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Improving mental health and social participation outcomes in older adults with depression and anxiety

Submission date
10/07/2019

Recruitment status
No longer recruiting

Registration date
14/07/2019

Overall study status
Ongoing

Last Edited
18/12/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Depression and anxiety in older populations are associated with poor physical health, disability, morbidity, increased costs of service use and medications as well as increased risk of cognitive decline. These disorders are also associated with reduced social participation, poor social support, and increased feelings of loneliness and isolation.

Depression and anxiety can be successfully treated in older adults using psychological therapies, particularly cognitive behavioural therapy. However, as in younger adults, while many people benefit from psychological therapy, not everyone does, and some people experience a relapse of symptoms over time. Therefore improvements to psychological treatments are needed to improve effectiveness. One promising innovation is to enhance existing treatments to increase social participation and reduce isolation in older adults.

The aim of this study is to evaluate the efficacy and cost-efficacy of a psychosocial intervention to treat emotional symptoms and increase social participation in anxious and/or depressed older adults, in comparison to current “best practice” standard CBT.

Who can participate?
Older adults, aged 65 years or older who experience clinically significant levels of anxiety and/or low mood. Individuals also need to be able to understand written and spoken English at a sufficient level (such as being able to read the newspaper).

What does the study involve?
1. Informed Consent
The first step is obtaining participants’ informed consent.

2. Assessments
An initial assessment includes both a face-to-face clinical interview at the Centre for Emotional Health Clinic at Macquarie University, Sydney Australia, as well as completion of self-report questionnaires about symptoms, wellbeing, demographics, medical and health service use.

Post-treatment assessments and 12-month post-baseline assessments will take the same format. These follow-up assessments enable us to evaluate changes in symptoms and wellbeing over time and compare the treatment conditions.

3. Random Allocation
Suitable participants will then be randomly allocated to receive one of the two treatment conditions: standard Cognitive Behavioural Therapy (CBT) or enhanced CBT. Both treatment conditions are very likely to be helpful to participants.

4. Therapy conditions
The standard CBT program will comprise our empirically validated CBT program for older age anxiety and depression, Ageing Wisely. This program will be delivered over 12 weekly individual sessions.

The enhanced CBT program comprises 12 weekly individual sessions, teaching the same CBT skills as the standard Ageing Wisely program, but with a stronger focus on bolstering social participation and connections within those skills.

5. Linking to health use data
Linked data will be used to monitor changes in health service use over time. These linked data come from the NSW Centre for Health Record Linkage (CHeReL) on Admitted Patient data, Emergency Department data and Mental Health Ambulatory data. This will be linked to participants' Medicare number.

What are the possible benefits and risks of participating?
The likely benefits are reductions in symptoms of anxiety and depression. There are few risks with participating. As the psychological assessment and treatment involve talking about participants' emotional state, some participants may experience discomfort in discussing these symptoms. However, discomfort is anticipated to be mild and temporary.

Where is the study run from?
This study will be conducted at the Centre for Emotional Health Clinic, Macquarie University, Sydney, Australia.

When is the study starting and how long is it expected to run for?
August 2019 to December 2026

Who is funding the study?
The project is co-funded by the National Health and Medical Research Council (NHMRC) and Beyond Blue.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
ACTRN12619000242123

Study information

Scientific Title
Social Participation in Ageing Adults with depression and anxiety

Acronym
SPAA

Study objectives
1. We predict that the enhanced program will lead to significantly greater reductions on our primary outcome, diagnostic severity of all anxiety and unipolar mood disorders, compared to standard CBT program. immediately post-treatment (Primary Hypothesis)
2. We predict that the enhanced program will lead to greater reductions in diagnostic severity of all anxiety and unipolar disorders compared to standard CBT at 12-month follow-up (Secondary Hypothesis).
3. We similarly predict that the enhanced program will show significantly better outcomes than standard CBT on a range of related measures including self-reported depression, anxiety, suicidal ideation, loneliness, and quality of life immediately post-treatment and at 12 month follow up (Secondary Hypotheses), and cognitive outcomes at 12 month follow up.
4. We predict that the enhanced CBT intervention will show greater cost-efficacy at 12-month follow-up compared with standard CBT (Secondary Hypothesis).
5. We predict treatment outcomes will be moderated by the presence of personality disorders, demographics, symptom severity and baseline cognitive ability.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/01/2019, the Macquarie University Human Research Ethics Committee Medical Sciences (Human Ethics Research Office Level 3, CSC Building Macquarie University Balaclava Road, NORTH RYDE NSW 2109, Australia), ref: 5201938336887.

Study design
Interventional, parallel group superiority randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anxiety and depression

Interventions
The main study design uses a parallel group superiority randomised controlled trial design to evaluate the clinical and cost-effectiveness of an enhanced CBT program for depressive and/or anxiety disorders in older adults, compared to standard CBT.). After baseline examination suitable participants will be randomised to either the 1) Standard CBT or 2) Enhanced CBT treatment condition.

