depression Scale-15 (GDS-15) [23] and Acceptance and Action Questionnaire-II (AAQ-II) [24].

Table 1. Secondary outcomes with respect to acceptability and feasibility

Secondary outcome measures	Results
Acceptability	
Failures to recruit due to lack of acceptability	No reports of eligible participants not being recruited due to dissatisfaction with the intervention being offered.
Participants dropped out due to lack of acceptability	A low rate of loss to follow-up ($n = 2$) and a low rate of withdrawal from the intervention alone ($n = 2$) due to dissatisfaction with the intervention.
CEQ after the first session of the intervention[a]	Adequate mean ratings of credibility (16.5, SD 5.0) and expectancy (14.5, SD 5.0).
Adverse or serious adverse events	A low rate of adverse or serious adverse events ($n = 4$ and $n = 3$, respectively), with none deemed to be related to the intervention.
Feasibility	
Eligible referrals	The overall rate of conversion of referrals to eligible participants was 47% (38/81).
Eligible participants recruited	The majority of eligible participants came from community mental health teams ($n = 23$, 61%), followed by Improving Access to Psychological Therapies services ($n = 9$, 24%).
Failures to recruit due to feasibility issues	There was only one case of an eligible participant not being recruited for feasibility-related reasons.
Participants dropped out due to feasibility issues	There was a relatively low rate of attrition due to feasibility-related reasons ($n = 5$, 14%).

CEQ = Credibility/Expectancy Questionnaire [43]. [a]Credibility and expectancy subscales ranged from 3 to 27, with higher scores indicating higher credibility/expectancy. Cost-related outcome measures were also collected but are reported elsewhere.

Statistical analyses

Categorical measures were summarised using frequencies and percentages, while continuous measures were summarised using means and standard deviations or medians and interquartile ranges for skewed distributions. Change scores across time (with accompanying 95% confidence intervals) were calculated for individuals who had observations at both baseline and 20-week follow-up, and then averaged across individuals. Change between baseline and 20-week follow-up was estimated using a linear mixed model with a random effect of participant to account for repeated measures from the same individual. Reliable Change Index (RCI) and Clinically Significant Change (CSC) scores were calculated using the Leeds Reliable Change Indicator calculator [25] for any mental health outcome that showed statistical evidence of pre–post changes in linear mixed models.

Sample size

A sample size of 40 was chosen following conventional recommendations for feasibility studies [26] and an estimated 12.5% loss to follow-up based on a preliminary study of ACT in older people with GAD [15].

Results

Study flow and baseline characteristics

Eighty-one potential participants were referred from 2 January 2018 to 31 October 2018, and 20-week follow-ups were conducted between 8 June 2018 and 24 April 2019. Thirty-seven eligible participants consented to participate in the study: 7 (19%) were lost to follow-up (see Figure 1). Data were collected from 92% ($n = 34$) of participants at baseline and 81% ($n = 30$) of participants at 20-week follow-up. Baseline characteristics are described in Table 2.

Session attendance

The mean waiting time for therapy was 10.2 weeks (SD 8.8). Twenty-two participants (59%) attended 16 sessions, with 26 (70%) attending ≥10 sessions. The mean number of sessions completed by the 20-week follow-up was 12.1 (SD 3.6). Although only one participant (3%) had attended 16 sessions by this point, 24 participants (65%) had attended at least 10 sessions. For ethical reasons, participants continued receiving therapy beyond the 20-week follow-up, if they had not received up to 16 sessions by this point. The number of weeks taken to receive up to 16 sessions ranged from 6 to 35 weeks (excluding withdrawals from the intervention or study).

Primary outcomes

The recruitment rate of 93% (37/40) and retention rate of 81% (30/37) exceeded the set targets. Seventy percent (26/37) of participants attended ≥60% sessions (i.e. ≥10 sessions). Sixty percent (18/30) of participants scored ≥21/30 on the satisfaction with therapy subscale, although 80% (24/30) were still undergoing the intervention at the 20-week follow-up.

