


# BMJ Open Improving depression outcomes among Australian primary care patients: protocol for a cluster randomised controlled trial

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## ABSTRACT

**Introduction** Depression is a common and debilitating condition. In Australia, general practitioners (GPs) are the key providers of depression care. However, available evidence suggests that case finding for depression in primary care is poor. This study will examine whether a systematic approach to screening for depression and assessing patient preferences for depression care improves depression outcomes among primary care patients.

**Methods and analysis** A cluster randomised controlled design will be used with general practice clinics randomly assigned to either the intervention (n=12) or usual care group (n=12). Patients who are aged 18 and older, presenting for general practice care, will be eligible to participate. Eighty-three participants will be recruited at each clinic. Participants will be asked to complete a baseline survey administered on a touch screen computer at their GP clinic, and then a follow-up survey at 3, 6 and 12 months. Those attending usual care practices will receive standard care. GPs at intervention practices will complete an online Clinical e-Audit, and will be provided with provider and patient-directed resources for depression care. Patients recruited at intervention practices who score 10 or above on the Patient Health Questionnaire-9 will have feedback regarding their depression screening results and preferences for care provided to their GP. The primary analysis will compare the number of cases of depression between the intervention and control groups.

**Ethics and dissemination** The study has been approved by the University of Newcastle Human Research Ethics Committee, and registered with Human Research Ethics Committees of the University of Wollongong, Monash University and University of New South Wales. Results will be disseminated through peer-reviewed journal publications and conference presentations.

**Trial registration number** ACTRN12618001139268; Pre-results.

## INTRODUCTION

Depression affects 350 million people worldwide.<sup>1</sup> It can have a profound impact on

## Strengths and limitations of this study

- This study will use a cluster randomised controlled design.
- Examining patient preferences for care as part of depression screening will facilitate a more patient-centred approach to care.
- It is not feasible to use a gold-standard clinical interview to diagnose depression; therefore, a Patient Health Questionnaire-9 score of 10 or more will be used to define 'cases' of depression at follow-up.

quality of life and is associated with unemployment and economic disadvantage.<sup>2,3</sup> Depression and anxiety are the second highest causes of disease burden in Australia, with mental disorders costing over \$6.38 billion annually in direct and indirect costs.<sup>4</sup> In 2015–2016, depression was the fourth most common problem managed by general practitioners (GPs), accounting for 4.2 in every 100 encounters<sup>5</sup> and depression accounts for 12% of primary care initiated referrals to allied health providers.<sup>5</sup>

Available evidence suggests one barrier to improving depression outcomes is poor case finding in the primary care setting. Mitchell's meta-analysis of 41 studies indicated that there was agreement between GPs' unassisted diagnoses of depression among primary care patients and diagnoses from structured interviews in only 47% of cases.<sup>6</sup> Our study, conducted with 51 GPs and over 1500 primary care patients, also demonstrated that GP unassisted diagnosis was highly specific (87%), but poor in terms of sensitivity (51%) compared with a standardised instrument, the Patient Health Questionnaire-9 (PHQ-9).<sup>7</sup>

Several reviews have addressed the question of whether providing GPs with feedback

about patients' scores on a standardised assessment of depression is effective in improving outcomes in the primary care setting.<sup>8–10</sup> The most recent systematic review identified just five studies relevant to the general adult primary care population.<sup>10</sup> Of the five trials, three reported no intervention effect.<sup>11–13</sup> Notably, the two studies which reported a positive impact also included additional staff support to assist with managing depression. In the first study, 47% of those newly identified with depression achieved remission in the intervention group, compared with 28% in the usual care group at 12 months.<sup>14</sup> In the second, 58% of people newly and previously identified as cases achieved remission in the intervention group, compared with 49% in the usual care group at 12 months.<sup>15</sup>

Despite the relative simplicity and potential benefits of providing feedback to GPs on patients' depression scores, there is a lack of methodologically adequate research to inform practice. Studies are characterised by a lack of power and high attrition.<sup>10</sup> Four out of five studies in O'Connor's review<sup>10</sup> were conducted in the USA, and no Australian trials have been conducted. Therefore, the applicability of available evidence to the Australian context is unknown.

Primary care patients who receive treatment that matches their preference recover more quickly<sup>16</sup> and are less likely to drop out of treatment<sup>17</sup> than those who perceive a mismatch between their preferred and received treatment. Therefore, information about patients' perceived needs and preferences for treatment are likely to be an important adjunct to information on severity of depressive symptoms. This study will examine the effectiveness of an intervention providing GPs with feedback about their patients' depressive symptoms, preferences and perceived need for help.

### Primary aim

To determine the effectiveness and cost-effectiveness of an intervention designed to facilitate delivery of patient-centred depression care in reducing the proportion of primary care patients identified as possible 'cases' for depression at 12 months follow-up.

### Secondary aims

To examine the impact of the intervention on GPs' patterns of referrals for mental healthcare and prescription of psychotropic medications over a 12-month follow-up period.

### Primary hypotheses

(1) Compared with those attending practices allocated to the usual care group, the proportion of patients scoring 10 or more on the PHQ-9 will be 10% lower in the intervention group at a 12-month follow-up. (2) The intervention will be cost-effective compared with usual care based on quality-adjusted life years (QALYs) and commonly employed willingness to pay thresholds.

## METHODS AND ANALYSIS

### Design

A two-arm cluster randomised controlled trial with general practices as the unit of allocation (please refer to figure 1). Consenting practices will be randomly allocated to either: (1) usual care or (2) intervention. Patient outcomes will be collected at baseline and at 3, 6 and 12 months follow-up. The primary endpoint will be the proportion of likely 'cases' of depression at a 12-month follow-up, as measured by the PHQ-9. Cost-effectiveness and delivery of depression care will be assessed using data that reflects the resources used to deliver the intervention, including implementation costs and health service utilisation, specifically the Pharmaceutical Benefits Scheme (PBS) and Medicare Benefits Schedule (MBS). Utilisation data will be obtained for the 12 months preceding patient recruitment and 12 months postrecruitment for consenting participants. Results will be reported in line with Consolidated Standards of Reporting Trials recommendations.<sup>18</sup>

### Setting

General practice clinics in Australia.

### General practice sample

#### Practice eligibility

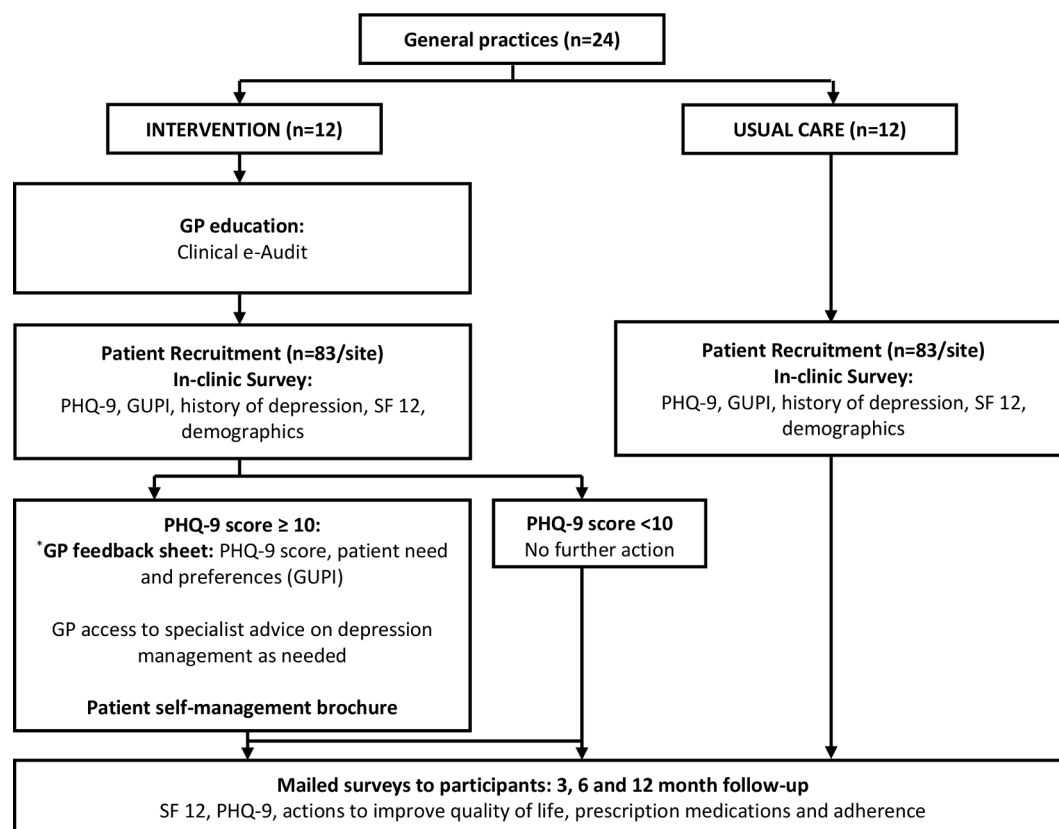
Eligible, practices must have at least one eligible GP who works at least 0.4 full time equivalent (or four sessions) a week who agrees to participate. Eligible GPs will have completed Royal Australian College of General Practitioners (RACGP) accredited GP Mental Health Skills Training. GPs who have previously completed the online Clinical e-Audit: Depression: Achieve remission, prevent relapse (92162) will not be eligible to participate. Sampling of practices will continue until 24 practices are recruited to the trial.

### Recruitment

Practices will be sent an invitation letter from one of the academic GP investigators; then contacted by telephone after 1 week to discuss participation. Informed written consent will be sought from both the practice and individual GPs within the practices.

### Randomisation

Practices will be randomly allocated to the intervention (n=12) or usual care group (n=12). Randomisation will be stratified according to practice characteristics, which influence the degree of colocation with mental health providers (community health centre, small private practice (1–3 GPs), large private practice (>3 GPs) and characteristics of the area in which the practice is located (metropolitan areas which are socioeconomically advantaged; metropolitan areas with lower socioeconomic advantage, and regional and remote areas). The latter has been shown to be associated with differences in patterns of depression care.<sup>19</sup> The Accessibility and Remoteness Index of Australia (ARIA+) will be used to define metropolitan (ARIA ≤2.4) and regional or remote (ARIA



**Figure 1** Flow chart of study process. \*For duty of care purposes, GPs will also be provided with feedback for usual care participants at baseline who score 20 or more on PHQ-9 (indicative of severe depression) or any participant who scores >1 on item 9 of PHQ-9 (indicative of potential self-harm). GP, general practitioner; GUPI, General Practice Users Perceived needs Inventory; PHQ, Patient Health Questionnaire; SF-12, Short Form Health Survey 12.

>2.4)<sup>20</sup>; while a median split of post codes will define high versus lower socioeconomic advantage according to the Index of Relative Socioeconomic Advantage and Disadvantage.<sup>21</sup> Randomisation will be conducted centrally by the Clinical Research Design, IT and Statistical Support unit at the Hunter Medical Research Institute. Due to the nature of the intervention, blinding of healthcare providers and patients will not be possible.

## Patient sample

### Eligibility

Those attending a participating practice aged 18 years or older, and who have sufficient English to complete a survey independently.

### Exclusion criteria

Patients judged by staff to be physically or cognitively unable to complete the survey or provide independent informed consent.

## Training of staff in recruitment processes

Recruitment will be conducted by trained practice staff (eg, a practice nurse or receptionist). Nominated practice staff will receive videos demonstrating patient recruitment processes, a recruitment manual and one-to-one tutorials. These will be conducted by Skype and/or telephone. During the tutorials, staff will practise recruitment

processes, including role-plays of simulated situations to assess competency and receive feedback. A researcher will make site visits to practices to ensure that recruitment processes are being implemented in accordance with the protocol and assist with trouble shooting. Practices will be reimbursed for staff time spent undergoing training. A fee of \$100 per participant recruited will be provided to cover staff time spent on recruiting participants.

## Recruitment of patients

Attending patients of participating GPs will be invited to participate in the study by practice staff on presenting to reception for their appointment. Written informed consent will also be obtained from all participants for the study (see online supplementary material). This will include consent for non-identifiable data to be shared with third parties to encourage scientific scrutiny or for the purpose of further research. Participants will also be asked to provide separate consent to access MBS and PBS data for the 12 months before and following recruitment.

## Data collection

### Baseline

Participants will complete a 5–10 min survey using a web-connected touch screen computer tablet while waiting for their GP consultation. The baseline survey

will include screening questions to confirm eligibility, as well as questions about sociodemographic characteristics, history of depression, medical conditions, PHQ-9, Short Form Health Survey 12 (SF-12v2), perceived need for GP help with behavioural risk factors (quitting smoking, improving diet, increasing exercise, reducing alcohol intake and losing weight), perceived need for GP help with emotional problems (assessed by the General Practice Users Perceived needs Inventory (GUPI)<sup>22</sup>) and the name of the GP they are seeing.

### Follow-up

The same participants will complete a follow-up pen-and-paper survey at 3, 6 and 12 months follow-up. The survey will include questions about the patient's health, the PHQ-9, SF-12, questions about actions taken to improve health and quality of life, and questions regarding adherence to any prescribed treatments. The follow-up survey will be mailed to participants with a preaddressed, reply paid envelope. A reminder package, including a second copy of the survey, will be sent to non-responders after 2 weeks. A second reminder package will be sent to non-responders after a further 2 weeks. Patients will be given the option to complete the survey online if they prefer, via a link provided in the package.

### Ethical usual care

Patients attending practices allocated to this condition will complete the baseline screening questionnaire. In line with our duty of care, GPs will be provided with feedback for patients in the usual care condition who score 20 or more at baseline on the PHQ-9 (indicative of severe depression)<sup>23</sup> and/or who score >1 on item 9 of the PHQ-9 (indicative of potential self-harm).<sup>24</sup> At follow-up, patients who score 20 on the PHQ-9 or who score >1 on item 9 of the PHQ-9 will be sent a letter by the research team. The letter will include information about potential sources of help, including their GP and a mental health helpline Lifeline Australia.

### Intervention

The intervention will comprise usual care in addition to the following steps.

#### Step 1: GP education

Consenting GPs will complete a RACGP-endorsed online active learning module prior to commencement of data collection. The module was developed by NPS MedicineWise and entitled 'Depression: Achieving remission, preventing relapse' (92162). The module is in the form of a Clinical e-Audit whereby participants are asked to enter data and reflect on the management of 10 of their adult patients who have been prescribed antidepressant medication. It covers both pharmacological and non-pharmacological treatments for depression, and will guide GPs in the development of personalised management plans, reviewing patient responses to treatment and modifying plans accordingly. Each GP will also have access to a Quick Reference Guide with contact details

of organisations available to support both clinicians and patients in managing depression.

#### Step 2: pre-GP consultation

Consenting patients will complete the baseline assessment via touch screen computer prior to their consultation with the GP. On survey completion, the web-based software will automatically calculate the patient's PHQ-9 score. The patient will hand the computer tablet back to the practice staff member on completion of the survey. The staff member will open a summary screen of the patient's responses to the PHQ-9 and GUPI. For those patients who score 10 or more on the PHQ-9, or greater than 0 on item 9, tailored feedback of the patient's PHQ-9 and GUPI results will be generated for provision to their GP. A copy of the feedback will be provided to the patient's GP.

#### Step 3: GP consultation

The feedback sheet will provide GPs with summarised information about the patient's severity of depressive symptoms (ie, PHQ-9 score) including information on the patient's response to the item 9 question about potential self-harm, and the patient's willingness to discuss help for depression with their GP and their preferred type of help (ie, GUPI). Together with the GP's knowledge of the patient's personal and medical history, this information can be used by the GP to guide secondary screening to determine whether the patient has a diagnosis of depression, and if so, which treatment approach should be recommended.

