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Trial of online support for primary care patients tapering off antidepressant medication

Submission date
04/04/2022

Recruitment status
Recruiting

Registration date
05/05/2022

Overall study status
Ongoing

Last Edited
15/07/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The use of antidepressants (ADs) is increasing globally, including within Australia, which has one of the highest rates of AD prescribing. Despite clear benefits for many people, there is reason to believe that the ongoing use of these medications is often not properly monitored or stopped (deprescribed) when a person returns to better Mental health. This trial sets out to test how well an online support tool (WiserAD) can help patients and their general practitioner to manage the careful and appropriate reducing and stopping of antidepressants, in primary care patients.

Who can participate?
Patients aged 18-75 years, who have been stable on their ADs for <=12 months, with no or mild depressive symptoms and no history of recurrent depression.

What does the study involve?
All participants will receive a phone call from the study team one week after randomisation. Participants allocated to the intervention arm will be provided with a personal login code for the study web portal and encouraged to complete the initial components of the intervention (Assess and Advise) which seek to determine participants' current support and management strategies and help them to understand their specific antidepressants. They will then complete the third component which contains three sub-sections to assist in creating a personal plan to help them cease their ADs: i) Prepare – management strategies for withdrawal symptoms and opportunities to discuss the plan with their GP or trusted mental health worker; ii) Schedule - Selecting a start time to begin tapering; iii) Share – Print out of the personalised action plan to keep and share with supportive family and/or friends. Participants will also be required to complete a daily check-in through the portal which will check current symptoms and highlight any negative changes in emotional wellbeing, they will also receive texts reminders to complete these tasks. Participants allocated to the usual care arm will receive usual care plus attention control which comprises a link to the beyondblue website and directed to the AD factsheet. Participants will not receive any instructions regarding their personal AD use (i.e. they will not be advised to cease or continue). Both arms will receive reminders to complete their research follow up measures online (or by phone if they prefer) at 3, 6, 12, 18 and 24 months.

What are the possible benefits and risk of participating?
WiserAD will provide AD users with the opportunity to reflect on their emotional health and well-being and current need for antidepressant medication. This will also help us to find out if the WiserAD support tool is effective. We do not anticipate any risks, side-effects, or discomforts. However, if patients are asked to taper (reduce down) their medication as part of the trial, we will monitor how well they are coping with this through a daily update from the WiserAD tool and the dosage may be adjusted accordingly, in consultation with a GP, who will remain their responsible clinician.

Where is the study run from?
The University of Melbourne, Department of General Practice, Australia.

When is the study starting and how long is it expected to run for?
March 2018 to December 2026

Who is funding the study?
National Health and Medical Research Council (NHMRC; ID no.: 1157337)

Who is the main contact?
Dr Cath Kaylor-Hughes
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Contact information

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT05355025

Secondary identifying numbers
ACTRN126220000567729, NHMRC ID no. 1157337

Study information

Scientific Title
WiserAD: A randomised trial of a structured online intervention to promote and support antidepressant deprescribing in primary care

Acronym
The WiserAD Study

Study objectives
WiserAD (a novel, structured approach to deprescribing antidepressants) will be more effective than usual practice in enabling GPs to help primary care patients to cease (or decrease) their antidepressant medication whilst maintaining patient mental health and wellbeing.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 21/07/2021, University of Melbourne Human Research Ethics Committee (HREC) (Level 5, Alan Gilbert Building, 161 Barry Street, Carlton, 3010, Australia; +61 03 8344 1376; HumanEthics-Enquiries@unimelb.edu.au), ref: 20558

Approved 12/08/2021, University of Melbourne Human Research Ethics Committee (HREC, Office of Research Ethics and Integrity, University of Melbourne, VIC 3010, Australia; +61 8344 1376; HumanEthics-Enquiries@unimelb.edu.au), ref: 20558

Study design
Single-blind parallel-arm randomized controlled trial

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

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
Decreasing antidepressant (AD) medication for depression

Interventions
All participants will receive a brief <10 minute check-in phone call from the study team one week after randomisation to make sure that they have access to the intervention or attention control.

Participants will be provided with a link and personal login code for the study web portal which has been purposely built for the trial. Participants will receive the code via automated email and will be encouraged to complete the initial components of the intervention (Assess and Advise) which seek to determine participants' current support and management strategies and help them to understand their specific antidepressants (ADs) (approx 10 minutes). They will then complete the third component which contains three sub-sections to assist in creating a personal plan to help them cease their ADs:
i) Prepare – management strategies for withdrawal symptoms and opportunities to discuss the plan with their GP or trusted mental health worker;
ii) Schedule - Selecting a start time to begin tapering;
iii) Share – Print out of the personalised action plan to keep and share with supportive family and /or friends (approx 5 minutes total to completed).

At this point, participants will also be asked to share their tapering schedule with their GP for modification if necessary. Participants will asked to complete their appointment with their GP within two weeks. Once the tapering schedule has been approved, participants will log back into the web portal and will be required to complete a daily check-in through the portal which will check current symptoms and highlight any negative changes in emotional wellbeing (approx 10 minutes), they will also receive texts reminders to complete these tasks. Apart from the reminder texts and email communications, all information will be provided to participants via the WiserAD web portal.

Participants will have access to the WiserAD online support tool for the duration of the study (minimum of 3-months post randomisation and until last data collected from the last participant, therefore up to 18-months), however they will be encouraged to begin tapering their ADs within two weeks of receiving approval of their tapering schedule. Use of the WiserAD online support tool will be monitored using purpose built analytics within the WiserAD web portal (unblinded study team access only).

Randomisation:
The treatment to which a participant is assigned will be determined by a computer generated pseudo-random code using random permuted blocks of varying size, created by the web developers and held on a secure server. Computer generated pseudo-random code using random permuted blocks of varying size, created by the web developers and held on a secure server. Participants will be allocated with equal probability to each treatment arm and stratified by site (GP clinic).

Intervention Type
Behavioural

Primary outcome measure
Proportion of patients successfully ceasing ADs at 6 months where successful cessation is defined as no AD use (as measured by the Resource Use Questionnaire (RUQ)) and the absence of clinically significant depressive symptoms (as measured by the Patient Health Questionnaire 9-item (PHQ-9)). Measured at 3-, 6-, 12-, 18-months post-baseline. Primary outcome is at 6-months post baseline.

Secondary outcome measures
1. Depressive symptoms (PHQ-9) - Measured at baseline, 3-, 6-, 12-, 18months.
2. Anxiety symptoms (GAD-7) - Measured at baseline 3-, 6-, 12-, 18-months.
3. Patient Activation (PAM) - Measured at baseline, 3-, 6-months.
4. Quality of Life (AQoL-4D) - Measured at baseline, 3-, 6-, 12-, 18-months.
5. Health Service Use (Resource Use Questionnaire) - Measured at baseline, 3-, 6-, 12-, 18-months.
6. Beliefs About Medication Questionnaire (BMQ) - Measured at baseline, 3-months.
7. Signs and Symptoms (A study specific 3-item text response measure for patient reported withdrawal symptoms) - Measured at 3-, 6-months.
8. User Engagement Scale-Short Form (UES-SF) - Measured at 3-, 6-months.
9. Accountability Measurement Tool (AMT) - Measured at 3-, 6-months.
10. Medical Benefit Scheme (MBS; health service use) and the Pharmaceutical Benefit Scheme (PBS; pharmaceutical use) data - collected at
11. the completion of the study (for the whole duration of participation in the study (18-months)).
12. Proportion of patients successfully ceasing ADs where successful cessation is defined as no AD use (as measured by the Resource Use Questionnaire (RUQ)) and the absence of clinically significant depressive symptoms (as measured by the Patient Health Questionnaire 9-item (PHQ-9))Measured at 3-, 12-, 18-months post baseline.

Overall study start date
07/03/2018

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. 18-75 years
2. Stable on AD for >=12m: (no depressive episodes)
3. No history of recurrent depression

4. Sufficient English language proficiency to provide informed consent
5. No or mild depressive symptoms as measured on the Personal Health Questionnaire (PHQ9)
6. Low risk of Suicide or Self-harm
7. Agree to consider reviewing their AD use
8. Agree to be randomized into the study
9. Willing to provide informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
312

Key exclusion criteria
1. Those currently experiencing a major life event in the next 3 months
2. Currently using ADs for any other health condition (other than depression)
3. Currently using non-SSRI or SNRI ADs, antipsychotics, or other mood stabiliser medication
4. Have no daily access to the internet

Date of first enrolment
25/04/2022

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
Australia

Study participating centre
Parkville Precinct Medical
1F Royal Parade
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Sponsor information

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University of Melbourne

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Sponsor type
University/education

Website
http://www.unimelb.edu.au/

ROR
https://ror.org/01ej9dk98

Funder(s)

Funder type
Government

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
Additional documents to be made available at a later date. Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/03/2027

Individual participant data (IPD) sharing plan
IPD will not be available publicly due to confidential information being collected as part of the trial. Data collected as part of the trial will be for research purposes only.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications		13/02/2024	15/02/2024	Yes	No