Secondary outcomes

Table 1 displays the results of secondary acceptability and feasibility outcomes. With respect to mental health outcomes, there was a two-point reduction between baseline and 20-week follow-up for both anxiety (GAI: −2.30; 95% CI:

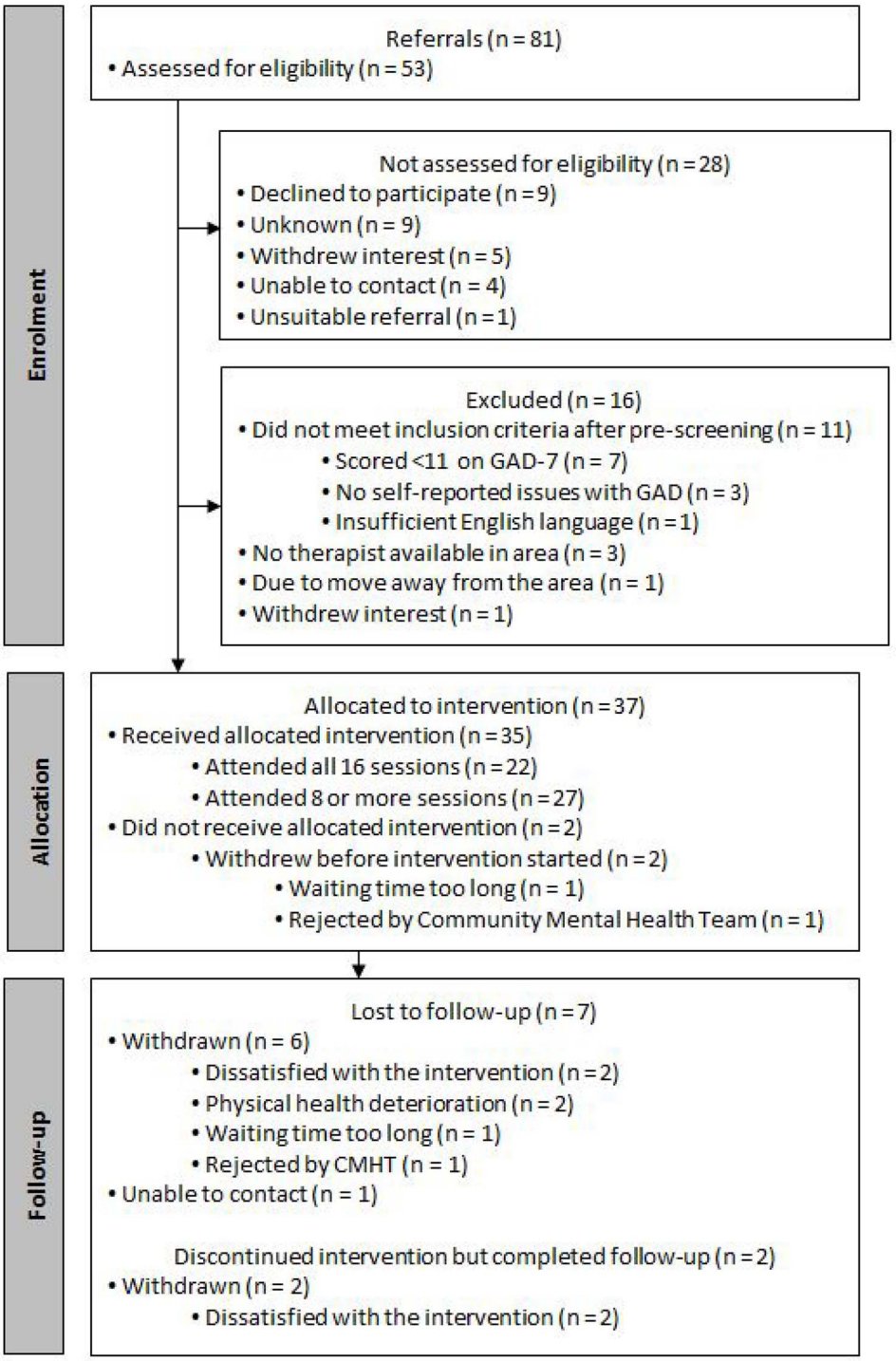

Figure 1. Summary of recruitment and follow-up of participants in the study.

−3.83 to −0.76) and depression (GDS-15: −2.04; 95% CI: −3.31 to −0.77) in the linear mixed model analysis (see Table 3). There was also a three-point reduction in psychological inflexibility (AAQ-II: −3.93; 95% CI: −7.16 to −0.70).

