Acceptance and commitment therapy for older people with treatment-resistant generalised anxiety disorder: the FACTOID feasibility study

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Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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Scientific summary

The FACTOID feasibility study

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Scientific summary

Background

Generalised anxiety disorder is the most common anxiety disorder among older people. It is characterised by excessive anxiety and worry, including feelings of fear, dread and uneasiness, which are experienced as difficult to control, on more days than not, for at least 6 months. Other symptoms include restlessness or feeling 'on edge', tiredness, irritability, muscle tension, difficulties with concentrating and sleeping, shortness of breath, fast heartbeat, sweating and dizziness. It is a condition that may persist for decades and is associated with numerous negative outcomes in older people. These include poorer health-related quality of life, increased disability and greater health-care utilisation in comparison with non-anxious older people.

First-line treatments for generalised anxiety disorder include pharmacological therapy (such as selective serotonin reuptake inhibitors) and psychological therapy (such as cognitive behavioural therapy and applied relaxation). However, many older people with generalised anxiety disorder find these treatments ineffective, leaving clinicians uncertain about how best to manage this condition in this population. At present, there is a lack of evidence to guide the management of treatment-resistant generalised anxiety disorder in older people. A previous systematic review was unable to identify any randomised controlled trial or prospective comparative study of either pharmacological or psychological interventions for treatment-resistant anxiety in older people [Barton S, Karner C, Salih F, Baldwin DS, Edwards SJ. Clinical effectiveness of interventions for treatment-resistant anxiety in older people: a systematic review. *Health Technol Assess* 2014;**18**(50)].

One possible intervention for managing treatment-resistant generalised anxiety disorder in older people is cognitive behavioural therapy. However, evidence of a lower efficacy of cognitive behavioural therapy for generalised anxiety disorder in older people than in working-age adults suggests that an alternative form of psychological intervention may be required. Acceptance and commitment therapy could be a particularly promising candidate for this age group for numerous reasons, including the fact that older people with chronic pain have been found to respond better to acceptance and commitment therapy than cognitive behavioural therapy. Consequently, the current study sought to assess whether or not a randomised controlled trial to examine the clinical effectiveness and cost-effectiveness of acceptance and commitment therapy for older people with treatment-resistant generalised anxiety disorder in the NHS is feasible.

Main objectives

These were to (1) develop an intervention based on acceptance and commitment therapy for older people with treatment-resistant generalised anxiety disorder using qualitative methodological approaches, (2) assess the acceptability and feasibility of the intervention in an uncontrolled feasibility study using both quantitative and qualitative methodological approaches, (3) clarify usual care for treatment-resistant generalised anxiety disorder in older people and (4) determine key study design parameters for a future substantive trial.

Phase 1

Systematic, qualitative methods were used alongside patient and public involvement to build on a protocol based on acceptance and commitment therapy that had been piloted with seven older people with generalised anxiety disorder (but not specifically those with treatment-resistant generalised

anxiety disorder). In stage 1, semistructured face-to-face interviews, telephone interviews and a focus group were conducted with 15 older people and 36 clinicians. These investigated intervention preferences and priorities, relevant experiences, and barriers to and facilitators of engaging with talking therapy. Participants were aged ≥ 65 years, had a primary diagnosis of generalised anxiety disorder as determined by the Structured Clinical Interview for *Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition, Axis I Disorders, and had failed to respond to front-line treatment for generalised anxiety disorder. They were recruited from general practices, Improving Access to Psychological Therapies services, Community Mental Health Teams and the community. Clinicians were health-care professionals who worked with older people with generalised anxiety disorder. Face-to-face interviews were audio-recorded and transcribed verbatim, and detailed research notes were made on telephone interviews. Data were analysed using framework analysis. Themes and subthemes were used to inform the development of the intervention.

