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Feasibility, acceptability and diagnostic test accuracy of frailty screening instruments in community-dwelling older people within the Australian general practice setting: a study protocol for a cross-sectional study

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ABSTRACT

Introduction Frailty is one of the most challenging aspects of population ageing due to its association with increased risk of poor health outcomes and quality of life. General practice provides an ideal setting for the prevention and management of frailty via the implementation of preventive measures such as early identification through screening.

Methods and analysis Our study will evaluate the feasibility, acceptability and diagnostic test accuracy of several screening instruments in diagnosing frailty among community-dwelling Australians aged 75+ years who have recently made an appointment to see their general practitioner (GP). We will recruit 240 participants across 2 general practice sites within South Australia. We will invite eligible patients to participate and consent to the study via mail. Consenting participants will attend a screening appointment to undertake the index tests: 2 self-reported (Reported Edmonton Frail Scale and Kihon Checklist) and 5 (Frail Scale, Groningen Frailty Index, Program on Research for Integrating Services for the Maintenance of Autonomy (PRISMA-7), Edmonton Frail Scale and Gait Speed Test) administered by a practice nurse (a Registered Nurse working in general practice). We will randomise test order to reduce bias. Psychosocial measures will also be collected via questionnaire at the appointment. A blinded researcher will then administer two reference standards (the Frailty Phenotype and Adelaide Frailty Index). We will determine frailty by a cut-point of 3 of 5 criteria for the Phenotype and 9 of 42 items for the AFI. We will determine accuracy by analysis of sensitivity, specificity, predictive values and likelihood ratios. We will assess feasibility and acceptability by: 1) collecting data about the instruments prior to collection; 2) interviewing screeners after data collection; 3) conducting a pilot survey with a 10% sample of participants.

Ethics and dissemination The Torrens University Higher Research Ethics Committee has approved this study. We will disseminate findings via publication in peer-reviewed journals and presentation at relevant conferences.

Strengths and limitations of this study

- To the authors' knowledge, this is among the first reported studies on frailty screening within the Australian general practice context.
- Our inclusion of feasibility and acceptability measures along with diagnostic test accuracy will strengthen the relevance of our study for policy and practice.
- The acceptability component of our study will measure acceptability of screening instruments to both health service providers (general practitioners and practice nurses) and consumers.
- This phase of the study will be limited to two general practice sites.
- The study will test only a subset of the full set of frailty screening instruments in international use due to inappropriateness for Australian context, excessive length or other exclusion criteria.

INTRODUCTION

Background

Population ageing is proceeding at an unprecedented pace throughout the world,[1] with frailty among its most challenging manifestations.[2 3] Frailty is associated with decreased quality of life,[4–6] disability,[4 5 7 8] increased healthcare utilisation,[4 5 7 9] falls,[9 10] institutionalisation[9 11] and death.[7 9 12] Despite the importance of frailty, there is currently no consensus regarding its prevalence.[13] One estimate based on a systematic review suggests a weighted average prevalence of 10.7% among community-dwelling persons aged 65+ years, although results vary widely.[13] Applying even this conservative rate to the future Australian population aged 65+ years

would result in a projection of over 1 million frail Australians by 2061,[14] a significant challenge for the healthcare system.

Geriatricians have traditionally provided specialist care for the frail. However, population ageing and the need for early identification, prevention and reversal of frailty highlights an increasing role for general practitioners (GPs) and healthcare teams in community settings as this population grows.[15–17] Despite research advances, frailty research in primary care remains a 'topic in its infancy'.[16] Consequently, a growing number of studies have addressed the development and validation of frailty screening instruments in general practice settings—an issue especially relevant in Australia, where research on this topic has been limited.[18] However, there remains much controversy over the validity and reliability of the instruments,[19 20] leading to calls for more validation to be conducted across diverse populations. Furthermore, there remains extensive disagreement among the experts over how extensive screening should be.[21–23] Regardless of the extent of screening, GPs and their teams will need accurate screening instruments to effectively identify those who are frail or at risk,[24 25] and if translation into busy practices is to be successful, also instruments that are logistically feasible and acceptable to health service providers and consumers.