Data used to calculate RCI and CSC scores for the GAI, GDS-15 and AAQ-II are outlined in Appendix 3, available in *Age and Ageing* online. As shown in Table 4, 45% of participants (13/29) showed a reliable improvement in scores on the GAI at 20-week follow-up, with six (21%) of these also meeting the criterion for clinically significant change (i.e. scored below the clinical cut-off). For both the GDS-15 and the AAQ-II, 24% (7/29) showed a reliable improvement in scores at 20-week follow-up, with five (17%) and four (14%) of these, respectively, also meeting the criterion for clinically significant change. Very few participants showed

Table 2. Demographic and clinical characteristics for all participants ($n = 37$)

Variable	*N* (missing *N*, %)	Mean (SD), median (IQR) or *N* (%)
Mean age (years)	37 (0, 0%)	74.8 (6.3)
Sex	37 (0, 0%)	
Female		30 (81%)
Male		7 (19%)
Ethnicity	37 (0, 0%)	
Asian/Asian British		1 (3%)
Black/Black British		1 (3%)
Mixed		1 (3%)
White/White British		32 (86%)
Other		2 (5%)
Marital status	37 (0, 0%)	
Married		14 (38%)
Divorced		8 (22%)
Single		3 (8%)
Co-habiting		1 (3%)
Widowed		8 (22%)
Separated		3 (8%)
Mean years of education	37 (0, 0%)	10.2 (2.9)
Highest educational qualification	37 (0, 0%)	
Post-graduate university qualification (e.g. Masters)		1 (3%)
University qualification (e.g. Degree)		5 (14%)
College qualification (e.g. A level/Baccalaureate)		4 (11%)
High school qualification (e.g. O level/GCSE/GCE)		3 (8%)
High school leaving certificate		3 (8%)
No educational qualifications		15 (41%)
Unclear		6 (16%)
Employment status	37 (0, 0%)	
Paid work		2 (5%)
Voluntary work		6 (16%)
Retired		28 (76%)
Other		1 (3%)
Mean GAD-7 total score (possible range 0–21)[a]	37 (0, 0%)	15.2 (2.7)
GAD-7 severity classification	37 (0, 0%)	
Moderate (possible range 11–15)		22 (60%)
Severe (possible range 16–21)		15 (41%)
Duration of current difficulties with worrying (years)	37 (0, 0%)	
<1		3 (8%)
1–5		13 (35%)
6–10		3 (8%)
11–20		4 (11%)
21–30		1 (3%)
>30		13 (35%)
No. of participants meeting MINI diagnostic criteria	37 (0, 0%)	
GAD		37 (100%)
Major depressive episode without melancholic features		8 (22%)
Major depressive episode with melancholic features		13 (35%)
Mood disorder with psychotic features		2 (5%)
Panic disorder		3 (8%)
Panic with agoraphobia		4 (11%)
Agoraphobia		7 (19%)
Social phobia		8 (22%)
Dysthymia		3 (8%)
OCD		3 (8%)
PTSD		4 (11%)
Psychotic disorders		0 (0%)
Manic episode		0 (0%)
Alcohol dependence		1 (3%)
Substance abuse		0 (0%)
No. of participants with ≥1 comorbid mental health disorder on the MINI	37 (0, 0%)	30 (81%)
Mean no. of mental health comorbidities on the MINI	37 (0, 0%)	1.5 (1.1)
Current use of >14 units of alcohol per week		
Yes		3 (8%)
No		31 (84%)

Continued

Table 2. Continued

Variable	*N* (missing *N*, %)	Mean (SD), median (IQR) or *N* (%)
Unclear		3 (8%)
Current suicidal ideation without active intent[b]	37 (0, 0%)	
Yes		27 (73%)
No		10 (27%)
History of suicide attempt or self-harm	37 (0, 0%)	
Yes		11 (30%)
No		26 (70%)
No. of participants meeting screening criteria for DSM-V Axis II personality disorders	37 (0, 0%)	
Avoidant		3 (8%)
Obsessive compulsive		3 (8%)
Borderline		2 (5%)
Dependent		1 (3%)
Current psychotropic medication	37 (0, 0%)	
Yes		27 (73%)
No		10 (27%)
Mean no. of psychotropic medications at assessment	37 (0, 0%)	1.4 (1.2)
No. of participants with changes to psychotropic medication within 2 months of assessment	37 (0, 0%)	5 (14%)
Previous pharmacotherapy	37 (0, 0%)	
Yes		29 (78%)
No		8 (22%)
Median no. of different types or episodes of previous pharmacotherapy (tried or declined)	37 (0, 0%)	1.0 (1.0–2.0)
Previous psychological therapy	37 (0, 0%)	
Yes		31 (84%)
No		6 (16%)
Mean no. of different types or episodes of previous psychological therapy (tried or declined)	37 (0, 0%)	1.7 (1.2)
Mean SMMSE total score (possible range 0–30)[c]	37 (0, 0%)	28.4 (1.5)
Cumulative Illness Rating Scale for Geriatrics	37 (0, 0%)	
Mean total no. of endorsed categories (possible range 0–14)[d]		4.7 (2.1)
Mean total score (possible range 0–56)[d]		10.4 (5.0)
Mean Severity Index[e]		2.1 (0.7)
Mean no. of level 3 severity categories (possible range 0–14)[f]		1.7 (1.3)
Mean no. of level 4 severity categories (possible range 0–14)[g]		0.2 (0.4)

