A randomised controlled trial of Acceptance and Commitment Therapy plus usual care in comparison to usual care alone for reducing anxiety in older people with treatment-resistant generalised anxiety disorder (CONTACT-GAD): trial protocol

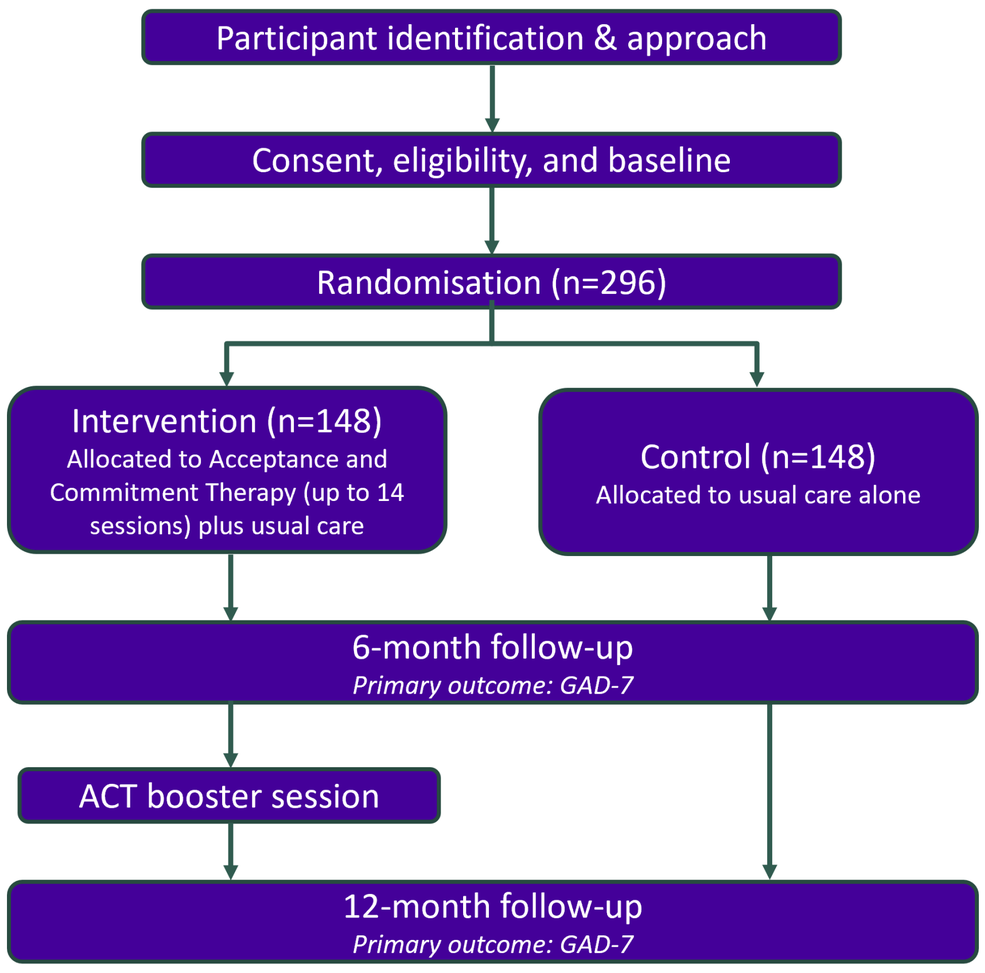
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Background

Generalised anxiety disorder (GAD) is the most common anxiety disorder in older people and is characterised by excessive anxiety and worry that is difficult to control. Current recommended first-line treatments for GAD include pharmacotherapy and psychological therapy, but some people experience GAD that does not respond to these treatments. Such treatment-resistant GAD (TR-GAD) is associated with numerous negative outcomes in older people. However, evidence-based guidance on how to manage TR-GAD in older people is lacking. Previous research suggests that Acceptance and Commitment Therapy (ACT), tailored to the needs and preferences of older people with TR-GAD, may help reduce anxiety in this population.

Figure 1. Timeline for older people with TR-GAD in the trial



Aim

To determine the clinical and cost-effectiveness of tailored ACT plus usual care (UC) in comparison to UC alone for reducing anxiety in older people with TR-GAD.

Methods

The CONTACT-GAD trial is an international, multi-centre, parallel, two-arm RCT with a 9-month internal pilot phase. 296 individuals aged≥60 years with TR-GAD will be recruited from primary and secondary care services (and their equivalent in Australia) and via self-referral at approximately 11 UK sites and 4 Australian sites. TR-GAD will be defined as GAD that has failed to respond adequately to pharmacotherapy and/or psychotherapy, as described in step 3 of the UK's stepped care model for GAD (and its equivalent in Australia). Participants will be randomly allocated to receive up to 14 one-to-one sessions of ACT, with a booster session at approximately 3-months post-intervention, plus UC or UC alone by an online randomisation system. Participants will complete outcome measures at baseline and 6- and 12-months post-randomisation. The primary outcome will be anxiety at six months. Secondary outcomes will include quality of life, depression, psychological flexibility and costs.

Results

The results are pending completion of the trial and are expected to be available in July 2027. Recruitment is now complete, and the trial is in the follow-up phase. A total of 307 participants were recruited into the trial (270 from 25 UK sites and 37 from 1 Australian site).

Discussion

The CONTACT-GAD trial will provide much needed evidence on the management of TR-GAD in older people.

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