In stage 2, semistructured face-to-face interviews, with the same older people who had completed stage 1, explored opinions about the developed intervention. Consultations with the Service User Advisory Group, academic clinicians and study therapists provided further feedback on the intervention. Face-to-face interviews were audio-recorded and transcribed verbatim, and detailed research notes were made on consultations. Data were analysed using framework analysis. Feedback was used to iteratively modify the intervention to improve its acceptability to older people with treatment-resistant generalised anxiety disorder. The revised intervention was subsequently evaluated in phase 2.

A brief online survey was also conducted in phase 1 with 58 older people with treatment-resistant generalised anxiety disorder and 86 health-care professionals to clarify what constitutes 'usual care' in this population. Older people and health-care professionals were recruited from the community, general practices, primary and secondary care services, and online forums. Approximately half of older people ($n = 28$, 48%) reported currently receiving pharmacotherapy, with antidepressants being the most commonly reported. By contrast, only one-quarter of older people ($n = 13$, 24%) reported currently receiving psychological therapy, with counselling being the most common. Health-care professionals reported that the most common types of pharmacotherapy they offered or referred for were antidepressants ($n = 55$, 64%) and anti-epileptics ($n = 26$, 30%). Cognitive behavioural therapy, mindfulness-based therapy and relaxation therapy were the most common types of psychological therapy they offered or referred for ($n = 66$, 77%; $n = 46$, 54%; and $n = 42$, 49%, respectively).

Phase 2

Design

An open, uncontrolled feasibility study.

Setting

Participants were recruited from general practices, Improving Access to Psychological Therapies services, Community Mental Health Teams and the community.

Participants

Participants were people aged ≥ 65 years with a primary diagnosis of generalised anxiety disorder, as determined by the Mini-International Neuropsychiatric Interview, who had failed to respond to front-line treatment, failed to tolerate this treatment or had previously refused this treatment and were still symptomatic.

Intervention

Participants received up to 16 one-to-one sessions of acceptance and commitment therapy, adapted specifically for older people with treatment-resistant generalised anxiety disorder, in addition to usual care. Sessions lasted up to 1 hour and were delivered by therapists in clinics or participants' homes.

Sessions were weekly for the first 14 sessions and fortnightly thereafter. Each session was associated with a specific set of skills, metaphors, experiential exercises and home practice tasks.

Therapists

Seventeen therapists based in primary and secondary care services received training to deliver the intervention. Therapists initially attended a 4-day training workshop on acceptance and commitment therapy. They were then asked to practise delivering acceptance and commitment therapy to two service users on their caseload while receiving fortnightly group supervision/consultation via telephone. Following the development of the intervention, therapists attended a 1-day training workshop on the specific application of acceptance and commitment therapy to older people with treatment-resistant generalised anxiety disorder.

Treatment fidelity

All therapy sessions were recorded using encrypted digital voice recorders to monitor adherence to the intervention. Ten per cent of sessions were randomly selected and assessed for treatment fidelity by an independent therapist experienced in acceptance and commitment therapy using the Treatment Integrity Coding Manual (Plumb JC, Vilardaga R. Assessing treatment integrity in acceptance and commitment therapy: strategies and suggestions. *Int J Behav Consult Ther* 2010;**6**:263–95). Therapists received feedback on treatment fidelity throughout intervention delivery. In addition, for each session, therapists completed a checklist of components, techniques, themes and therapy-inconsistent deviations from the manual.

Usual care

In addition to receiving the intervention, all participants received usual care, which was monitored using a modified version of the Client Service Receipt Inventory. Participants were required to refrain from engaging in other forms of psychotherapy during intervention receipt.

Data collection

This was conducted face to face at screening and 0 weeks (baseline) and face to face or by telephone at 20 weeks (follow-up). Baseline assessments were completed within 2 weeks of starting the intervention.