MINI = Mini International Psychiatric Inventory. SMMSE = Standardised Mini-Mental State Examination [44]. [a]Higher scores indicate greater severity of GAD. [b]Potential participants were not eligible to take part in the study if they were expressing suicidal ideation with active intent at screening. [c]Higher scores indicate better global cognition. [d]Higher scores indicate poorer health in 14 categories (e.g. vascular, neurological and psychiatric illness). [e]Severity Index = Total score/Total no. of endorsed categories on the Cumulative Illness Rating Scale for Geriatrics [38]. [f]Level 3 severity = severe, constant significant disability or 'uncontrollable' chronic problems. [g]Level 4 severity = extremely severe, immediate treatment required, end organ failure or severe impairment in function.

reliable or clinically significant deterioration on the GAI, GDS-15 and AAQ-II.

Treatment integrity

High rates of overall adherence to the manual (mean score of 4.2/5, SD 0.8) and overall ACT competence of therapists (mean score of 4.1/5, SD 0.8) were observed using the ACT Treatment Integrity Coding Manual. Crucially, there was no evidence of ACT-inconsistent items in the rated sessions nor reports of ACT-inconsistent deviations from the manual.

Discussion

This study showed that it is feasible to recruit and retain older people with TR-GAD in a study of ACT with a 20-week follow-up. Three out of four indicators of success were met. Excellent feasibility in terms of recruitment and retention, and good acceptability in terms of session attendance were found, which was further supported by secondary outcomes. However, the percentage of participants who were satisfied with therapy was only adequate (60%). Finally, although the study was not powered to examine clinical effectiveness, there was preliminary evidence of improvements in scores on the GAI, GDS-15 and AAQ-II from baseline to 20-week follow-up. Furthermore, reliable changes in scores were found in almost half (45%) of participants on the GAI. This is promising, given that participants were recruited on the basis of having a treatment-resistant disorder, and ACT, with its focus on 'living better' rather than 'feeling better', is not primarily aimed at symptomatic reduction.

Satisfaction with therapy may have been lower than wished for numerous reasons. First, 80% of participants had not finished receiving therapy at the time of the 20-week

Table 3. Estimated change in mental health outcome measures between baseline and 20-week follow-up

	Baseline		20-week follow-up		Analysis of change[e]		Linear mixed model[f]	
Outcome measure	*N*	Mean (SD)	*N*	Mean (SD)	*N*	Estimated change (95% CI)	*N*	Estimated change (95% CI)
GAI (possible range 0–20)[a]	34	15.8 (4.1)	30	13.8 (5.1)	29	−2.62 (−4.28 to −0.96)	35	−2.30 (−3.83 to −0.76)
PSWQ (possible range 16–80)[b]	34	64.4 (10.6)	29	61.9 (11.5)	28	−4.64 (−9.72 to 0.43)	35	−3.05 (−7.73 to 1.63)
GDS-15 (possible range 0–15)[c]	34	9.82 (3.21)	30	7.83 (4.04)	29	−2.10 (−3.49 to −0.72)	35	−2.04 (−3.31 to −0.77)
AAQ-II (possible range 7–49)[d]	34	34.4 (8.0)	30	30.6 (10.3)	29	−4.07 (−7.63 to −0.51)	35	−3.93 (−7.16 to −0.70)

SD = standard deviation. GAI = Geriatric Anxiety Inventory. PSWQ = Penn State Worry Questionnaire. GDS-15 = Geriatric Depression Scale-15. AAQ-II = Acceptance and Action Questionnaire-II. [a]Higher scores indicate greater anxiety. [b]Higher scores indicate greater worry. [c]Higher scores indicate greater depression. [d]Higher scores indicate greater psychological inflexibility. [e]Only includes participants with data at both timepoints. [f]Includes participants with data at either timepoint or both.