The standard CBT program will comprise our empirically validated CBT program for older age anxiety and depression, Ageing Wisely. Ageing Wisely consists of 11, weekly sessions to teach practical skills to help manage anxiety and depression including: goal setting, activity scheduling, problem solving, graded exposure, cognitive restructuring, assertiveness skills, and sleep hygiene. For the current trial we will add one treatment session to equate contact hours between treatment conditions. Homework exercises are a critical component that assists skills to be generalised and maintained.

The enhanced CBT program comprises 12 weekly sessions, teaching the same CBT skills as the standard Ageing Wisely program, but with a stronger focus on bolstering social participation and connections within those skills. In both treatment conditions, all sessions will be run by clinical psychologists and intern psychologists trained in the delivering of the treatment protocols. To control for therapist differences, all therapists will be trained in and will conduct both treatments (allocated randomly). Supervision will be provided by CIs and postdoctoral fellows managing the trial with treatment adherence and differentiation between conditions as a core focus.

All therapy sessions will be recorded, and a random 25% will be rated by an independent expert unaware of the study hypotheses for fidelity to the therapeutic model using a codebook and form based on Waltz et al. (1993). The effectiveness of the programs will be established using mixed model analysis to compare the differences in clinical diagnostic severity (established by clinicians blind to treatment allocation) and scores on self-report measures at pre-treatment, post-treatment, and at a 12-month follow up period. Treatment integrity and adherence checks will be conducted to ensure treatment conditions were accurately delivered. In addition, an

economic evaluation will be undertaken to measure the relative benefit in health outcomes and resource use for the enhanced intervention compared to standard CBT. Moderation analyses will examine the impact of moderators on treatment outcomes.

Intervention Type
Behavioural

Primary outcome(s)
Disorder Severity indicated by the Mean Clinical Severity Rating of all anxiety and mood disorders assessed in the Anxiety and Related Disorders Interview Schedule 5th edition (ADIS-V) at post-treatment (i.e., 14 weeks from baseline assessment).

Key secondary outcome(s))
1. Disorder Severity indicated by the Mean Clinician's Severity Rating of all anxiety and mood disorders based on the ADIS-V 12 months from the start of therapy.
2. Changes in Symptomatology measured at baseline, 14 weeks from baseline assessment, and 12 months from the start of therapy on the following measures:
2.1. Geriatric Anxiety Inventory.
2.2. Geriatric Anxiety Scale.
2.3. The Geriatric Depression Scale.
2.4. The Depressive Symptoms Inventory – Suicide Subscale.
3. Changes in Social Participation measured at baseline, 14 weeks from baseline assessment, and 12 months from the start of therapy on the following measures:
3.1. De Jong Gierveld Loneliness Scales.
3.2. The Lubben Social Network Scale.
3.3. The Bille- Brahe Social Support scale.
4. Cost-Effectiveness measured at baseline, 14 weeks from baseline assessment, and 12 months from the start of therapy on the following measures:
4.1. Australian Quality of Life total score.
4.2. The iMTA Productivity Cost Questionnaire total score.
4.3. The Australian Community Participation Questionnaire short form total score.
4.4. The Use of Service Questionnaire total score.
4.5. Health Resource Use: data will be sourced using a purpose-built medical cost questionnaire, supplemented with linked data from the NSW Centre for Health Record.
4.6. Linkage (CHeReL) on Admitted Patient data, Emergency Department data, and Mental Health Ambulatory data, along with the Medicare Benefit Schedule (MBS) and Pharmaceutical Benefit Schedule (PBS) data.

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Aged 65 years or older.
2. Primary anxiety and/or unipolar depressive disorder as assessed by the Anxiety and Related Disorders Interview Schedule (ADIS-V).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 years

Upper age limit
100 years

Sex
All

Total final enrolment
173

Key exclusion criteria
1. English language illiteracy.
2. Psychosis or bipolar disorder.
3. Active suicidality.
4. Significant uncorrected hearing loss and likely moderate to severe dementia based on a standardised cognitive screener test (i.e. the scores on the six-item Cognitive impairment Screener).

Date of first enrolment
01/08/2019

Date of final enrolment
30/06/2024

Locations

Countries of recruitment
Australia

Study participating centre
Centre for Emotional Health Clinic at Macquarie University.
Level 1, Australian Hearing Hub, 16 University Avenue, Macquarie University.
North Ryde
Australia
2109

Sponsor information

Organisation
National Health and Medical Research Council

ROR
https://ror.org/011kf5r70

Organisation
Beyond Blue

Funder(s)

Funder type
Government

Funder Name
National Health and Medical Research Council

Alternative Name(s)
National Health and Medical Research Council, Australian Government, NHMRC National Health and Medical Research Council, NHMRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Australia

Funder Name
Beyond Blue

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		27/06/2022	28/06/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes