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# **RESEARCH PAPER**

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

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# 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  $\geq$ 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  $\geq$ 32 participants and retention of  $\geq$ 60% at follow-up) and acceptability (defined as participants attending  $\geq$ 10 sessions and scoring  $\geq$ 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  $\geq$ 10 sessions. A total of 18/30 (60%) participants scored  $\geq$ 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

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(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 controlorientated strategies (e.g. trying to eliminate problems that cannot be solved) are detrimental to older people's wellbeing 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:

- 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  $\geq 11$  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-toface 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 20week follow-up. Baseline assessments were completed in the 2 weeks prior to starting ACT.

## Outcomes

The primary outcomes were

- (i) Acceptability:
- (a) Participants attending  $\geq 60\%$  sessions (i.e.  $\geq 10$  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  $\geq 21/30$ .
- (ii) Feasibility:
  - (a) Recruitment of  $\geq 80\%$  of the target sample size (n = 40) in a 10-month recruitment period;
  - (b) Retention rate of  $\geq 60\%$  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	Ι.	Secondary	outcomes with	respect to	acceptabilit	y and	feasibility
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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 <sup>a</sup>	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]. <sup>a</sup>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 followup 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  $\geq$ 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  $\geq$ 60% sessions (i.e.  $\geq$ 10 sessions). Sixty percent (18/30) of participants scored  $\geq$ 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 <i>N</i> (%)
Mean age (years)	37 (0, 0%)	74.8 (6.3)
Sex	37 (0, 0%)	
Female		30 (81%) 7 (10%)
Frhnicity	37 (0, 0%)	/ (19%)
Asian/Asian British	57 (0, 070)	1 (3%)
Black/Black British		1 (3%)
Mixed		1 (3%)
White/White British		32 (86%)
Other Marital status	37 (0, 0%)	2 (5%)
Married	57 (0, 070)	14 (38%)
Divorced		8 (22%)
Single		3 (8%)
Co-habiting		1 (3%)
Widowed		8 (22%) 2 (804)
Separated Mean years of education	37 (0, 0%)	3(8%) 10 2 (2 9)
Highest educational qualification	37 (0, 0%)	10.2 (2.)
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%)
No educational gualifications		5 (8%) 15 (41%)
Unclear		6 (16%)
Employment status	37 (0, 0%)	
Paid work		2 (5%)
Voluntary work		6 (16%)
Retired		28 (76%) 1 (3%)
Mean GAD-7 total score (possible range 0–21) <sup>a</sup>	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%)	2 (00/)
<1 1_5		2 (8%) 13 (35%)
6–10		3 (8%)
11–20		4 (11%)
21–30		1 (3%)
>30	27 (0, 00()	13 (35%)
No. of participants meeting MINI diagnostic criteria	37 (0, 0%)	37 (100%)
Maior 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%)
Agoraphodia Social phobia		/ (19%) 8 (22%)
Dysthymia		3 (8%)
OCD		3 (8%)
PTSD		4 (11%)
Psychotic disorders		0 (0%)
Manic episode		U (U%) 1 (3%)
Substance abuse		0 (0%)
No. of participants with $\geq 1$ 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%) 21 (949()
INO		31 (84%)

#### Table 2. Continued

Variable	N (missing $N$ , %)	Mean (SD), median (IQR) or $N$ (%)
		2 (90/.)
Current suicidal ideation without active intent <sup>b</sup>	37 (0, 0%)	3 (8%)
	57 (0, 078)	27 (73%)
ies No		2/ (/ 3%)
NO History of quiside attempt or self harm	27 (0, 00/)	10 (27%)
Voc	57 (0, 070)	11 (2004)
ies		26(70%)
No. of neutricinents massing careening aritaria for DSM V Aris II neuropolity disorders.	27 (0, 00/)	20 (7098)
Avoidant	37 (0, 0%)	3 (80%)
Avoidant		2 (8%)
Baudantina		3(8%)
Donandant		2(3%)
Dependent	27 (0, 00/)	1 (5%)
V	57 (0, 0%)	27 (720/)
10S		2/ (/3%)
	37 (0, 00/)	10(2/%)
Near no. or psychotropic medications at assessment	37 (0, 0%)	1.4(1.2)
No. of participants with changes to psychotropic medication within 2 months of	37 (0, 0%)	3 (14%)
assessment	27 (0, 00/)	
Previous pnarmacotherapy	37 (0, 0%)	20 (780/)
10S		29 (/8%)
	37 (0, 00()	8 (22%)
Median no. or different types or episodes or previous pharmacotherapy (tried or	37 (0, 0%)	1.0 (1.0-2.0)
Densioner and the signal the second	27 (0, 00/)	
V	57 (0, 0%)	21 (9/0/)
Yes N-		51(84%)
	37 (0, 00()	0(10%)
Mean no. of different types or episodes of previous psychological therapy (tried or	37 (0, 0%)	1./ (1.2)
declined)	27 (0, 00/)	20.4(1.5)
Mean SMMSE total score (possible range $0-30$ )°	37 (0, 0%)	28.4 (1.5)
Cumulative liness Rating Scale for Geriatrics	37 (0, 0%)	(7(2))
Mean total no. of endorsed categories (possible range $0-14$ ) <sup>a</sup>		4./(2.1)
Mean total score (possible range 0–56) <sup>a</sup>		10.4 (5.0)
Mean Severity Index <sup>2</sup>		2.1(0.7)
Mean no. of level 3 severity categories (possible range $0-14$ )		1./ (1.3)
Mean no. of level 4 severity categories (possible range $0-14)^{B}$		0.2 (0.4)

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

	Baseline		20-week follow-u	р	Analysis of change <sup>e</sup>		Linear mixed model $^{\rm f}$	
Outcome measure	N	Mean (SD)	N	Mean (SD)	N	Estimated change (95% CI)	N	Estimated change (95% CI)
GAI (possible range 0–20) <sup>a</sup>	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) <sup>b</sup>	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 $0-15$ )°	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) <sup>d</sup>	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)

Table 3	Estimated	l change i	n mental	health	outcome	measures	between	baseline an	d 20-	-week fo	llow-up
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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. <sup>a</sup>Higher scores indicate greater anxiety. <sup>b</sup>Higher scores indicate greater worry. <sup>c</sup>Higher scores indicate greater depression. <sup>d</sup>Higher scores indicate greater psychological inflexibility. <sup>e</sup>Only includes participants with data at both timepoints. <sup>f</sup>Includes participants with data at either timepoint or both.

T-LL / D 1.11 1 1	1 11	1 • . • •	1 1	1. 1.20 1.0.11	( 20)
Ladie 4. Keliable change and	clinically significant	changes in partici	pants with data at bas	seline and 20-week follo	w-110(n = 29)
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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 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  $\geq 21/30$ . If a criterion of  $\geq 18/30$ 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.

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