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# Stepped-care effectiveness trial for ageing adults with anxiety and depression

**Submission date**
09/07/2019

**Recruitment status**
No longer recruiting

**Registration date**
15/07/2019

**Overall study status**
Ongoing

**Last Edited**
09/01/2025

**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
A universal challenge for evidence-based treatment is to integrate validated programs into routine health service delivery. Evidence-based treatments are more likely to be incorporated within public services when they can demonstrate maximum cost-effectiveness. Stepped care delivery is increasingly being promoted as an innovative system by which to optimise the balance between outcomes and costs. Stepped care models rely on the provision of low intensity (e.g. maximum clinical outcome for the lowest cost) evidence-based services first, followed by higher intensity (higher cost) evidence-based services only to those who need additional assistance. Researchers currently have solid, scientific evidence for the efficacy of both low intensity and high-intensity treatments for older adults suffering from depression and anxiety, laying the groundwork for a translational (effectiveness) evaluation. Therefore, the delivery of treatments for anxiety and depression in older adults through the Australian health service network is highly feasible. What researchers now need to know is whether evidence-based treatments for older adults experiencing anxiety and depression can be delivered through existing health services utilising a stepped care model; whether this model reduces costs and/or increases outcomes over existing treatments; and whether this model of service delivery is acceptable and viable for consumers and providers. A multidisciplinary team has developed evidence-based low intensity and higher intensity psychological interventions for depression and anxiety in older adults which they have demonstrated to be effective in a number of randomised controlled trials. The aim of this study is to evaluate the feasibility of delivering these evidence-based programs within existing services representing public (urban, regional) and private organisations. The researchers will examine the effectiveness and cost-effectiveness of these stepped psychological interventions compared to treatment as usual. The results of this study will inform the translation of evidence-based stepped care models of psychological interventions for anxiety and depression in older adults into the Australian mental health system.

Who can participate?
Adults aged 65 and older with anxiety and/or depressive symptoms

What does the study involve?
Participants suitable to participate will be offered one of two treatment conditions: stepped care or treatment as usual. Participants are randomly allocated to one of two groups.

Participants allocated to Stepped Care Treatment Program will receive a low-intensity intervention in the first instance (Step 1). The participants can choose to receive CBT either via an Internet-based program or a telephone supported work at home program. At the end of the low-intensity intervention period participants who are not sufficiently improved will receive a high-intensity intervention (Step 2) including face-to-face CBT sessions. Participants will also complete questionnaires and assessments at fixed timepoints throughout the study (before the start of the study (baseline); 13, 26 weeks and 12 months from the start of treatment).

What are the benefits and risks of participating?
It is expected that both treatment approaches used in this study will reduce the participant's anxiety and/or depression. As part of the study, participants will be asked to respond to some personal questions about their mental health. There is a minor risk that they may find this distressing at times, but this will be comparable to what is encountered from the questions they will be asked as part of a routine assessment. There are no foreseeable major risks in participating in this study.

Where is the study run from?
Centre for Emotional Health Clinic (Macquarie University); the Older People's Mental Health (OPMH) service, Western NSW Local Health District (location Orange, Dubbo & Bathurst) and University of New South Wales (Centre for Healthy Brain Ageing, Department of Psychiatry, Clinical Research Unit for Anxiety Disorders); Euroa Centre, Prince of Wales Hospital - Old Age Mental Health Services.

When is the study starting and how long is expected to run for?
September 2018 to December 2025

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

Who is the main contact?
Dr Jessamine Chen Jessamine.Chen@mq.edu.au
(updated 03/08/2021, previously: Prof. Viviana Wuthrich, Viviana.wuthrich@mq.edu.au)

# Contact information

### Type(s)
Scientific


### Contact name
Dr Jessamine Chen

### ORCID ID
http://orcid.org/0000-0001-8753-8863

### Contact details
Department of Psychology
Centre for Emotional Health
Room 706, 4 First Walk
Macquarie University
Sydney

Australia
2109
+61 2 9850 9882
jessamine.chen@mq.edu.au

# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
ACTRN12619000219189

# Study information

### Scientific Title
Translating evidence-based psychological interventions for older adults with depression and anxiety into public and private mental health settings using a stepped care framework: a clinical and cost-effectiveness trial

### Study objectives
The purpose of this study is to test the clinical- and cost- effectiveness of a stepped care psychological interventions compared to treatment as usual for ageing adults with anxiety and depression within existing services representing public (urban, regional) and private mental health organisations.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 21/12/2018, South Eastern Sydney Local Health District (SESLHD) (Administration Support Officer, Research Support Office G71, East Wing Edmund Blacket Building, Prince of Wales Hospital, Randwick NSW 2031, Australia; +61 0(2) 9382 3386; +61 0(2) 9113 2481; Andrew.Bohlken1@health.nsw.gov.au), Approval ID: 18/218 (HREC/18/POWH/447)

Site-Specific Approval:
1. Approved 03/05/2019, Macquarie University Human Research Ethics Committee Medical Sciences Ethics Committee (Ethics Secretariat, Research Services, Level 3, 17 Wally's Walk, Macquarie University, NSW 2109, Australia; +61 (0)2 9850 4459 (Administration); +61 (0)2 9850 7850 (HREC: Humanities and Social Sciences); +61 (0)2 9850 4194 (HREC: Medical Sciences)), Approval ID: 5201951017095
2. Approved 14/03/2018, Western NSW Local Health District Research ethics Committee - site-specific approval for the locations Orange, Dubbo and Bathurst (Western LHDs) (Research Ethics and Governance, Allied Health, Research Governance Officer, PO Box 143, 39 Hampden Park Road, Bathurst. 2795, Australia; +61 (0)2 6330 5948; Phil.Sanders@health.nsw.gov.au), Approval

ID: SSA/19/GWAHS/16
3. Approved 14/12/2020, Northern Sydney Local Health District Research Ethics Committee - site-specific approval for the site Royal North Shore Hospital (Research Office - Northern Sydney Local Health District; +612 9926 4590; nslhd-research@health.nsw.gov.au, Approval ID: 2020 /STE03897)

## Study design
Pragmatic randomised controlled trial - longitudinal design

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Other

## Study type(s)
Treatment

## Participant information sheet
Not available in web format - please use contact details to request a participant information sheet

## Health condition(s) or problem(s) studied
Depression - anxiety - ageing - stepped care

## Interventions
Suitable participants will provide informed consent and will subsequently be randomized within each service to receive the stepped care intervention or treatment as usual in block. A Faculty Statistician (independent of the research team) will create the randomisation schedule to allocate individuals to condition. Suitable participants will be randomly allocated by the Research Assistant off-site. Due to the nature of randomisation by site, clinicians and participants will not be blinded to condition controlled trial

Stepped Care intervention compromising two steps:
1. STEP 1 (low intensity) choose between: a) Internet program (iCBT): Six online lessons completed over 10 weeks (one hour per session).
This Cognitive Behavioral Therapy (CBT)- based internet program teaches the older adults skills to help manage and overcome their anxiety and depression. Treatment lessons involve (a) psychoeducation about depression and how cognitive and behavioural factors can maintain the cycle of depression, (b) behavioural activation, (c) identifying and challenging unhelpful thinking patterns (d) structured problem solving, (e) graded exposure, (f) assertiveness skills training, and (g) relapse prevention. Following each lesson, patients are instructed to download homework summaries and complete therapy tasks that reinforce the content of that lesson, prior to next week's session. Patients complete treatment over 10 weeks with a maximum of one session completed each week. Treatment is fully automated and completed by the patient (e.g. online at home), however, clinicians will contact their patients each week (15-minute phone call) to check on well fare and give support and promote treatment adherence.

b) The telephone supported work at home CBT program is a 10-week program that comprises a work-at-home workbook (Happy Healthy Ageing) outlining the skills covered in the Ageing Wisely program (see below) and practice task that are supported by brief (15 minute) weekly therapist telephone calls over 10 weeks.