Australian care context and purpose for screening

In Australia, opportunities for comprehensive assessment for older people in general practice through the 75+ Health Assessment and associated care planning receive government rebates under the Medical Benefits Scheme (MBS).[26] Through chronic disease and management health plans, older people can then access rebated allied health (although limited) and psychology services. GPs are also able to refer to specialist geriatricians for Comprehensive Geriatric Assessment (CGA) for which also there is a specialist rebate. Access to medical services might vary by geographical region.

Means tested but publicly funded Aged Care Services that provide for home case support services and some therapy services are accessible through the centralised portal, My Aged Care. A brief assessment of multiple domains is undertaken but where care needs are identified as high, a more comprehensive assessment occurs through the Aged Care Assessment Programme. The older person might then be approved for more coordinated in home care and support or residential aged care. Some service providers provide for day therapy services. At all times, older people are also able to access therapy and support services privately and when acute care is required, older people might access specialist geriatrics, rehabilitation and palliative care service through both the public and private hospital systems, although in some regions, these services might be limited.

Therefore, screening for frailty risk in general practice might allow the GP to identify earlier those aged 75 years and older who might benefit from a comprehensive assessment via the 75+ Health Assessment, following which a management plan including further investigation and referral to various services might occur in a proactive rather than a reactive approach. The relative 'safety net' provided by the MBS-funded items has important implications for how we approach the issue of accuracy within this study. The most important consideration for Australian GPs is likely to be avoiding false negatives, so as to avoid missing people who actually are frail. In contrast, the consequences of false positives are less significant given the options for subsequent follow-up. We are thus emphasising sensitivity over specificity in our study.

Aside from accuracy, feasibility and acceptability will also be critical factors in the selection of screening instruments. The feasibility and acceptability of frailty screening instruments within general practice has been significantly under-researched.[16] Consequently, we have drawn on several feasibility studies addressing the introduction of non-frailty instruments in developing our approach,[27] along with early results from focus groups on frailty conducted with Australian GPs. We will assess the feasibility and acceptability of the index tests from three perspectives: 1) feasibility of implementation within the context of a busy general practice environment; 2) acceptability to health service providers; 3) acceptability to consumers.

Within health research, passive case-finding (eg, using medical records) has been promoted as potentially advantageous over active case-finding due to lower cost and burden on study participants.[28] It therefore could be viewed as a viable alternative to the active and rather intensive screening approach adopted in our study. However, passive case-finding is unviable within this context given that routinely collected medical records would be unlikely to capture the range of data required to detect frailty (with the possible exception of the construction of a frailty index) and are subject to high variability, a globally observed finding.[28] These factors suggest an insufficiently reliable basis for its inclusion within our study.

In the absence of an Australian policy directive on frailty screening, screening will likely be directed to the most appropriate perceived candidates rather than to all persons of a given age. Preliminary findings from an aligned study of Australian GP perspectives on frailty and frailty screening[29] indicate that in identifying potential candidates, it is probable that psychosocial factors may play a key role in GP considerations. For example, people who live alone, suffer depression or who have few social supports could potentially be at more risk from the impacts of frailty than those who have greater personal resources. The association of psychosocial factors with frailty is an emerging trend that has been reported within the research literature,[30–35] although results to date have been mixed.[36] Consequently, in order to better characterise those diagnosed as frail, we will also collect a range of psychosocial measures from our sample.

Objectives

Our study is designed to assess the (1) feasibility, (2) acceptability (to health service providers and consumers) and (3) diagnostic test accuracy of a number of frailty screening instruments within the context of Australian general practice. A fourth objective will be to explore the association of a range of psychosocial measures with frailty.

METHODS AND ANALYSIS

We will employ a prospective, cross-sectional and observational research design. We have reviewed our study design against the Standards for Reporting of Diagnostic Accuracy and Quality Assessment of Diagnostic Accuracy Studies (QUADAS-2) criteria. The study will be conducted between July 2017 and June 2018.

Setting

We will conduct the study within two general practice sites within South Australia, one metropolitan and one non-metropolitan. We will select practices based on purposive sampling.

Four practice nurses (registered nurses working in general practice)—two at each site—will be contracted to administer the index tests. Potential screeners will sign a consent form to enrol in the study. The screeners will attend training prior to commencement.