Table 4. Reliable change and clinically significant changes in participants with data at baseline and 20-week follow-up ($n = 29$)

Outcome measure	Clinically significant deterioration	Reliable deterioration	No reliable change	Reliable improvement	Clinically significant improvement
Geriatric Anxiety Inventory	0 (0%)	1 (3%)	15 (52%)	13 (45%)	6 (21%)
Geriatric Depression Scale-15	0 (0%)	0 (0%)	22 (76%)	7 (24%)	5 (17%)
Action and Acceptance Questionnaire-II	0 (0%)	3 (10%)	19 (66%)	7 (24%)	4 (14%)

Clinically significant improvement = improvement from pre-treatment that meets both Reliable Change Index (RCI) *and* Clinically Significant Change (CSC) criteria (i.e. a reliable change that is also clinically significant). Reliable improvement = improvement from pre-treatment that meets RCI, but *not* CSC criteria (i.e. a reliable change that is not clinically significant). No reliable change = the magnitude of any change following treatment is within the expected range due to measurement error. Reliable deterioration = deterioration from pre-treatment that meets RCI, but *not* CSC criteria (i.e. a reliable change that is not clinically significant). Clinically significant deterioration = deterioration from pre-treatment that meets both RCI *and* CSC criteria (i.e. a reliable change that is also clinically significant). Established norms for clinical and non-clinical populations (means and standard deviations), estimates of reliability (Cronbach's alpha) and cut-off scores (indicating 'recovery') used to calculate reliable and clinically significant changes are listed in Appendix 3, available in *Age and Ageing* online.

follow-up. Satisfaction may have been higher if participants had finished receiving therapy by this point. This suggests that completing up to 16 sessions in 20 weeks was not feasible, and that a longer time interval is necessary. Second, there is no set definition of what constitutes 'satisfactory' on the satisfaction with therapy subscale and so this was defined as a total score of ≥21/30. If a criterion of ≥18/30 had been chosen, which corresponds to a 'neutral' rating on all items (i.e. the lowest limit of 'satisfactory'), then 70% of participants would have rated the therapy as 'satisfactory'. Third, qualitative feedback from participants and therapists indicated that some participants struggled with the aim of ACT to live as best a life as possible with worry and anxiety, rather than trying to change or get rid of this. Some participants reported they had been struggling with worry for many years, and some continued to demonstrate fusion with beliefs about their ability to change (e.g. due to age), as well as strong attachment to self-narratives (e.g. 'I've always been a worrier'). This indicates that the intervention may require further refinement, such as (i) examining participants' expectations about therapy and motivation to change from the outset (e.g. the degree to which they are wanting to get rid of anxiety); (ii) more frequently revisiting the workability of control strategies and beliefs about the self (e.g. looking at how well strategies for getting rid of anxiety are helping the person to live their life in service of their values); and (iii) including more exercises and metaphors that facilitate acceptance rather than avoidance of uncomfortable experiences and explicitly linking this to values-driven behaviour. Other factors that may influence satisfaction with therapy include treatment credibility and treatment adherence. Both of these factors were found to predict treatment satisfaction in an RCT of CBT vs. enhanced usual care for older people with GAD

[27], and thus should be explored further in any larger-scale study of ACT for TR-GAD.

Only a handful of studies have examined ACT in older people. The majority have examined chronic pain [28–31], with the remainder focusing on GAD [14], veterans with depression [32], and those living in long-term care facilities [33]. A preliminary RCT of ACT vs. CBT for older people with GAD ($n = 16$) reported pre–post improvements in worry and depressive symptoms, but not anxiety [14]. Improvements in depression were observed in an observational study of ACT for older veterans with depression ($n = 76$) in a routine clinical setting [32]. Finally, a pilot RCT of ACT vs. wait-list control for older people with symptoms of depression and/or anxiety living in long-term care facilities ($n = 41$) reported significantly lower depression but not anxiety scores following ACT [33]. Our findings of pre–post improvements in depressive and anxiety symptoms are consistent with these previous studies. Overall, these findings suggest that ACT may have the potential to reduce symptoms of anxiety and depression and increase psychological flexibility in older people with TR-GAD.