Primary outcome measures

The co-primary outcome measures for acceptability were participants attending $\geq$ 60% sessions (i.e. $\geq$ 10 sessions) and 'satisfactory' ratings of therapy using the Satisfaction with Therapy subscale of the Satisfaction with Therapy and Therapist Scale-Revised. The co-primary outcome measures for feasibility were recruitment of $\geq$ 80% of the target sample size ($n = 40$) in a 10-month recruitment period and a retention rate of $\geq$ 60% at the final follow-up assessment.

Secondary outcome measures

These included additional measures of acceptability and feasibility as well as patient-reported outcome measures. Additional measures of acceptability were failures to recruit due to lack of acceptability of the intervention, participant dropouts owing to lack of acceptability of the intervention, and credibility of therapy and treatment expectancy (measured immediately after the first therapy session using the Credibility/Expectancy Questionnaire). Additional measures of feasibility were eligible referrals, eligible participants recruited, failures to recruit for reasons other than dissatisfaction with therapy, participant dropouts for reasons other than dissatisfaction with therapy, scores on the Treatment Integrity Coding Manual, and therapy-inconsistent deviations from the manual using an adherence checklist. Patient-reported outcome measures included self-reported measures of anxiety (Geriatric Anxiety Inventory), worry (Penn State Worry Questionnaire), depression (Geriatric Depression Scale-15) and psychological flexibility (Acceptance and Action Questionnaire-II).

Health economic outcome measures

These were intervention costs, health-related quality of life (measured using the EuroQol-5 Dimensions, five-level version), quality-adjusted life-years and resource use (measured using a modified version of the Client Service Receipt Inventory).

Quantitative data analysis

Binary and other categorical measures were summarised using frequencies and percentages, and continuous measures were summarised using means and standard deviations (or medians and interquartile ranges for very skewed distributions). Changes in scores on patient-reported outcome measures between 0 and 20 weeks were estimated by calculating a change score for each individual who had observations at both time points and estimating the average change across individuals, as well as the accompanying 95% confidence interval. Change between 0 and 20 weeks was also estimated using a linear mixed model with a random effect of participant to account for repeated measures from the same individual at the two time points. This model analysed all available data, including from participants with missing data at either 0 or 20 weeks. A further linear mixed model with a random effect of participant was fitted to adjust for symptom severity, cognitive function, psychiatric comorbidity and use of psychotropic medication at baseline. Clustering by therapist was assessed by fitting models with a random effect of both therapist and participant and comparing these with models with a random effect of participant only. The Leeds Reliable Change Indicator calculator was used to identify whether or not any changes in scores on patient-reported outcome measures between 0 and 20 weeks were reliable (i.e. greater in magnitude than could be explained by measurement error or artefacts of repeated measurement) or clinically significant (i.e. indicating clinical 'recovery').

Health economic analysis

Intervention costs (including costs of training and supervision) were calculated by participant, with and without overheads, using nationally published costs. Utility scores were collected with the EuroQol-5 Dimensions, five-level version, and accompanying quality-adjusted life-years were calculated using two methods: a value set for England and a 'crosswalk' model. Changes in utility scores from 0 to 20 weeks were analysed as for other patient-reported outcome measures. Resource use in the preceding 3 months was collected at 0 and 20 weeks and was calculated using nationally published costs. The overall mean cost per participant (with 95% confidence intervals) was calculated at 20 weeks, adjusting for baseline service use.

Qualitative interviews and data analysis

Qualitative data on the perceived acceptability and feasibility of the intervention were gathered via semistructured interviews with a sample of older people who had participated in the uncontrolled feasibility study and therapists who had delivered the intervention. Purposive sampling of older people was conducted based on sex, ethnicity, recruitment source and session attendance to explore a range of perspectives. All therapists were invited to participate in qualitative interviews. Interviews with older people were completed after each participant had finished receiving their therapy sessions. Interviews with therapists were completed once each therapist had finished delivering their therapy sessions to participants. Interviews were audio-recorded and transcribed verbatim, and data were analysed using thematic analysis.