Participants

Eligibility

Inclusion criteria

We will employ convenience sampling to recruit our sample. Patients will be eligible if they were aged 75+ years as at 30th June 2016 and booked to attend at the study sites for an upcoming appointment over a prespecified period during 2017.

Patients with dementia will be included as participants if written, informed consent is given by a responsible person who is available to attend with them at the study sessions. Inclusion will be discussed on a case-by-case basis with the patient's doctor. Doctors will cosign all consent forms involving patients with impaired ability to consent.

Exclusion criteria

We will exclude from the study those patients too ill to be assessed (ie, undergoing palliative care treatment or currently hospitalised), resident within residential care facilities or whose English is insufficient to fully participate.

Substudy 1: diagnostic test accuracy

Data collection

Figure 1 outlines the overall data collection process for the diagnostic test accuracy aspect of the study.

Recruitment

We will mail eligible participants an invitation letter, consent form and participant information sheet. We will ask potential participants to sign a consent form (or if unable to consent, a family member will be asked to sign on their behalf) to be returned to the research team via self-addressed envelope. Participants will be given the right to withdraw from participation should they wish to, as well as to opt out of completing individual instruments. We will collect demographic information (age, sex) from those electing not to participate in order to compare participants with non-participants.

On receipt of the consent form, we will telephone the participant to make an appointment to attend the

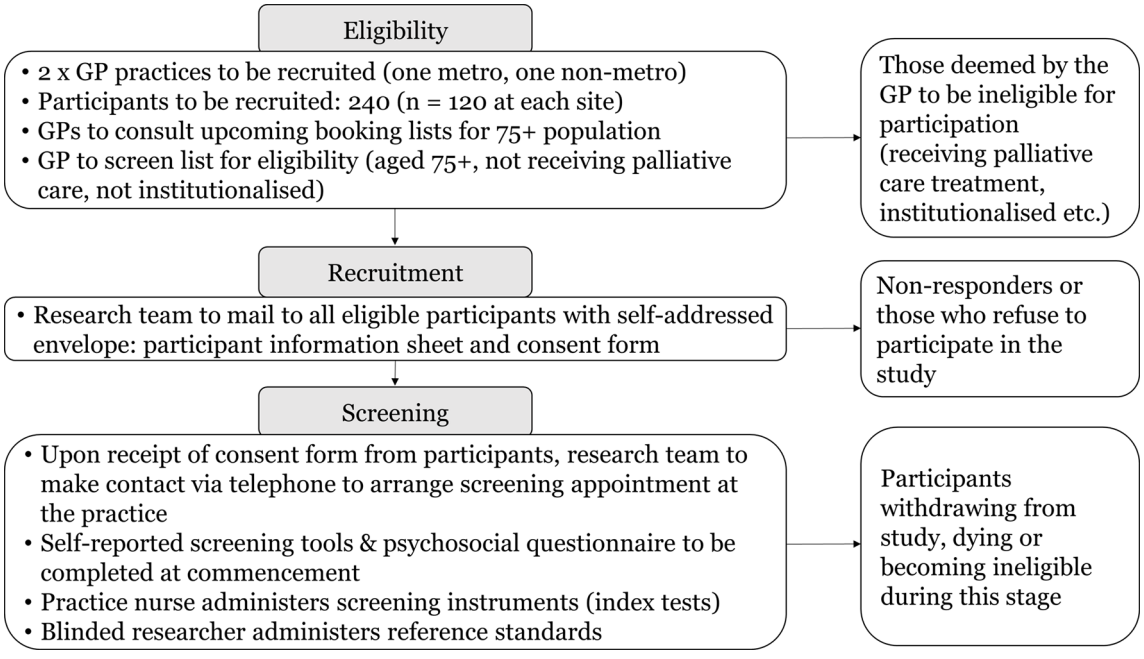

Figure 1 Study flow diagram (diagnostic test accuracy component). GP, general practitioner.

screening session within 2 weeks to ensure information currency.

Recruitment will conclude on successful achievement of the required sample size (n=120 from each practice).

