

Getting it Right: study protocol to determine the diagnostic accuracy of a culturally-specific measure to screen for depression in Aboriginal and/or Torres Strait Islander people

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Abstract

Introduction: A freely available, culturally valid depression screening tool is required for use by primary care services across Australia to screen for depression in Aboriginal and/or Torres Strait Islander populations. This is the protocol for a study aiming to determine the validity, sensitivity and specificity of the culturally adapted 9-item Patient Health Questionnaire (aPHQ-9).

Methods and analysis: Cross sectional validation study. A total of 500 people who self-identify as Aboriginal and/or Torres Strait Islander, are ≥ 18 years of age, attending one of 10 primary health care services or service events across Australia and able to communicate sufficiently to answer study questions will be recruited. All participants will complete the aPHQ-9 and the criterion standard MINI International Neuropsychiatric Interview (MINI) 6.0.0. The primary outcome is criterion validity of the aPHQ-9. Process outcomes related to acceptability and feasibility of the aPHQ-9 will be analysed only if the measure is found to be valid.

Ethics and dissemination: Lead ethical approval was obtained jointly from the University of Sydney Human Research Ethics Committee (project 2014/361) and the Aboriginal Health and Medical Research Council of New South Wales (project 1044/14). Results will be disseminated via the usual scientific forums including peer-reviewed publications and presentations at international conferences following presentation to, discussion with and approval by participating primary health care service staff and community.

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STRENGTHS AND LIMITATIONS OF THIS STUDY

The main strengths of the current study are that it will determine the criterion validity of a culturally adapted depression screening tool (aPHQ-9) for use across multiple States and Territories across Australia. A widely used psychiatric structured diagnostic interview, the MINI International Neuropsychiatry Interview (MINI) 6.0.0, is the reference standard. There are insufficient resources, nor will it be feasible, to use the ultimate reference standard reference measure, an experienced culturally competent psychiatrist or highly trained mental health clinician using a semi-structured clinical interview.

BACKGROUND

There is a need to focus our attention on overcoming the health disadvantage experienced by the world's more than 370 million Indigenous peoples.[1] In Australia, chronic disease (cardiovascular disease, cerebrovascular disease, diabetes, chronic kidney disease, and chronic obstructive pulmonary disease) accounts for 80% of the life expectancy gap experienced by Aboriginal and/or Torres Strait Islander (hereafter referred to as Indigenous) people[2] who are estimated to make up 3% (669,900 people) of the total Australian population.[3]

It is estimated that up to 20% of the general population with chronic disease will have a diagnosis of comorbid major depression.[4] Approximately similar proportions will additionally meet criteria for moderate or minor depression.[5, 6] Among people with existing chronic disease, co-morbid depression is associated with increased disability, longer length of hospital stay, reduced quality of life, and higher costs amongst those who experience an acute vascular event.[4, 7] Major depression also significantly complicates the long-term management of co-morbid conditions by negatively impacting upon adherence to medications and other secondary preventative strategies.[8]

Mental illness and depression are also considered to be key contributors to the development of chronic disease.[9-12] The presence of depression approximately doubles the risk of first myocardial infarction or cardiac death, but amongst patients with established ischaemic heart disease the risk of a future serious cardiovascular event is increased three to four fold by comorbid depression.[6, 13] However, none of this research has been conducted with, by or in Indigenous populations in Australia.

The identification and proactive management of depression in general primary care in Australia has been shown to improve outcomes (reduced depression and improved treatment intensification sustained over 12 months, with a reduction in 10-year cardiovascular disease risk) in people with diabetes and heart disease.[14] A freely available, culturally valid depression screening tool for use across Australia is required to achieve the same benefit in Indigenous peoples attending primary care.

Two screening tools for depression have been determined valid, in comparison with semi-structured clinical interviews, for use by Indigenous Australians residing in specific Australian communities. The more comprehensive validation study is of the Kimberley Indigenous Cognitive Assessment of Depression (KICA-dep) scale. This study was conducted with 250 Indigenous people (18 with depressive disorder) aged 45 years or more residing in six communities in the Kimberley region.[15] In the other study the 9-item Patient Health Questionnaire (PHQ-9[16]) was adapted for use in a small sample (n=34, 9 with depression) of Aboriginal primary care patients with coronary heart

disease attending a single primary health care centre in the Northern Territory in Australia.[17] In a subsequent conceptual adaptation study[18, 19] the original PHQ-9 was assessed by men from five Aboriginal language groups in Central Australia as requiring modification for use in their community and was modified (adapted 9-item Patient Health Questionnaire, aPHQ-9) accordingly to ensure cross-cultural validity, and found valid in a community sample of 78 Indigenous people from Central Australia. No measure has been validated in more than one Australian State or Territory.