In both low-intensity programs of STEP, the involved clinicians will monitor patients' progress and symptoms through treatment and any questions the patient may have will be answered. Elevated level of distress will be measured using the Kessler 10- item (K10).

At the end of the low-intensity program, clinicians will contact the older adult and discuss their progress and continuing needs. They will discuss whether they want to go on to receive face-to-face treatment or if they are sufficiently improved to stop receiving help. Those interested in proceeding will then be offered STEP 2.

2. STEP 2 (high intensity): Individual face-to-face Cognitive Behavioural therapy sessions using a manualised CBT program (Ageing Wisely). This CBT program teaches them skills to manage symptoms of depression and anxiety including: goal setting, activity scheduling, problem-solving, graded exposure, cognitive restructuring, assertiveness skills, and sleep hygiene. This program will be delivered one-on-one with a clinician for an hour a week for 11 weeks (to be completed in 13 weeks). If in-person visits are not practical, Skype/Zoom sessions or hour-long telephone sessions will be offered.

Similar to STEP 1 programs, clinicians at each site will monitor patients' progress through treatment and will instigate further assessment and emergency procedures as needed. Elevated level of distress will be measured using the Kessler 10- item (K10).

At the end of Step 2, if needed the patients will receive additional therapy and referrals as indicated by the team psychiatrist. Additional therapy may involve a referral to the GP for psychiatric review.

In both STEP 1 and STEP 2, all treatment sessions will be run by, site staff trained in the delivering of the treatment protocols of the stepped care intervention. To control for therapist differences, all therapists will be trained in and will conduct both treatments (allocated randomly).

Treatment as Usual (TAU): Participants allocated to TAU will receive usual practice at their site parallel to those allocated to the stepped care intervention. What constitutes normal procedures will be extracted from participant files and coded after the study.

## Intervention Type
Behavioural

## Primary outcome measure
Illness severity assessed using the Clinical Global Impression scores (CGI-S) at baseline assessment - (prior to program entry and completed during intake), post-treatment 13 weeks assessment (13 weeks from start of therapy), primary endpoint post-treatment 26 weeks assessment (26 weeks from start of therapy), and follow –up 12 months assessment (12 months from start of therapy)

## Secondary outcome measures
1. Anxiety symptoms measured by the Geriatric Anxiety Inventory (GAI- 5) total score at baseline assessment (prior to program entry and completed during intake), post-treatment 13 weeks