Screening session

On arrival, we will ask participants to complete a questionnaire including standard demographic information along with a select number of psychosocial instruments. They will then complete two self-reported index tests, returning each test as completed so that time to complete can be recorded. The practice nurse will then administer five administered index tests in random order. A blinded researcher (RA) will then administer the two reference standards. The total estimated duration of the appointment will be between 45 and 60 min.

Follow-Up

Where either of the reference standards indicates frailty, the participant will be offered a follow-up appointment with their GP. The research team will not collect data at this appointment.

Test methods

Index tests: overview

Following a literature review, we shortlisted 14 frailty screening instruments as candidates for inclusion as index tests through discussion with the clinician members of the research team. We considered validity (sensitivity at least 0.6), appropriateness to context (in English, transferable to Australia) time to implement (≤20 min) and delivery method (administered, ie, not solely records-based) in our deliberations. We ultimately selected the following instruments for inclusion: FRAIL Screening Instrument; Groningen Frailty Index; Program on Research for Integrating Services for the Maintenance of Autonomy (PRISMA-7); Edmonton Frail Scale; Gait Speed; Reported Edmonton Frail Scale and Kihon Checklist.

Index tests: administered by practice nurse

FRAIL Screening Instrument

The FRAIL Screening Instrument is a 5-item instrument addressing five aspects of frailty: fatigue, resistance, ambulation, illness and loss of weight.[37] Each component is allocated one point and all components are summed, resulting in a scale from 0 to 5. The original cut-points will be used in this study and were: frail (3–5), prefrail (1–2) and robust (0) health status.

Groningen Frailty Indicator

The Groningen Frailty Indicator is a multidomain frailty instrument found to be reliable and valid in a Dutch community-dwelling population.[38 39] It has 15 items, resulting in a summed score from 0 to 15, with the frailty cut-point—also used in this study—set at 4 or more points.

PRISMA-7

The PRISMA-7 is a screening instrument validated in a community-dwelling population aged 75 years and older.[40] It consists of a set of seven yes/no questions. Previous research indicates high sensitivity but limited specificity in identifying frailty.[41] In the original formulation, also used in this study, three or more 'yes' responses indicated frailty.[40]

Edmonton Frail Scale

The Edmonton Frail Scale (EFS) is a measure developed and validated on a community-dwelling population aged 65+ years.[42] Scored from 0 to 17, it measures frailty across ten domains including cognition, social support, medication use and functional performance. The original study does not provide a specification for frailty cut-point; this study will consequently follow previous studies in adopting a cut-point of 8 or more points to define frailty.[43 44]

Gait speed

Gait speed is a reliable and valid measure widely applied within the research literature.[45 46] It has been found to have high sensitivity (but limited specificity) in identifying frailty.[41] Following the recommendations of Castell *et al* and the wide application of this cut-off point in practice,[46] we will apply a ≤0.8 m/s cut-off point for frailty in our study.

Index tests: self-reported

Reported Edmonton Frail Scale

The Reported Edmonton Frail Scale is a self-reported version of the Edmonton Frail Scale.[44] The resultant scale ranges from 0 to 18 with the following cut-points defined: 'not frail' (0–5), 'apparently vulnerable' (6–7), 'mild frailty' (8–9), 'moderate frailty' (10–11) and 'severe frailty' (12–18). We will apply the original reported cut-point of 8 or more in our study.

The Kihon Checklist

The Kihon Checklist is reported to be a reliable self-reported instrument for predicting frailty in older adults.[47] It consists of 25 yes/no questions covering a range of domains. We will replicate the frailty cut-point reported in Sewo Sampaio *et al*[48] of a total of seven or more 'yes' questions.

Reference standards

We consulted prior research for potential reference standards, identifying three commonly used candidates[25 41]: CGA, the Frailty Phenotype (based on the Cardiovascular Health Study definition[7]) and Frailty Index (based on the Canadian Study of Health and Aging[49]).

The CGA, an interdisciplinary diagnostic procedure aiming to identify a range of issues in older people, is commonly thought to be the gold standard for frailty identification.[25] However, its time-consuming and resource intensive nature,[41 50] makes it beyond the scope of implementation as a reference standard within our study.