#### Step 4: patient self-management strategies

GPs will also be provided with printed brochures on self-management strategies that can be offered to patients at GP discretion. For example, they may be offered to patients who indicate a preference for self-management strategies; or to those for whom self-management strategies are likely to be a useful adjunct to the agreed treatment approach. The brochures will comprise of the publicly available 'beyondblue Connect toolkit.' The toolkit consists of six worksheets with information and general advice for improving well-being through activities such as simple cognitive behavioural strategies. The toolkit also includes telephone and web contact details for beyondblue mental health support services.

### Measures

Participants will complete a survey at baseline, 3, 6 and 12 months follow-up.

#### Primary outcome

PHQ-9<sup>23</sup> (nine items) is a brief depression screening tool which has been widely used in primary care settings. Frequency of symptoms is rated from 0 (not at all) to 3 (nearly every day). Higher scores indicate more severe depression. A recent meta-analysis has shown that the tool has high specificity (81%) and sensitivity (85%) when used to screen for major depression.<sup>25</sup> The pooled

positive likelihood ratio was 5.37 and the negative likelihood ratio was 0.21. A high Cronbach's alpha of 0.89 has been reported in a primary care sample.<sup>23</sup> The PHQ-9 will be administered at baseline and each follow-up.

### Secondary outcomes

Quality of life will be measured using the SF-12. This instrument asks patients to self-rate their health and their ability to undertake normal activities. The SF-12 is a reliable measure of health-related quality of life among people with mental health conditions<sup>26</sup> and has been validated for use within the Australian population.<sup>27</sup> Estimates for total health service utilisation and medication use for each participant will be sourced from the linked MBS and PBS data. Delivery of mental health services specifically will be assessed via the following MBS items: GP mental health treatment items (2700–2717); Provision of Focused Psychological Strategies (2721–2727); Provision of Psychological Therapy Services by a Clinical Psychologist (80000–80020) and Consultant Psychiatrist Referred Patient Assessment and Management Plan (296, 299, 361, 291, 293, 359). For each service, details such as the following will be provided: Date of service, Medicare item number; item description; provider charge; schedule fee; benefit paid; patient out of pocket; scrambled rendering provider number; date of referral; rendering provider postcode; ordering provider postcode.

Psychotropic medications: For each participant, the following details regarding prescription of psychotropic medications will be obtained: medication type; date of supply; date of prescription; PBS item code; item description; patient category; patient contribution; net benefit; scrambled prescriber number; pharmacy postcode.

### Explanatory variables collected at baseline

Patient sociodemographics and health variables: Age, gender, marital status, education, Aboriginal and Torres Strait Islander status, postcode, number of family/household members, pregnancy, any diagnosed chronic diseases including depression and name of GP patient is seeing will be collected at baseline.

GUPI:<sup>22</sup> This instrument asks respondents to indicate their need for: (1) information about emotional problems and treatments; (3) medication to help manage emotional problems; (3) counselling for emotional problems; (4) help with practical issues such as housing or money and (5) help with ability to work and care for oneself.

### Explanatory variables collected at each follow-up

Use of self-management strategies: Participants will be asked if they undertook any self-management strategies or resources from their GP in the past 3 months; and to indicate the type and frequency of use of any self-management strategies or resources. Adherence to medications for depression: Patients will be asked if they have been prescribed any antidepressant medications in the past 3 months. Self-reported type of antidepressant medications will be crosschecked with PBS data. Participants

who report having been prescribed antidepressants will be asked whether, in the past week, they have (1) missed any doses; (2) taken any doses late and/or (3) taken more than the prescribed dose.

### Practice measures

Data on location, number full time equivalent GPs and whether or not the practice employs a nurse will be obtained from each practice.

### GP measures

GPs will answer a short survey at the time of consent to self-report characteristics including age; sex; number of years worked in general practice; employment status and number of sessions worked per week. Details of training in mental health skills will be sought including type of course undertaken and year of course completion. Data about the number of full time equivalent GPs, and whether or not the practice employs a nurse will be obtained, as well as whether the practice bulk bills.