Two observations with respect to participant characteristics merit further discussion. First, a bimodal distribution of age of GAD onset was found, with 35% of participants ($n = 13$) experiencing difficulties for 1–5 years and 35% experiencing difficulties for over 30 years. This mirrors other findings in working-age adults and older people with GAD [34–36]. Whether there are differences in treatment response between these sub-populations should be explored further in a larger study given that higher rates of psychiatric comorbidity have been reported in older people with an earlier compared to later GAD onset [34], and psychiatric comorbidity is associated with poorer treatment response in GAD [37]. Second, psychiatric and medical comorbidity was common, with 81% of participants ($n = 30$) meeting criteria for one or more comorbid mental health disorders, 73% ($n = 27$) reporting suicidal ideation without active intent, and 78% ($n = 29$) reporting severe problems in at least one category on the Cumulative Illness Rating Scale for Geriatrics [38]. While these rates may seem high, they are unsurprising given that medical and psychiatric comorbidities are associated with poor treatment response in anxiety disorders [39] and strong associations have been reported between GAD and suicidal ideation, even after controlling for psychiatric comorbidity [40–42].

To our knowledge, this is the first study to report the acceptability, feasibility and preliminary estimates of the effectiveness of a psychological intervention developed specifically for older people with TR-GAD. However, there are a few limitations of the study. First, the majority of participants were White women in their 60s/70s, and so the results cannot be generalised to a broader population. Second, participants were only recruited from urban and suburban areas within London, UK, further limiting external validity. Third, as outcome measures were only assessed at 0 and 20 weeks, it is uncertain whether any gains were maintained or further gains made beyond 20 weeks. Finally, as this was an uncontrolled feasibility study (and hence any changes in outcomes could be due to non-specific therapeutic factors such as social support or spontaneous recovery), findings on mental health outcomes should be interpreted with caution.

Conclusions

There was excellent evidence of feasibility and good evidence of acceptability of ACT for older people with TR-GAD. However, satisfaction with therapy scores suggested that further refinement of the intervention may be necessary. There was preliminary evidence of improvements in anxiety, depression and psychological flexibility, with some participants showing clinically meaningful change. Overall, findings suggest that a fully powered RCT to evaluate the clinical and cost-effectiveness of ACT for older people with TR-GAD is warranted.

Supplementary Data: Supplementary data mentioned in the text are available to subscribers in *Age and Ageing* online.

Acknowledgements: We would like to thank the participants who took part in the study, and clinicians who made referrals to the study. We would also like to thank our Patient and Public Involvement collaborator and members of our Service User Advisory Group who attended meetings, provided invaluable advice and guidance about key issues, reviewed themes in qualitative data analyses, contributed to the development and revision of the intervention manual and provided feedback on study materials and the final study results. Finally, we would like to thank the North Thames Clinical Research Network and the South London Clinical Research Network for their support in conducting the study. We would like to thank the United Kingdom National Institute of Health Research (NIHR) Health Technology Assessment Programme for funding this study. We would also like to thank the following National Health Service (NHS) Trusts for providing funding for excess treatment costs to cover therapist training, supervision and intervention delivery: South London and Maudsley NHS Foundation Trust, Barnet, Enfield and Haringey Mental Health NHS Trust, Camden and Islington NHS Foundation Trust, Whittington Health NHS Trust, and North East London NHS Foundation Trust.

Declaration of Conflicts of Interest: None.

Declaration of Sources of Funding: This work was supported by the National Institute for Health Research (NIHR) Health Technology Assessment Programme (grant number 15/161/05). The views expressed are those of the authors and not necessarily those of the National Health Service (NHS), the NIHR or the Department of Health and Social Care. The Funder commissioned the research and had an initial role in stipulating brief details about the study design but was otherwise not involved in study design, execution, analysis, interpretation or

manuscript preparation. Authors were supported by the NIHR Biomedical Research Centre at University College Hospitals London and South London and Maudsley NHS Trust.