assessment (13 weeks from start of therapy), primary endpoint post-treatment 26 weeks assessment (26 weeks from start of therapy), and follow-up 12 months assessment (12 months from start of therapy)
2. Depressive symptoms measured by the Geriatric Depression Scale (GDS - 15) total score is assessed at baseline assessment - (prior to program entry and completed during intake), post-treatment 13 weeks assessment (13 weeks from start of therapy), primary endpoint post-treatment 26 weeks assessment (26 weeks from start of therapy), and follow -up 12 months assessment (12 months from start of therapy)
3. Depressive symptoms measured using the Depressive Symptoms Inventory – Suicide Subscale total score at baseline assessment - (prior to program entry and completed during intake), post-treatment 13 weeks assessment (13 weeks from start of therapy), primary endpoint post-treatment 26 weeks assessment (26 weeks from start of therapy), and follow-up 12 months assessment (12 months from start of therapy)
4. Diagnostic severity measured using the Anxiety Disorders Interview Schedule 5th edition (ADIS -5) for DSM-5 at baseline assessment (prior to program entry and completed during intake), post-treatment 13 weeks assessment (13 weeks from start of therapy), primary endpoint post-treatment 26 weeks assessment (26 weeks from start of therapy) and follow-up 12 months assessment (12 months from start of therapy)
5. Personality traits measured using the Personality Inventory for DSM-5—Brief Form (PID-5-BF) at baseline assessment - (prior to program entry and completed during intake), post-treatment 13 weeks assessment (13 weeks from start of therapy), primary endpoint post-treatment 26 weeks assessment (26 weeks from start of therapy), and follow-up 12 months assessment (12 months from start of therapy)
6. Quality of life and health outcomes across eight domains measured using the Australian Quality of Life (AQoL-8D) measure (economic evaluation) at baseline assessment - (prior to program entry and completed during intake), post-treatment 13 weeks assessment (13 weeks from start of therapy), primary endpoint post-treatment 26 weeks assessment (26 weeks from start of therapy), and follow-up 12 months assessment (12 months from start of therapy)
7. Health resource use (data extraction) over time measured using a purpose-built medical cost questionnaire (see secondary outcome 10), supplemented with linked data from the NSW Centre for Health Record Linkage (CHeRel) on Admitted Patient data, Emergency Department data, and Mental Health Ambulatory data, along with Medicare Benefit Schedule (MBS) and Pharmaceutical Benefit Schedule (PBS) data and captured at baseline assessment (prior to program entry and completed during intake) and at the 12 month follow-up assessment (12 months from start of therapy)
8. Consumer-related feedback (participants experiences, benefits, barriers and dislikes) captured using standardised YES (Your Experience of Service) survey used by NSW mental health services completed by the client at the post-treatment 13 weeks assessment (13 weeks from start of therapy) and at the post-treatment 26 weeks assessment (26 weeks from start of therapy)
9. Frequency and source of use of care services measured using the Use of care Services Survey (Health Resource Use) at baseline assessment (prior to program entry and completed during intake), post-treatment 13 weeks assessment (13 weeks from start of therapy), primary endpoint post-treatment 26 weeks assessment (26 weeks from start of therapy), and follow-up 12 months assessment (12 months from start of therapy)
10. Behaviour, impairment, symptoms and social functioning measured using the Health of National Outcomes Scale (HoNOS 65+) at baseline assessment (prior to program entry and completed during intake), post-treatment 13 weeks assessment (13 weeks from start of therapy), primary endpoint post-treatment 26 weeks assessment (26 weeks from start of therapy), and follow-up 12 months assessment (12 months from start of therapy)
11. Patient and therapist satisfaction with the treatment program offered evaluated using consumer and staff surveys. The consumer survey will be administered at the post-treatment 13 weeks assessment (13 weeks from start of therapy) and the post-treatment 26 weeks

assessment (26 weeks from start of therapy). The staff survey will be administered annually and completed by each clinician involved.
12. Staff beliefs and attitudes towards the new treatment program measured using an additional staff survey before and after attending a clinician training in the aspects of the treatment program
13. Health-related productivity losses including presenteeism and absenteeism in paid and unpaid work measured using the iMTA Productivity Cost Questionnaire total score administered at baseline assessment (prior to program entry and completed during intake), post-treatment 13 weeks assessment (13 weeks from start of therapy), primary endpoint post-treatment 26 weeks assessment (26 weeks from start of therapy), and follow-up 12 months assessment (12 months from start of therapy)

Previous secondary outcome measure 4:
4. Diagnostic severity measured using the Structured Clinical Interview. International Neuropsychiatric Interview (M.I.N.I. version 7.0.2 for DSM-5) at baseline assessment - (prior to program entry and completed during intake), post-treatment 13 weeks assessment (13 weeks from start of therapy), primary endpoint post-treatment 26 weeks assessment (26 weeks from start of therapy), and follow-up 12 months assessment (12 months from start of therapy)

### Overall study start date
14/09/2018

### Completion date
31/12/2025

## Eligibility

### Key inclusion criteria
1. Older adults aged 65 years or older
2. Anxiety and/or depression is the main interfering problem according to the intake assessment and indication of significant anxiety and/or depression symptoms on the Health of National Outcomes Scale 65+ (HoNOS 65+)
3. Access to either the Internet or a phone

