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## Feasibility, Acceptability and Diagnostic Test Accuracy of Frailty Screening Instruments in Community-Dwelling Older People within General Practice Settings: A Study Protocol

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## Title

Feasibility, Acceptability and Diagnostic Test Accuracy of Frailty Screening Instruments in Community-Dwelling Older People within General Practice Settings: Study Protocol

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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, also collecting a range of psychosocial measures via questionnaire. 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, 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. A blinded researcher will then apply 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.

## Keywords

Frailty, General practice, Older people, Diagnostic test accuracy, Feasibility, Sensitivity and specificity

## Strengths and Limitations of this Study

### Strengths

- 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.
- Our study will include both metropolitan and non-metropolitan practice sites.
- Results will inform the design and implementation of a second phase of the project to be conducted across multiple sites and contexts.
- 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.
- The frailty screening instruments to be tested display high variability in terms of reported sensitivity and specificity.

## 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],[5],[6], disability [7],[4],[8],[5], increased health care utilisation [7],[4],[9],[5], 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+, although results vary widely [13]. Applying even this conservative rate to the future Australian population aged 65+ would result in a projection of over one million frail Australians by 2061 [14], a significant challenge for the health care 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] [16][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. Further, 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 [27] and associated care planning receive government rebates under the Medical Benefits Scheme (MBS). Through chronic disease and management health plans, older people can then access rebated allied health (although limited) and psychology services. General practitioners are also able to refer to specialist geriatricians for Comprehensive Geriatric Assessment 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 Program. 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 hospital and private hospital systems although in some regions, these services might be limited.

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3 Therefore, screening for frailty risk in general practice might allow the  
4 general practitioner to identify earlier those aged 75 years and older who  
5 might benefit from a comprehensive assessment via the 75+ Health  
6 Assessment, following which a management plan including further  
7 investigation and referral to various services might occur in a proactive  
8 rather than a reactive approach. The relative 'safety net' provided by the  
9 MBS-funded items has important implications for how we approach the  
10 issue of accuracy within this study. The most important consideration for  
11 Australian GPs is likely to be avoiding false negatives, so as to avoid missing  
12 people who actually are frail. In contrast, the consequences of false  
13 positives are less significant given the options for subsequent follow-up. We  
14 are thus emphasising sensitivity over specificity in our study.  
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22 Aside from accuracy, feasibility and acceptability will also be critical factors  
23 in the selection of screening instruments. The feasibility and acceptability  
24 of frailty screening instruments within general practice has been  
25 significantly under-researched [16]. Consequently we have drawn on  
26 several feasibility studies addressing the introduction of non-frailty  
27 instruments in developing our approach [26], along with early results from  
28 focus groups on frailty conducted with Australian GPs. We will assess the  
29 feasibility and acceptability of the index tests from three perspectives: 1)  
30 Feasibility of implementation within the context of a busy general practice  
31 environment; 2) Acceptability to health service providers; 3) Acceptability  
32 to consumers.  
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39 In the absence of an Australian policy directive on frailty screening,  
40 screening will likely be directed to the most appropriate perceived  
41 candidates rather than to all persons of a given age. In identifying potential  
42 candidates, it is probable that psychosocial factors will play a key role. For  
43 example, people who live alone, suffer depression or who have few social  
44 supports could potentially be at more risk from the impacts of frailty than  
45 those who have greater personal resources. The association of psychosocial  
46 factors with frailty is an emerging trend that has been reported within the  
47 research literature [27–30], although results to date have been mixed [31].  
48 Consequently, in order to better characterise those diagnosed as frail by  
49 either reference standard, we will also collect a range of psychosocial items  
50 from our sample.  
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## 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 (STARD) and QUADAS-2 criteria.

### Setting

We will conduct the study within 2 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) – 2 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 30<sup>th</sup> June 2016 and booked to attend at the study sites for an upcoming appointment over a pre-specified 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 co-sign all consent forms involving patients with impaired ability to consent.

We will make every effort to include participants with low English proficiency. To do so, the team will employ a range of strategies, including liaison with practice staff and family members, translation of the

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3 information sheet and consent form where required, and enlisting  
4 interpreters.  
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### 7 Exclusion Criteria

8 We will exclude those patients too ill to be assessed (i.e. undergoing  
9 palliative care treatment or currently hospitalised) or resident within  
10 residential care facilities from the study.  
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## 13 Substudy 1: Diagnostic Test Accuracy

### 14 Data Collection

15 Figure 1 outlines the overall data collection process for the diagnostic test  
16 accuracy aspect of the study.  
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19 <Figure 1 to go here>  
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### 22 Recruitment

23 We will mail eligible participants an invitation letter, consent form,  
24 participant information sheet and questionnaire (demographic and  
25 psychosocial instruments).  
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28 We will ask potential participants to sign a consent form (or if unable to  
29 consent, a family member will be asked to sign on their behalf) to be  
30 returned to the research team via a self-addressed envelope along with their  
31 completed questionnaire. Participants will be given the right to withdraw  
32 from participation should they wish to, as well as to opt out of completing  
33 individual instruments. We will collect demographic information (age, sex)  
34 from those electing not to participate in order to compare participants with  
35 non-participants.  
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38 Upon receipt of the consent form, we will telephone the participant to make  
39 an appointment to attend the screening session within two weeks to ensure  
40 information currency.  
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### 43 Screening session

44 On arrival, we will ask participants to complete the two self-reported index  
45 tests, returning each test as completed so that time to complete can be  
46 recorded. The practice nurse will then administer the 5 index tests in  
47 random order. A blinded researcher (RA) will then administer the  
48 reference standards.  
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## 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, further reducing the list based on clinical advice, validity and reliability, appropriateness to the study population and context, time to implement and delivery method. We ultimately selected the following instruments for inclusion: FRAIL Screening Instrument; Groningen Frailty Index; 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 [32]. 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), pre-frail (1-2), and robust (0) health status.

#### *Groningen Frailty Indicator*

The Groningen Frailty Indicator is a multi-domain frailty instrument found to be reliable and valid in a Dutch community-dwelling population [33][34]. 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 [35]. It consists of a set of seven yes/no questions. Previous research indicates high sensitivity but limited specificity in identifying frailty [36]. In the original formulation, also used in this study, three or more 'yes' responses indicated frailty [35].

#### *Edmonton Frail Scale*

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3 The Edmonton Frail Scale (EFS) is a measure developed and validated on a  
4 community-dwelling population aged 65+ years [37]. Scored from 0 to 17, it  
5 measures frailty across ten domains including cognition, social support,  
6 medication use and functional performance. The original study does not  
7 provide a specification for frailty cut-point; this study will consequently  
8 follow previous studies in adopting a cut-point of 8 or more points to define  
9 frailty [38][39].  
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### 14 *Gait Speed*

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16 Gait speed is a reliable and valid measure widely applied within the  
17 research literature [40][41]. It has been found to have high sensitivity (but  
18 limited specificity) in identifying frailty [36]. Following the  
19 recommendations of Castell et al and the wide application of this cut-off  
20 point in practice [41], we will apply a  $\leq 0.8$  m/s cut-off point for frailty in  
21 our study.  
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### 25 Index Tests: Self-Reported

#### 26 *Reported Edmonton Frail Scale*

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28 The Reported Edmonton Frail Scale is a self-reported version of the  
29 Edmonton Frail Scale [39]. The resultant scale ranges from 0 to 18 with the  
30 following cut-points defined: ‘Not Frail’ (0–5), ‘Apparently Vulnerable’ (6–  
31 7), ‘Mild Frailty’ (8–9), ‘Moderate Frailty’ (10–11) and ‘Severe Frailty’ (12–  
32 18). We will apply the original reported cut-point of 8 or more in our study.  
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#### 37 *The Kihon Checklist*

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39 The Kihon Checklist is reported to be a reliable self-reported instrument for  
40 predicting frailty in older adults [42]. It consists of 25 yes/no questions  
41 covering a range of domains. We will replicate the frailty cut-point reported  
42 in Sewo Sampaio et al [43] of a total of 7 or more ‘yes’ questions.  
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### 46 Reference Standards