### Acceptability data

Acceptability of the intervention (intervention GPs only): At the conclusion of recruitment, GPs at intervention sites will be invited to complete a telephone interview to provide feedback about intervention acceptability and feasibility.

### Monitoring of intervention and protocol fidelity

A protocol implementation checklist will be used by the trial coordinator to monitor the implementation of trial procedures. GPs will be asked to self-report completion of the educational module, and the trial coordinator will record the date of provision of intervention materials to each intervention GP.

### Data monitoring

Practices, GPs and patients will have access to a 1800 telephone number where any adverse events can be reported. Unintended effects will also be explored through analysis of trial outcome data on depressive symptoms and health service use.

The investigator team will take responsibility for monitoring adverse events, and determining, in consultation with relevant ethics committees, what steps need to be taken to minimise further adverse events.

### Data management

Data collected at baseline via an online survey will be automatically captured. Data collected at follow-up by paper and pencil will be entered into an SAS database. A number of quality assurance processes will be used to ensure data entry is accurate. First, programming of SAS will restrict the number of valid entries for a given question, thus alerting to a potential error if data outside these values is entered. A random sample of 20% will be double entered. Finally, data cleaning will take place to identify anomalies in the data that may require cross-checking with original surveys. Survey data from baseline and each

follow-up will be linked for each participant. These data will be linked to data obtained from the Department of Human Services on the use of MBS services and medications obtained via the PBS.

## Statistical analysis

### Consenters versus non-consenters

**Practices:** Characteristics of consenting and non-consenting practices will be compared with identify any consent bias using the  $\chi^2$  test for categorical variables and the t-test or a non-parametric equivalent for continuous variables.

**Patients:** Examination of the demographic characteristics of consenting and non-consenting patients will also be tested. Data will be analysed using the intent to treat principal. Base-line data will be summarised as the number of observations, means, SD, medians, minimums and maximums where the data are continuous and as number of observations and frequencies where the data are categorical. The data will be presented separately by treatment group.

### Aim 1

For the primary outcome, a PHQ-9 score of less than 10 at 12 months, we will test for group differences using a generalised linear mixed effects regression model, with a log link and a binomial distribution. The dichotomous outcome at each follow-up (baseline, 3, 6 and 12 months) is the dependent variable. The model will include fixed effect for baseline history of depression, treatment group (intervention vs usual care), time, and treatment\*time interaction, and a random intercept for each practice (assumed to be normally distributed) to account for the hierarchical structure in the data of patients nested within practices. Treatment group comparisons at postbaseline each visit will be estimated by differences in LS means from the treatment\*visit interaction and will be presented as risk ratios with accompanying p values and 95% CIs, with the primary comparison being that at 12 months. We will investigate various variance-covariance structures for the within-subject repeated measures (such as autoregressive, unstructured and compound symmetric) and choose the model with the best fit according to the smallest Akaike information criteria. As a sensitivity analysis, we will perform analyses under a variety of plausible assumptions regarding the missing data mechanism to investigate the impact of departures from the missing data assumptions.

### Aim 2

The proportion of newly identified cases at baseline who receive appropriate care at follow-up will be compared between groups using a generalised linear mixed model as described above, but the cohort will be restricted to the individuals that are identified as new cases at baseline, and the outcome will be whether or not they received appropriate care at each follow-up time point.

### Sample size

A sample of 720 patients per treatment arm (~60 per practice) at 12 months follow-up will give the study 80% power to detect a 10% decrease in the proportion of

patients who score more than 10 on the PHQ-9 in the experimental group compared with usual care at a significance level of 5%. This calculation assumes, based on data from our prior study, an intraclass correlation coefficient of 0.04, and 20% of the patients in the usual care group will have PHQ-9 scores of more than 10. Allowing for 10% attrition at each follow-up, we will need to recruit 2000 eligible consenting patients (~83 per practice). Prior trials of depression screening interventions among general adult populations in primary care have demonstrated differences between study arms in depression outcomes of between 10% and 20%,<sup>10</sup> therefore, an effect size of 10% was considered feasible for this study. The study outcome, a score of 10 or more on the PHQ-9, was selected because this threshold has been shown to identify clinically significant depressive symptoms with a high degree of accuracy.<sup>25</sup> Therefore, a reduction of the proportion of people experiencing clinically relevant symptoms of depression of 10% may be considered clinically important, not only for the individuals affected but also on a population level.