The alternatives—the Frailty Phenotype and Frailty Index—have admittedly been labelled as 'different instruments for different purposes',[51] due largely to the inclusion of disability items in the Frailty Index versus the Phenotype. Our inclusion of both as reference standards might therefore be seen as controversial, if not for the fact that the version of the Frailty Index we will apply in this study explicitly excludes disability items.

The remaining differences between the two standards mainly relate to the feasibility of applying them within general practice, a factor that does not apply here given their use as reference standards rather than index tests. Additionally, the risk of differential verification bias, present when not all test subjects undertake both reference standards,[52] is not expected to impact our study as all participants will undertake both reference standards equally. Results for both standards will be presented, along with a detailed analysis of cases varying between the two.

We contend that our decision to include both reference standards offers a significant contribution to the frailty evidence base, given we are operating with an absence of consensus about which reference standard is superior. Including both reference standards will ensure our research remains relevant into the future, regardless of subsequent changes in expert opinion. Given we are still at an early stage of our understanding about frailty screening within Australia, we maintain that in this instance, more information will ultimately prove better than less.

Frailty Phenotype

The Frailty Phenotype has received broad acceptance worldwide,[46] having been externally validated within several large epidemiological studies.[41 53] Recognised drawbacks include its lack of cognitive and psychosocial domains,[33] however, it has predicted significant negative health-related outcomes across numerous studies to date.[33 54]

This study will implement original formulation by Fried *et al*, as shown below [7:M156].

- *Shrinking* (unintentional weight loss of ≥10 pounds in the prior year or, at follow-up, of ≥5% of body weight in the prior year by direct measurement of weight), as assessed by the question: *"n the last year, have you lost more than 10 pounds unintentionally (ie, not due to dieting or exercise)?"*
- *Weakness:* we will measure grip strength with a handheld Jamar dynamometer, assessing maximal grip strength (kg) in the dominant hand (average of three measures). Fried's cut-points are shown in table 1 and will be used in this study.
- *Poor endurance and energy:* indicated by self-reported exhaustion based on the Center for Epidemiological Studies-Depression (CES-D) scale.[55] The frailty criterion is satisfied if the participant response is 'a moderate amount' or 'most of the time' in answer to the following:
  - *(a) "I felt that everything I did was an effort."*
  - *(b) "I could not get going."*
- *Slowness:* measured by gait speed (time taken to walk 15 feet). We will employ the cutoffs reported in Fried *et al*: ≥7 s (men of height ≤173 cm and women ≤159 cm), and ≥6 s (men of height >173 cm and women >159 cm).
- *Low physical activity level:* measured by the short-form Minnesota Leisure Time Activity questionnaire.[56] The questionnaire is used to derive a weighted score of kilocalories expended/week, with the following cut-points: men <383 and women <270 kcals/week.

Table 1 Fried cut-off criteria for frailty (grip strength)

Men		Women	
BMI	**Cut-off (kg)**	**BMI**	**Cut-off (kg)**
≤24	≤29	≤23	≤17
24.1–26	≤30	23.1–26	≤17.3
26.1–28	≤30	26.1–29	≤18
>28	≤32	>29	≤21

BMI; body mass index.

The frailty cut-points specified in the original model and used within this study were that three or more components meeting the criteria indicate frailty.

Adelaide Frailty Index

The second reference standard is the Adelaide Frailty Index (AFI), a 42-item variant of a standard frailty index based on the methodology reported by Searle *et al*.[57] It was developed by Mark Thompson as part of ongoing work within the regional geriatric health service (Thompson *et al*, unpublished).[58] The frailty cut-point for the AFI, also applied within this study, is a score of 9 or more (ie, 21% or more).