47 We consulted prior research for potential reference standards, identifying  
48 three commonly used candidates [25,36]: Comprehensive Geriatric  
49 Assessment (CGA), the Frailty Phenotype (based on the Cardiovascular  
50 Health Study definition [7]) and Frailty Index (based on the Canadian  
51 Study of Health and Aging [44]).  
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55 The CGA, a “multidimensional, interdisciplinary diagnostic procedure”  
56 aiming to identify a range of issues in older people, is commonly thought to  
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3 be the gold standard for frailty identification [25:189]. However, its time-  
4 consuming and resource intensive nature [36,45], make it beyond the scope  
5 of implementation as a reference standard within our study.  
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8 The alternatives - the Frailty Phenotype and Frailty Index – have  
9 admittedly been labelled as “different instruments for different purposes”  
10 [46], due largely to the inclusion of disability items in the Frailty Index  
11 versus the Phenotype. Our inclusion of both as reference standards might  
12 therefore be seen as controversial, if not for the fact that the version of the  
13 Frailty Index we will apply in this study explicitly excludes disability items.  
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16 The remaining differences between the two standards mainly relate to the  
17 feasibility of applying them within general practice, a factor that does not  
18 apply here given their use as reference standards rather than index tests.  
19 Additionally, the risk of differential verification bias, present when not all  
20 test subjects undertake both reference standards [47], is not expected to  
21 impact our study as all participants will undertake both reference standards  
22 equally. Results for both standards will be presented, along with a detailed  
23 analysis of cases varying between the two.  
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26 We contend that our decision to include both reference standards offers a  
27 significant contribution to the frailty evidence base, given we are operating  
28 with an absence of consensus about which reference standard is superior.  
29 Including both reference standards will ensure our research remains  
30 relevant into the future, regardless of subsequent changes in expert  
31 opinion. Given we are still at an early stage of our understanding about  
32 frailty screening within Australia, we maintain that in this instance, more  
33 information will ultimately prove better than less.  
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### 36 *Frailty Phenotype*

37 The Frailty Phenotype has received broad acceptance worldwide [41],  
38 having been externally validated within several large epidemiological  
39 studies [36,48]. Recognised drawbacks include its lack of cognitive and  
40 psychosocial domains [30], however it has predicted significant negative  
41 health-related outcomes across numerous studies to date [30,49].  
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44 This study will implement Fried et al’s original formulation, as shown  
45 below [7:M156].  
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- *Shrinking* (unintentional weight loss of  $\geq 10$  pounds in the prior year or, at follow-up, of  $\geq 5\%$  of body weight in the prior year by direct measurement of weight), as assessed by the question: “*In the last year, have you lost more than 10 pounds unintentionally (i.e., not due to dieting or exercise)?*”

*Weakness:* We will measure grip strength with a hand-held Jamar dynamometer, assessing maximal grip strength (kilograms) in the dominant hand (average of 3 measures). Fried’s cut-points are shown in Table 1 and will be used in this study:

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

<b>Men</b>		<b>Women</b>	
<i>BMI</i>	<i>Cut-off (kg)</i>	<i>BMI</i>	<i>Cut-off (kg)</i>
$\leq 24$	$\leq 29$	$\leq 23$	$\leq 17$
24.1–26	$\leq 30$	23.1–26	$\leq 17.3$
26.1–28	$\leq 30$	26.1–29	$\leq 18$
$> 28$	$\leq 32$	$> 29$	$\leq 21$

- *Poor endurance and energy:* Indicated by self-reported exhaustion based on the Center for Epidemiological Studies-Depression (CES-D) scale [50]. 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:  $\geq 7$  seconds (men of height  $\leq 173$  cm and women  $\leq 159$  cm), and  $\geq 6$  seconds (men of height  $> 173$  cm and women  $> 159$  cm).
- *Low physical activity level:* Measured by the short-form Minnesota Leisure Time Activity questionnaire [51]. 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.