Aims

The primary aim is determine the validity of the aPHQ-9[18], compared against a reference standard (criterion standard) MINI International Neuropsychiatric Interview (MINI) 6.0.0[20] as a screening instrument for depression. The secondary aim is to determine the contribution that seven additional questions identified during in-depth qualitative research, make to the detection of depression via the aPHQ-9 in Indigenous people attending primary health care services. A process evaluation will be conducted following the completion of recruitment to formally evaluate the processes, lessons learnt and impact of implementing the study on recruitment sites and staff. Process evaluation methods will be described in a separate protocol.

METHODS

‘Getting it Right’ is a national, multicentre, prospective diagnostic accuracy, observational study to be conducted through a network of Indigenous primary health care services across Australia’s States and Territories. The study was conceived, designed and will be conducted in keeping with the principles of Reciprocity, Respect, Equality, Responsibility, Survival and Protection and Spirit and Integrity important to Aboriginal and Torres Strait Islander communities and described in the National Health and Medical Research Council’s *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*[21]. The investigator team includes Aboriginal and non-Aboriginal researchers, relationships will be developed between the project team and key personnel at each service, local community members will be employed at each service to undertake data collection, the data collected at each site will remain the property of that site, feedback sessions will be conducted at each service for staff and community members, and services and individual research participants will receive compensation for participation.

PARTICIPANTS

The study will be conducted in approximately 10 urban, rural and remote primary health care services (sites) in Australia with a predominantly Indigenous client base.

Consent process and participant inclusion and exclusion criteria

Written approval from each participating site's Board, if a community controlled organisation, institutional review board, research committee, community jury, letter of support, or similar must be obtained, as well as from any local Human Research Ethics committee or other relevant regional or national body, before recruitment can commence.

Inclusion criteria

All patients are eligible for the study if, at the time of presentation at a participating health service or community event, they meet each of the following criteria:

1. ≥ 18 years of age,
2. self-identifies as Aboriginal and/or Torres Strait Islander,
3. able to communicate sufficiently to answer study questions,
4. able to give informed consent.

Exclusion criteria

Patients will be excluded from the study if at the time of presentation, they are known (diagnosis documented in medical records or information provided when asked) to have psychosis or bipolar disorder.

Recruitment

Consecutive eligible patients will be invited to participate in the study on any given recruitment day. Trained staff members nominated by each service will obtain individual participant written or verbal consent to participate in the study. Recruitment began on the 25th March 2015 and will continue until 500 participants have completed both interviews.

Background care

All patients within the primary health care service or people attending service-led events will be managed by their general practitioner or other allied health professional. Their management should be best practice standard of care according to regional guidelines and the duty of care always remains with the health care service.

Study outcome

The primary outcome is criterion validity of the aPHQ-9[18]. The reference standard is a clinical diagnosis of depression ascertained using the MINI 6.0.0[20], having two categories: "current major depressive episode" and "no current major depressive episode."

In addition we also aim to determine the contribution that seven additional questions identified during in-depth qualitative research make to the detection of depression via the aPHQ-9[18],

criterion validity of the aPHQ-2 (the first two questions of the aPHQ-9) and feasibility of assessment using the aPHQ-9 within primary health care services. Should the aPHQ-9 (with or without the addition of one or more of the seven additional questions) have acceptable sensitivity and specificity as a screening tool for depression, we will seek qualitative feedback on feasibility from primary health care staff during the 'feedback of study results' to sites. Site staff will be asked about the impact of screening on them, their study participants and the practice, the effect on the participant/health-professional relationship, the usefulness of the aPHQ-9 and the extent to which practice routines must be adapted to integrate the aPHQ-9 into their service delivery should it be found to be valid.