The AFI includes elements drawn from the following frailty risk factors: shrinking, exhaustion, low energy expenditure, slowness, weakness, cognitive impairment, falls and balance, urinary incontinence, polypharmacy, oral health, pain, mental health and chronic conditions. Several questions within the AFI were derived from validated screening instruments in common use within those domains. The AFI intentionally excludes disability items, in recognition of the distinction between disability and frailty.[59]

Psychosocial instruments

In recognition of the complex relationship between psychosocial factors and frailty, we will administer five psychosocial instruments within the self-complete questionnaire. Depression is associated with frailty among older people[34] and is measured here via the commonly used Geriatric Depression Scale-15.[60] Social isolation will be measured by an abbreviated version of the Lubben Social Network Scale-6, which has been widely used worldwide to measure isolation among older people.[61 62] A measure relating to sense of perceived control, as originally conceptualised and validated by Lachman and Weaver,[63] has previously been demonstrated to play a mediating role with respect to frailty[35] and will be included within the set. Likewise, negative self-perceptions of ageing have been found to have a modifying effect on frailty[64] and will be included in the form of the Brief Ageing Perceptions Questionnaire.[65] Lastly, a specific measure of older people's quality of life will be measured using the ICEpop CAPability measure for Older people (ICECAP-O).[66]

Other measures

In addition to the index tests collected at the screening appointment, the practice nurse will also collect the Nottingham Extended ADL scale (NEADL).[67] The NEADL is a valid and reliable measure of functioning that has been widely applied among older populations.[68]

Data management

We will collect data manually, verifying it where required against clinical records. We will identify participants by a unique identifier, with linkage keys to be stored separately from the data. Data will be entered into an SPSS database. We will subject 5% of the records to a random audit by a second researcher to test data quality. We will store all deidentified study data on a password-protected drive.

Statistical methods

Sample size

We derived a sample size estimate using a methodology reported by Buderer incorporating consideration of disease prevalence.[69] This calculation was complicated by the absence of a reliable Australian frailty prevalence rate, so we drew on a number of community-based studies to derive a prevalence estimate. Two Australian studies suggested frailty prevalence rates of 25% for the 75+ and 17.5% for the 70+ (Thompson *et al*, unpublished data and Widagdo *et al*[18]), and a Spanish study reported a 19% prevalence among the 75+.[46] Ultimately, we selected a 20% prevalence rate as a conservative choice, applying this figure within Buderer's formula along with sensitivity of 90% and specificity of 60%. The clinically acceptable width of the 95% CIs for sensitivity and specificity was set to be no larger than 10, giving a minimum estimated sample size of 173 persons. We will aim to recruit at least 240 participants. This allows for a buffer of 25% above the minimum sample to address attrition in the short period between consent and attendance at the screening appointment while also allowing for the possibility of a lower than estimated prevalence of frailty in the population.

Analysis

We will examine the distribution of quantitative variables visually and by using the Shapiro-Wilk test for normality.[70] Categorical variables will be described as frequencies. Quantitative variables will be displayed as mean±SD, where normally distributed or as medians with 25th and 75th percentiles were asymmetrically distributed. Where the results for an index test or reference standard are indeterminate or incomplete, results for that participant will be excluded. No imputation will be performed for missing data.

Our accuracy analysis will compare the results of each index test against each reference standard. We will construct variables reflecting each frailty instrument and define the presence of frailty according to the specified cut-points. We will create standard 2×2 tables for each index test against each reference standard, and calculate sensitivity and specificity with their corresponding 95% CIs, along with positive and negative predictive values and likelihood ratios. We will determine the extent of agreement between the index tests and reference standards by calculating Cohen's kappa.

To analyse the relationship between the psychosocial variables and frailty, we will define the presence of frailty as a binary variable (frail/not frail) according to the Fried criteria as measured in the Frailty Phenotype. We will use binomial (binary) logistic regression to analyse the association strength (OR) for the frail state with the psychosocial variables using the non-frail state as the comparison category. We will consider a p value of <0.05 to be statistically significant. The data will be analysed using the latest available version of the SPSS statistical software (version 24.0 SPSS, Chicago, Illinois, USA).

To test inter-rater reliability, 8 subjects tested by each screener (32 in all) will be asked to repeat the index test session including self-reported tests with a second blinded screener within 48 hours after the initial rating. Given the binary nature of the outcome (ie, frail/not frail) and multiple raters, the kappa coefficient will be used to ascertain agreement, with the minimum acceptable value set to 0.6. We will ask every third participant participating at each research site in the main study to participate in the inter-rater reliability component, proceeding until such time as the site and screener quota is reached.