References

1. Wolitzky-Taylor KB, Castriotta N, Lenze EJ *et al.* Anxiety disorders in older adults: a comprehensive review. Depress Anxiety 2010; 27: 190–211.
2. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. 4th edition. Washington, DC: American Psychiatric Association, 2000.
3. Lenze EJ, Mulsant BH, Mohlman J *et al.* Generalized anxiety disorder in late life: lifetime course and comorbidity with major depressive disorder. Am J Geriatr Psychiatry Off J Am Assoc Geriatr Psychiatry 2005; 13: 77–80.
4. Porensky EK, Dew MA, Karp JF *et al.* The burden of late-life generalized anxiety disorder: effects on disability, health-related quality of life, and healthcare utilization. Am J Geriatr Psychiatry Off J Am Assoc Geriatr Psychiatry 2009; 17: 473–82.
5. Cairney J, Corna LM, Veldhuizen S *et al.* Comorbid depression and anxiety in later life: patterns of association, subjective well-being, and impairment. Am J Geriatr Psychiatry Off J Am Assoc Geriatr Psychiatry 2008; 16: 201–8.
6. Lawrence V, Kimona K, Howard RJ *et al.* Optimising the acceptability and feasibility of acceptance and commitment therapy for treatment-resistant generalised anxiety disorder in older adults. Age Ageing 2019; 48: 741–50.
7. Lanouette NM, Stein MB. Advances in the management of treatment-resistant anxiety disorders. Focus 2010; 8: 501–24.
8. Barton S, Karner C, Salih F *et al.* Clinical effectiveness of interventions for treatment-resistant anxiety in older people: a systematic review. Health Technol Assess (Winch Eng) 2014; 18: 1–59 v–vi.
9. Kishita N, Laidlaw K. Cognitive behaviour therapy for generalized anxiety disorder: is CBT equally efficacious in adults of working age and older adults? Clin Psychol Rev 2017; 52: 124–36.
10. Hayes S, Strosahl K, Wilson K. Acceptance and Commitment Therapy: An Experiential Approach to Behavior Change. New York: The Guilford Press, 1999.
11. Hann KEJ, LM MC. A systematic review of randomized controlled trials of acceptance and commitment therapy for adults with chronic pain: outcome domains, design quality, and efficacy. J Contextual Behav Sci 2014; 3: 217–27.
12. A-Tjak JGL, Davis ML, Morina N *et al.* A meta-analysis of the efficacy of acceptance and commitment therapy for clinically relevant mental and physical health problems. Psychother Psychosom 2015; 84: 30–6.
13. Isaacowitz DM, Seligman MEP. Cognitive style predictors of affect change in older adults. Int J Aging Hum Dev 2002; 54: 233–53.
14. Weissman MM, Markowitz JC, Klerman GL. Comprehensive Guide to Interpersonal Psychotherapy. New York: Basic Books, 2000.
15. Wetherell JL, Afari N, Ayers CR *et al.* Acceptance and commitment therapy for generalized anxiety disorder in older adults: a preliminary report. Behav Ther 2011; 42: 127–34.
16. Sheehan DV, Lecrubier Y, Sheehan KH *et al.* The Mini-International Neuropsychiatric Interview (M.I.N.I.): the development and validation of a structured diagnostic psychiatric interview for DSM-IV and ICD-10. J Clin Psychiatry 1998; 59: 22–33 quiz 34-57.
17. First M, Gibbon M, Spitzer R *et al.* Structured Clinical Interview for DSM-IV Axis II Personality Disorders (SCID-II). Washington, DC: American Psychiatric Press, 1997.
18. Spitzer RL, Kroenke K, Williams JBW *et al.* A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med 2006; 166: 1092–7.
19. Plumb JC, Vilardaga R. Assessing treatment integrity in acceptance and commitment therapy: strategies and suggestions. Int J Behav Consult Ther 2010; 6: 263–95.
20. Oei TPS, Green AL. The satisfaction with therapy and therapist scale-revised (STTS-R) for group psychotherapy: psychometric properties and confirmatory factor analysis. Prof Psychol Res Pract 2008; 39: 435–42.
21. Pachana NA, Byrne GJ, Siddle H *et al.* Development and validation of the geriatric anxiety inventory. Int Psychogeriatr 2007; 19: 103–14.
22. Meyer TJ, Miller ML, Metzger RL *et al.* Development and validation of the Penn State worry questionnaire. Behav Res Ther 1990; 28: 487–95.
23. Yesavage JA, Brink TL, Rose TL *et al.* Development and validation of a geriatric depression screening scale: a preliminary report. J Psychiatr Res 1982; 17: 37–49.
24. Bond FW, Hayes SC, Baer RA *et al.* Preliminary psychometric properties of the acceptance and action questionnaire–II: a revised measure of psychological inflexibility and experiential avoidance. Behav Ther 2011; 42: 676–88.
25. Morley S, Dowzer C. Manual for the leeds reliable change indicator: simple excel (tm) applications for the analysis of individual patient and group data. 2014. Published online. Available at https://dclinpsych.leeds.ac.uk/wp-content/uploads/sites/26/2018/09/Manual-for-Leeds-RCI-CSC-calculators.pdf.
26. Teare MD, Dimairo M, Shephard N *et al.* Sample size requirements to estimate key design parameters from external pilot randomised controlled trials: a simulation study. Trials 2014; 15: 264.
27. Hundt NE, Armento ME, Porter B *et al.* Predictors of treatment satisfaction among older adults with anxiety in a primary care psychology program. Eval Program Plann 2013; 37: 58–63.
28. Alonso MA, López A, Losada A *et al.* Acceptance and commitment therapy and selective optimization with compensation for older people with chronic pain: a pilot study. Behav Psychol Psicol Conduct Rev Int Clínica Salud 2013; 21: 59–79.
29. Alonso-Fernández M, López-López A, Losada A *et al.* Acceptance and commitment therapy and selective optimization with compensation for institutionalized older people with chronic pain. Pain Med Malden Mass 2016; 17: 264–77.
30. McCracken LM, Jones R. Treatment for chronic pain for adults in the seventh and eighth decades of life: a preliminary study of acceptance and commitment therapy (ACT). Pain Med Malden Mass 2012; 13: 860–7.
31. Wetherell JL, Afari N, Rutledge T *et al.* A randomized, controlled trial of acceptance and commitment therapy and