Data collection

During recruitment, consecutive patients attending the primary health care service on a recruitment day or people attending service events, who appear to meet the inclusion criteria, will be approached by a trained clinic staff member. Site study staff will record the date of presentation of all people considered for participation in the study on the study screening log, whether they were eligible, whether they consented to participate and if not, the reason for non-participation. All consecutive consenting participants will be recorded on the study enrolment log.

TEST METHODS

The aPHQ-9 and its development has been described previously[18]. In brief, the PHQ-9 was modified to ensure cross-cultural validity. A structured process was followed using the expertise of five focus groups comprising male members of primary Indigenous language groups in central Australia. Bi-lingual experts from each language group translated the PHQ-9. Each translation was discussed with the research team, clarity sought on meaning for difficult items, and problematic translations were identified, discussed and amended (where necessary). This resulted in some words and phrases being modified to provide linguistic or conceptual equivalence, and single questions with divergent English meanings being split into two. During the modification process, seven key features of depression in Aboriginal men were identified that were not covered by the aPHQ-9. These additional features include anger, weakened spirit, homesickness, irritability, excessive worry, rumination, and drug/alcohol use.

Reference standard: MINI 6.0.0

The MINI[22] is a short structured interview for the major Axis I psychiatric disorders. Validation and reliability studies have shown that the MINI has acceptably high validation and reliability scores compared to the Structured Clinical Interview for DSM Disorders and the World Mental Health Composite International Diagnostic Interview, can be administered within 19 minutes on average,

and can be modularised and administered by clinicians and lay interviewers after appropriate training. The MINI is the most widely used psychiatric structured diagnostic interview instrument in the world and has been validated for use in over 100 countries. There are insufficient resources (trained personnel) available, nor will it be feasible, to use the ultimate reference standard method of diagnosis of depression by an experienced culturally competent psychiatrist or highly trained mental health clinician using a semi-structured clinical interview.

Assessment 1

Following consent, a trained member of the primary health care service staff will interview each participant using a short paper-based or computer-assisted questionnaire during a face-to-face interview (or telephone if required). Participants can answer questions directly using paper-based or computer-assisted forms or the questionnaire can be interviewer-administered at the discretion of the interviewer and participant. Data will be collected on the method of assessment (interviewer-administered or self-completed, paper-based or computer-assisted, language in which interviews were conducted), response to the 11 questions on the aPHQ-9, the additional seven questions, one question regarding how much any identified problems impact on their daily lives, and questions about the acceptability and ease of use of the aPHQ-9. These questions are followed by an open ended question where participants can provide feedback about the aPHQ-9. Study staff will encourage participants to provide feedback about aPHQ-9 acceptability and any issues of concern.

Demographic information to be collected includes gender, age, whether Aboriginal language(s) is spoken at home, marital status, living arrangements (alone/with others), recent activity-restricting illness, recent (in the last two months) bereavement, highest educational qualification, lifetime and current occupation, main income earner and medical history (primary history of chronic disease and mental illnesses and whether any associated medications are taken).

If a participant has difficulty reading or requires any assistance for whatever reason, the aPHQ-9 will be read to them by a trained member of staff or an interpreter. This person will also enter the responses on to the paper or computer-assisted form on behalf of the participant. All data will be entered in the secure web-based study database.

Assessment 2

On the same day, or within seven days of completing Assessment 1, all participants will be administered the MINI 6.0.0 interview and questions on smoking and alcohol consumption in a face-to-face (or telephone if required) interview by a trained MINI interviewer who did not complete and will be blind to the results of Assessment 1. Three MINI 6.0.0 modules will be administered for this study: the full set of major depressive episode/disorder questions (current, recurrent),

posttraumatic stress disorder (past month), and generalized anxiety disorder (past six months). These will be followed by questions about smoking and alcohol consumption.

Co-enrolment

There are no methodological contraindications to co-enrolment of participants into other research projects.

Training

Prior to initiation of the study at any site, all participating primary health care service staff involved in the study will receive study-specific training. Training relates to the study protocol, source documentation, screening and enrolment logs, Good Clinical Research Practice, informed consent, questionnaire completion, interviewing participants for research purposes, safety protocols, accessing and completing data entry on the study-specific secure internet-based study database, and study documentation. Training will be provided in person by SF (the project manager) and MH (the chief investigator) in the first instance. Subsequent re-training, or training of new staff may be provided via telephone and/or video links where available.