Substudy 2: feasibility and acceptability

We will apply a convergent parallel mixed methods approach to the analysis of feasibility and acceptability. We define mixed methods research, following Johnson *et al*, as a type of research combining 'elements of qualitative and quantitative research approaches … for the broad purposes of breadth and depth of understanding and corroboration' (Johnson *et al*, p. 123).[71] Mixed methods have increasingly been applied within the health sciences in recent years, where a more complete understanding of an issue is allowed than by a quantitative or qualitative approach alone.[72]

Data collection and management

Feasibility

We will measure the feasibility of the index tests by collecting the following information about each test:

Noted by research team prior to data collection

- Education or training required to administer each test
- Special equipment/devices required
- Physical space required

Collected by practice nurse during session

- Time to administer each instrument
- Instrument completion by respondents (include any reasons for non-completion)

Acceptability to health service providers

We will ask the screeners to complete a standardised form to capture initial impressions of the instruments during the data collection period. We will also request that screeners participate in an interview conducted within

a week after data collection has concluded to gather their overall impressions of the instruments. We will rate each instrument against a 1–10 Likert scale measuring ease of implementation as well as including a number of open-ended questions. We will ask screeners to rank the instruments in order of preference.

Acceptability to consumers

We will pilot an acceptability questionnaire with 26 participants during data collection (13 to be recruited from each research site, respectively). This figure represents just over a 10% sample of participants, as well as exceeding the n=25 threshold recommended by Herzog in her discussion of appropriate sample sizes for aims related to instrumentation.[73] We will ask every second participant participating at each research site in the main study to participate in the acceptability component. Sampling will proceed until the site quota is reached.

After applying each index test the screener will ask participants their impressions of the instrument and record the response. We will also ask participants to complete a 1–10 Likert-scale questionnaire measuring perceived ease in completing each instrument. In addition, screeners will collect refusal rates from all respondents, including reason for refusal.

Data management

Separate variables will be developed in SPSS to represent each numerical data measure. We will record and transcribe the screener interviews, uploading the transcripts to the NVivo software package. We will also store and analyse comments reflecting impressions of the instruments within NVivo. Otherwise, we will follow similar data security and deidentification procedures as specified under Diagnostic Accuracy.

Data analysis

Feasibility

We will use descriptive statistics and tables to describe the results of the feasibility analysis, structuring these according to themes drawn out in our early focus groups.

Acceptability to health service providers

Two researchers will employ a thematic analysis approach to code the data contained within the screener transcripts. We will use these codes to develop acceptability categories and themes. Codes and themes will be reviewed with a third researcher experienced in qualitative methodology to promote rigour.

We will create joint displays (ie, side-by-side comparison tables) of ranking results for the screening instruments and qualitative comments about screener impressions of the instruments to facilitate data integration.

Acceptability to consumers

We will present consumer ratings for each instrument (Likert scale) as frequency tables, along with reporting the mean, range and proportion in each group. We will use a joint display to add indicative qualitative comments about these results, aiming to represent the range of opinion for each instrument. Against each instrument, we will also present summary descriptive data based on the whole sample describing refusal rates and reason for refusal.

Interpretation

We will structure our discussion of the results by each dimension of feasibility/acceptability, noting the extent of convergence between the qualitative and quantitative data sources where appropriate. Where divergence occurs, we will discuss potential causes and implications.

ETHICS AND DISSEMINATION

Ethics and informed consent

The study has been approved by the Torrens University Higher Research Ethics Committee. Written informed consent will be obtained from all participants and screeners prior to participation. Where informed consent cannot be obtained due to cognitive impairment, consent will be sought from an attendant person responsible for the participant and cosigned by the GP.

Participant safety

At each site the health service provider will do a brief safety analysis prior to commencement to ensure it is safe to proceed. We will offer participants the right to refuse participation in physical tests they deem unsafe. Where participants are unable to complete their appointment due to fatigue, we will offer them the option to attend a separate session within the following 48 hours in order to complete data collection.

Dissemination

We will publish our findings within peer-reviewed journals and present at relevant conferences within the field. Separate publications will address findings for the diagnostic test accuracy and psychosocial research objectives. At no time will participants be identifiable within the research dissemination process.

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