Results

With respect to primary outcomes, 70% of participants (26/37) attended $\geq$ 60% of sessions (i.e. $\geq$ 10 sessions). A rating of $\geq$ 21 out of 30 points on the Satisfaction with Therapy subscale of the Satisfaction with Therapy and Therapist Scale-Revised was given by 60% of participants (18/30), although 80% of participants had not finished receiving their therapy sessions at the time of rating. A total of 93% (37 participants) of the target sample size ($n = 40$) was recruited in the recruitment

period, which exceeded the goal of ≥ 80%. The retention rate, as measured by attendance at the final follow-up assessment, was 81% (30/37 participants), which exceeded the goal of ≥ 60%.

With respect to secondary outcomes, there were no reports of failure to recruit due to a lack of acceptability of the intervention. Only two participants (5%) were lost to follow-up owing to dissatisfaction with the intervention; a further two participants withdrew from the intervention for this reason, but remained in the study. The mean ratings of credibility (16.5, standard deviation 5.0) and expectancy (14.5, standard deviation 5.0) on the Credibility/Expectancy Questionnaire were adequate. There were a small number of adverse events ($n = 4$) and serious adverse events ($n = 3$), none of which was related to the intervention. The overall rate of conversion of referrals to eligible participants was 47% (38/81 referrals), and 97% of these (37/38 eligible participants) were recruited. There was only one report of a failure to recruit for reasons other than dissatisfaction with therapy. Five participants (14%) were lost to follow-up for reasons other than dissatisfaction with therapy. Scores on the Treatment Integrity Coding Manual indicated high rates of overall adherence to the intervention and overall competence of therapists.

There was a 2-point reduction between 0 and 20 weeks for both anxiety (Geriatric Anxiety Inventory score −2.30 points, 95% confidence interval −3.83 to −0.76 points) and depression (Geriatric Depression Scale-15 score −2.04 points, 95% confidence interval −3.31 to −0.77 points) in the unadjusted linear mixed-model analysis. There was also a 3-point reduction in psychological inflexibility (Acceptance and Action Questionnaire-II score −3.93 points, 95% confidence interval −7.16 to −0.70 points). Improvements of similar magnitude were observed after adjusting for potentially confounding variables. Reliable improvements in scores were found in 45% of participants (13/29 points) on the Geriatric Anxiety Inventory and in 24% of participants (7/29 points) on the Geriatric Depression Scale-15 and the Acceptance and Action Questionnaire-II.

Health economic data

Findings suggested that a future substantive trial of the cost-effectiveness of acceptance and commitment therapy for older people with treatment-resistant generalised anxiety disorder would be feasible.

Qualitative data

Qualitative interviews were conducted with 18 older people and 11 therapists. Data further supported the feasibility and acceptability of the intervention.

Conclusions

A high level of feasibility was demonstrated by a recruitment rate of 93% and a retention rate of 81%. A high level of acceptability was found with respect to session attendance (70% of participants attended ≥ 10 sessions), and satisfaction with therapy was adequate (60% of participants scored ≥ 21/30 points on the Satisfaction with Therapy subscale of the Satisfaction with Therapy and Therapist Scale-Revised, although 80% of participants had not finished receiving their therapy sessions at the time of rating). Secondary outcome measures and qualitative data further supported the feasibility and acceptability of the intervention. Even though the study was not powered to examine clinical effectiveness, there was indicative evidence of improvements in scores for anxiety, depression and psychological flexibility from 0 to 20 weeks. These results are particularly impressive given the fact that all participants had failed to respond to prior pharmacological and/or psychological therapy for generalised anxiety disorder. The results of this small, uncontrolled feasibility study suggest that a larger-scale RCT is warranted.

Limitations

Non-specific therapeutic factors were not controlled for, and recruitment was limited to London areas.

Trial registration

This trial is registered as ISRCTN12268776.

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This report

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