Training related to administration and scoring of the MINI will be provided face to face or via video link by NG (the study psychiatrist). This will be followed by inter-rater assessments of up to four pre-recorded role plays. Pre-recorded role plays will be scored by NG, who will inform SF when the MINI interviewers are competent. Sites will only be activated after MINI results have been checked by and discussed with NG.

Safety

The safety and welfare of the participants is of primary importance in the study. Participation is voluntary and non-participation will in no way affect the quality of care provided to the participant by study staff. We will work with each primary health care service to ensure depression, deliberate self-harm and suicidal ideation and intent protocols are in place for follow-up and care of study participants.

We require one nominated responsible person at each recruiting primary health care service to check all completed aPHQ-9 questionnaires at the end of each day. In addition, we will notify the primary health care service of any participant who:

- 1) scores 10 or more on the aPHQ-9 assessment and/or
- 2) is considered to have a major depressive episode during the MINI interview
- 3) indicates suicidal ideation or suicidal intent during the aPHQ-9 or the MINI interview.

The primary health care service will be notified by way of a standard email. The email will indicate our reason for concern and provide some suggestions on clinical management options based on current guidelines. Completed case report forms can be printed by interviewers and (or electronically) attached to medical records to facilitate ongoing clinical assessment.

We will provide local [to each site] mental health crisis line numbers and access to online psychological interventions (www.ecouch.com.au, <http://www.mindspot.org.au>) to each site. Study staff may also offer to email this information to participants.

The suggestions in our email to the primary health care service are:

- 1) Consider non-pharmacological treatments such as advising an increase in social outlets, regular exercise or referral to a clinical psychologist. Clinical psychology can be accessed through the Medicare Better Access initiative and is available free of charge to Australian residents and citizens. There is provision for up to 10 sessions per year as part of a GP mental health treatment plan (<http://www.health.gov.au/internet/main/publishing.nsf/Content/mental-ba-over>).
- 2) If you feel that antidepressant medication is necessary, then either yourself or their treating doctor might consider the attached guidelines <https://www.nice.org.uk/guidance/cg90> [23]
- 3) Consider referral to a specialist e.g. psychologist or psychiatrist.

Participants can opt to have any detected condition NOT communicated to their clinician unless it is felt that the level of risk is so great that we need to breach confidentiality: a HIGH on the suicidality risk level on the MINI. Site study staff will be able to contact the study psychiatrist to discuss any safety concerns via telephone or email.

STATISTICAL METHODS

Sample size

We computed the sample size based on the target precision for the estimation of sensitivity and specificity of the aPHQ-9 used for the screening of a major depressive episode. Assuming a major depressive episode prevalence (assessed by the MINI) of 10% and a true sensitivity of 0.85, a sample size of 500 participants will give us a precision of 0.1 for the sensitivity's 95% confidence interval. For the specificity, 500 participants will provide a precision of 0.04 for the specificity's 95% confidence interval, assuming a true specificity of 0.75 and the same prevalence of 10%. If the prevalence of major depressive episodes is in fact higher, for example 15%, the precision for the sensitivity will be 0.08. For the analysis of the contribution of additional questions to the aPHQ-9, a sample size of 500 will give us 80% probability (power) of detecting a true improvement of 0.05 in the area under the ROC curve, fixing the type I error at 0.05.

Data analysis

For descriptive purposes baseline characteristics will be presented. Discrete variables will be summarised by frequencies and percentages, continuous variables by use of standard measures of central tendency and dispersion, mean and standard deviation (SD) or median and interquartile range (IQR).

Primary aim analyses

We will assess the validity of the aPHQ-9 when compared to the MINI, using two common criteria for major depression: I - a score of 2 or above on one of the first two items of the aPHQ-9 plus 4 or more items with a score of 2 or above (the last question is counted if a score of 1 or above is indicated) and II - a total score of 10 points or above, similar to the usual cut-off for the original PHQ-9.[24] The original scoring method will be used with the two 'split questions' (questions 5 and 8 on the original PHQ-9) on the aPHQ-9 being scored once only. However, given this is an adaptation of the original questionnaire, we will explore the properties of other cut-off points by constructing a receiver operating characteristic (ROC) curve. The sensitivity and specificity will also be computed for subgroups (e.g., individuals with chronic disease) using logistic regressions to allow adjustment for potential demographic differences between the subgroups. All the estimates will be presented with 95% confidence intervals.