### Participant type(s)
Patient

### Age group
Senior

### Lower age limit
65 Years

### Sex
Both

### Target number of participants
N = 666

### Total final enrolment

### Key exclusion criteria
1. English language illiteracy
2. Psychosis
3. Bipolar disorder
4. Drug/alcohol dependence
5. Active suicidality
6. Significant uncorrected hearing loss
7. Likely moderate to severe dementia based on standardized cognitive screener tests (varies across sites e.g. six-item Cognitive Impairment Screener, Mini Mental State Examination (MMSE), Rowland University Dementia Scale (RUDAS), the Montreal Cognitive Assessment (MOCA) or the Addenbrooke's Cognitive Examination – version 3 (ACE- III))
8. Participants need to have adequate physical (health) ability to complete internet/phone based therapy
9. Co-morbidity with other psychiatric diagnoses (with the exception of psychotic or bipolar disorder) is allowed in order to establish a clinically relevant, broadly representative sample

### Date of first enrolment
15/07/2019

### Date of final enrolment
31/12/2023

## Locations

### Countries of recruitment
Australia

### Study participating centre
**Prince of Wales Hospital**
Old Age Mental Health Services
Euroa Centre
Centre for Healthy Brain Ageing
Barker St
Sydney
Australia
2031

### Study participating centre
**The Older People's Mental Health (OPMH) service, Western NSW Local Health District - location Orange**
Curran Centre
145-147 March Street
Orange
Australia
2800

**Study participating centre**
**The Older People's Mental Health (OPMH) service, Western NSW Local Health District - location Bathurst**
Bathurst Hospital
Bathurst
Australia
2795

**Study participating centre**
**The Older People's Mental Health (OPMH) service, Western NSW Local Health District - location Dubbo**
41 Bultje Street
Dubbo
Australia
2830

**Study participating centre**
**Macquarie University - Centre for Emotional Health Clinic**
The Australian Hearing Hub, 16 University Ave
Sydney
Australia
2109

**Study participating centre**
**Royal North Shore Hospital**
Older Peoples Mental Health Service
Level 3, 2C Herbert Street
St Leonards
Australia
2065

# Sponsor information

**Organisation**
Macquarie University

**Sponsor details**
Centre for Emotional Health
Department of Psychology

Balaclava Road
North Ryde
Australia
2109
(02) 9850 8711
ehc.admin@mq.edu.au

**Sponsor type**
University/education

**Website**
https://www.mq.edu.au/research/research-centres-groups-and-facilities/healthy-people/centres/centre-for-emotional-health-ceh

**ROR**
https://ror.org/01sf06y89

# Funder(s)

**Funder type**
Government

**Funder Name**
Beyond Blue

**Funder Name**
National Health and Medical Research Council

**Alternative Name(s)**
NHMRC

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
Australia

# Results and Publications

**Publication and dissemination plan**

The results of the study will be presented at national and international conferences, in the media, on websites at the various organisations involved in this study. In these instances, only de-identified data will be used, and only averages will be reported. Planned publication in high-impact peer-reviewed journals of the study results (and study protocol). In addition, the results will also be available after the study completion (in 2022) and can be accessed via the website www.mq.edu.au/ceh. No individually identifying information will be reported. Additional study documents (study protocol and treatment manuals) will also be available after study completion through the website www.mq.edu.au/ceh.

## Intention to publish date
31/12/2026

## Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the study will be available upon request. This research project will be conducted, and its associated data collected and destroyed, in line with Human Research Ethics requirements. With the exception of data related to the use of ambulatory and hospital services, the data collected about treatment will be stored and held securely for a minimum of 15 years. At the conclusion of the study, once all information that relates to the participants and that could be used to identify participants have been removed, this treatment data may be shared with other researchers and will be stored in online data storage repositories at Macquarie University. Sharing of the participants' de-identified data, which cannot be linked back to the participant, is a standard practice that helps with the conduct of future research.

## IPD sharing plan summary
Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | | 01/05/2021 | 29/03/2021 | Yes | No |