## Cost-effectiveness analysis

The economic study will be based on a cost-effectiveness analysis using within-trial outcomes and will be undertaken from a healthcare provider perspective. The study will capture the costs and consequences from the intervention and compare them to usual care. Costs will be estimated based on the additional resources required for intervention delivery, as well as net costs associated with healthcare utilisation. Unit cost data for all resources associated with an intervention will be collated based on the Pharmaceutical Benefits Advisory Committee manual of resource items<sup>28</sup> and the Medicare Schedule, measured in real prices for the selected reference year. The measure of effect will be QALYs. QALYs will be calculated from SF-6D, a multiattribute utility instrument that can be derived from the responses to the SF-12. The costs and health outcomes will be used to determine the incremental cost-effectiveness ratio, reflecting the additional cost per QALY gained. Cost-effectiveness and acceptability will be assessed against commonly accepted willingness to pay estimates per QALY. The economic results will be considered in the context of decision-making criteria: strength of evidence; capacity of the intervention to reduce inequity; acceptability to stakeholders; feasibility and sustainability. The analysis will conform to National Health and Medical Research Council protocols for economic evaluations.

## RESEARCH ETHICS AND DISSEMINATION

### Confidentiality and privacy of information

All participant data will be de-identified. The consent form which will link the participant name to their unique study identification number will be stored separately to survey data in a locked filing cabinet. Electronic files containing survey data will be stored on the University

of Newcastle server in a password-protected file. Only the chief investigators and staff employed to work directly on the study will have access to data.

## Patient and public involvement

This research was informed by our prior work and the work of others on patient experiences and preferences for depression care. This includes our work that shows that many patients with elevated depression are not identified as depressed by their doctors.<sup>7</sup> Research by others has shown that patients have varied preferences for the management of psychological concerns.<sup>29</sup> As a consequence, unlike other screening trials, our screening assessment covers both patient depressive symptoms and preferences for management. Patients have not been directly involved in the design of the study. Patients will be asked to participate in the study via the procedures outlined previously. On consenting the study, participants will be asked if they would like to receive a summary of the study findings at the completion of the study. Objective data obtained through Medicare will allow us to quantify differences in healthcare contacts attributable to the intervention, thus providing an indication of participant burden. GPs will be asked to self-report their views about the impact of the intervention on practice functioning. Processes measures including consent rates, and drop-out rates will be used to monitor acceptability.

## Dissemination

This will develop new knowledge that is applicable to the Australian healthcare system, and provide policy-relevant information regarding the benefit of the intervention and its potential for broad adoption. Study findings will be disseminated through conference presentations and publications in peer-reviewed journals.

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**Contributors** MC, AW and JW contributed to study conception and design, undertook the first draft of the manuscript and approved the final version for publication. NZ, DM, GM, LP, RS-F, FH, BK, SD, AS and CO contributed to conception and design, redrafting the manuscript and approved the final version for publication. No patients were involved in the design of the study or production of this manuscript.

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**Competing interests** None declared.

**Patient consent for publication** Not required.

**Ethics approval** The study has been approved by the University of Newcastle Human Research Ethics Committee (EC00144; Ref No. H-2017-0291), with this approval accepted and registered by Monash University Human Research Ethics Committee (EC00234; Project No. 14048); Joint University of Wollongong and Illawarra Shoalhaven Local Health District Health and Medical Human Research Ethics Committee (EC00150/EC00394; Ref No. 2018/143) and; University of New South Wales (UNSW) Sydney (H-2017-0291). Any changes to the protocol will be communicated to the study investigators and approved by each of the ethics committees. Approval to access PBS and MBS data was granted by the External Request Evaluation Committee (EREC), Department of Human Services (Ref No. MI9644).

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