Secondary aim analyses

We will assess the validity of aPHQ-9 plus the additional seven culturally specific questions when compared to the MINI. The contribution of each question will be initially analysed separately and we will select for further analysis any questions that individually contribute to a better discrimination property of the questionnaire while maintaining the internal validity of the instrument. We will compare the area under the ROC curves of the original score with the one obtained by individually adding each question, in the total sample, and in those with, and in those without chronic disease. We will also compute Cronbach's alpha to evaluate if the new question is measuring the same underlying construct as the aPHQ-9.

After this step, we will use a stepwise strategy to evaluate the addition of multiple questions to the aPHQ-9. We will first consider the aPHQ-9 plus the question with highest improvement in the area under the ROC curve, then we will add the second best question and evaluate if this question still contributes to an increase in the area under the ROC curve and so on. If any of the additional questions prove to be useful, we will study the psychometric properties of this new instrument in more detail, as well as recommend major depressive episode screening cut-points.

Missing Outcome Data

The calculation of the global score for the aPHQ-9 is given by the sum of all the answers on the questionnaire. If one question is left unanswered, the score cannot be directly computed. For incomplete questionnaires, as long as there are 5 or more questions answered, we will compute a partial score summing the answered questions. Then, the global score will be derived with a proportional transformation of the partial scores, based on the number of unanswered questions. For example, if a participant has a partial score of 12 based on 8 questions, the global score will be computed as $(12 \times 9) \div 8 = 13.5$. The underlying assumption for this procedure is that the unanswered question(s) follows a similar pattern to the answered ones. If a questionnaire has only 4 or fewer questions answered it will be excluded from the analysis. For other variables in the study we will use all the available information for the respective analysis.

Data management

The internet-based data management system will be managed centrally by the project manager from The George Institute for Global Health. Registration and data entry will be performed at the participating sites via a password-protected connection. Only trained staff listed in the delegation log will be given unique passwords to access the database. Paper case report forms will be provided to sites preferring to use these for initial data collection.

Confidentiality and privacy

Every precaution will be taken to respect the privacy of study participants. Each participant's MINI result will be provided to and checked by the primary health care service. The general practitioner of a participant who is assessed as experiencing a psychiatric disorder will be encouraged to arrange re-assessment, treatment or formal referral for depressive or other abnormal mood symptoms according to their clinical judgment.

ETHICS AND DISSEMINATION

The findings of this study will be disseminated via the usual scientific forums, including peer-reviewed publications and presentations at international conferences following presentation to, discussion with and approval by participating primary health care service staff and community. Participants will have the option to receive information (via post, text or email) on the study findings, when available. The study will be administered by the George Institute for Global Health, with the design and conduct overseen by a steering committee (authors). This committee has expertise in Indigenous health, cardiovascular health and mental health research. This study will adhere to the National Health and Medical Research Council Values and Ethics - Guidelines for

Ethical Conduct in Aboriginal and Torres Strait Islander Health Research. Formal ethical approval for this study has been obtained from the University of Sydney Human Research Ethics Committee (project 2014/361) and the Aboriginal Health and Medical Research Council of New South Wales (project 1044/14).

CONCLUSIONS

This study responds to the lack of understanding of the natural history, trajectories and outcomes of depression and comorbid chronic disease in the Indigenous people of Australia, and the performance of primary health care services in identifying and managing depression and comorbid chronic disease. This work will directly contribute to the evidence base for identifying depression and developing culturally specific primary health care depression interventions for Indigenous people by providing the evidence on whether to recommend use of the aPHQ-9 as a screening tool for depression. If validated the aPHQ-9 will enable exploration of the burden and correlates of depressive symptoms with co-morbid chronic disease and chronic disease risk factors in Indigenous patients routinely attending primary health care and assessment of the effectiveness of management strategies for depression in Indigenous patients routinely attending primary health care.

Contributorship statement

MLH, NG, TS, AC & AB conceived the project. All authors (MLH, SF, NG, TS, ATP, DA, GG, AC & AB) contributed to the design of the study, are involved in the implementation of the project and had the final responsibility for the decision to submit for publication.

Competing interests

None

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