cognitive-behavioral therapy for chronic pain. Pain 2011; 152: 2098–107.
32. Karlin BE, Walser RD, Yesavage J *et al.* Effectiveness of acceptance and commitment therapy for depression: comparison among older and younger veterans. Aging Ment Health 2013; 17: 555–63.
33. Davison TE, Eppingstall B, Runci S *et al.* A pilot trial of acceptance and commitment therapy for symptoms of depression and anxiety in older adults residing in long-term care facilities. Aging Ment Health 2017; 21: 766–73.
34. Le Roux H, Gatz M, Wetherell JL. Age at onset of generalized anxiety disorder in older adults. Am J Geriatr Psychiatry 2005; 13: 23–30.
35. Rhebergen D, Aderka IM, van der Steenstraten IM *et al.* Admixture analysis of age of onset in generalized anxiety disorder. J Anxiety Disord 2017; 50: 47–51.
36. Chou K-L. Age at onset of generalized anxiety disorder in older adults. Am J Geriatr Psychiatry 2009; 17: 455–64.
37. Noyes R Jr. Comorbidity in generalized anxiety disorder. Psychiatr Clin North Am 2001; 24: 41–55.
38. Miller MD, Paradis CF, Houck PR *et al.* Rating chronic medical illness burden in geropsychiatric practice and research: application of the cumulative illness rating scale. Psychiatry Res 1992; 41: 237–48.
39. Bystritsky A. Treatment-resistant anxiety disorders. Mol Psychiatry 2006; 11: 805–14.
40. Boden JM, Fergusson DM, Horwood LJ. Anxiety disorders and suicidal behaviours in adolescence and young adulthood: findings from a longitudinal study. Psychol Med 2007; 37: 431–40.
41. Sareen J, Cox BJ, Afifi TO *et al.* Anxiety disorders and risk for suicidal ideation and suicide attempts: a population-based longitudinal study of adults. Arch Gen Psychiatry 2005; 62: 1249–57.
42. de Beurs D, Ten Have M, Cuijpers P *et al.* The longitudinal association between lifetime mental disorders and first onset or recurrent suicide ideation. BMC Psychiatry 2019; 19: 345.
43. Devilly GJ, Borkovec TD. Psychometric properties of the credibility/expectancy questionnaire. J Behav Ther Exp Psychiatry 2000; 31: 73–86.
44. Molloy DW, Alemayehu E, Roberts R. Reliability of a standardized Mini-mental state examination compared with the traditional Mini-mental state examination. Am J Psychiatry 1991; 148: 102–5.

Received 8 November 2020; editorial decision 4 February 2021