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3 The frailty cut points specified in the original model and used within this  
4 study were that 3 or more components meeting the criteria indicate frailty.  
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### 8 *Adelaide Frailty Index*

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10 The second reference standard is the Adelaide Frailty Index (AFI), a 42-  
11 item variant of a standard frailty index based on the methodology reported  
12 in Searle et al [52]. It was developed by Mr. Mark Thompson as part of  
13 ongoing work within the regional geriatric health service (Thompson et al,  
14 unpublished)[53]. The frailty cut point for the AFI, also applied within this  
15 study, is a score of 9 or more (i.e. 21% or more).  
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20 The AFI includes elements drawn from the following frailty risk factors:  
21 Shrinking, Exhaustion, Low Energy Expenditure, Slowness, Weakness,  
22 Cognitive Impairment, Falls and Balance, Urinary Incontinence,  
23 Polypharmacy, Oral Health, Pain, Mental Health and Chronic Conditions.  
24 Several questions within the AFI were derived from validated screening  
25 instruments in common use within those domains. The AFI intentionally  
26 excludes disability items, in recognition of the distinction between  
27 disability and frailty [54].  
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### 33 *Psychosocial Instruments*

34 In recognition of the complex relationship between psychosocial factors  
35 and frailty, we will collect a range of psychosocial instruments within the  
36 self-complete questionnaire. They include the Pearlin Mastery Scale [55],  
37 the General Self-Efficacy Scale (GSE) [56], the Brief Ageing Perceptions  
38 Questionnaire (BAP-Q) [57], the Lubben Social Network Scale [58], the  
39 UCLA Loneliness Scale (Version 3) [59], The Geriatric Depression Scale  
40 [60], the SF-12 [61] and the Nottingham Extended ADL scale (NEADL)  
41 [62].  
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### 47 *Data Management*

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

### Sample Size

We derived a sample size estimate using a methodology reported in Buderer incorporating consideration of disease prevalence [63]. 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+ respectively (Thompson et al, unpublished data and Widagdo et al [18]), and a Spanish study reported a 19% prevalence among the 75+ [41]. 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. Allowing for attrition of 25% as well as the true population prevalence rate potentially being lower than we estimate, we will aim to recruit at least 240 participants

### Analysis

Participant characteristics, index test scores, and reference standard scores will be described as numbers and percentages for qualitative variables and as medians with 25th and 75th percentiles for quantitative variables.

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 x 2 tables for each index test against each reference standard, and calculate sensitivity and specificity with their corresponding 95% confidence intervals (95% CI), 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.

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. The data will be analysed using the latest version of the STATA statistical software.



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 nominal nature of the outcome (i.e. frailty present/frailty absent) and multiple raters, the kappa coefficient will be used to ascertain agreement, with the minimum acceptable value set to 0.6.

## 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.”[64:123] Mixed methods have increasingly been applied within the health sciences in recent years where a more complete understanding of an issue than is allowed by quantitative or qualitative approach alone is sought [65].

### Data Collection and Management

#### 1) 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
- Tool completion by respondents (Include any reasons for non-completion)

#### 2) Acceptability to health service providers

We will ask the screeners to complete a standardised form to capture initial impressions of the tools 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 tools. We will rate each tool against a 1-10 Likert scale measuring ease

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3 of implementation as well as including a number of open-ended questions.  
4 We will ask screeners to rank the tools in order of preference.  
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### 7 3) Acceptability to consumers.

8 We will pilot an acceptability questionnaire with a 10% sample of  
9 participants (i.e. n=24) during data collection. After applying each index  
10 test the screener will ask participants their impressions of the tool and  
11 record the response. We will also ask participants to complete a 1 - 10  
12 Likert-scaled questionnaire measuring perceived ease in completing each  
13 tool. In addition, screeners will collect refusal rates from all respondents,  
14 including reason for refusal.  
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### 19 Data Management

20 Separate variables will be developed in SPSS to represent each numerical  
21 data measure. We will record and transcribe the screener interviews,  
22 uploading the transcripts to the NVivo software package. We will also store  
23 and analyse comments reflecting impressions of the instruments within  
24 Nvivo. Otherwise, we will follow similar data security and de-identification  
25 procedures as specified under Diagnostic Accuracy.  
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### 30 Data Analysis

#### 31 1) Feasibility

32 We will use descriptive statistics and tables to describe the results of the  
33 feasibility analysis, structuring these according to themes drawn out in our  
34 early focus groups.  
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#### 39 2) Acceptability to health service providers

40 Two researchers will employ a thematic analysis approach to code the data  
41 contained within the screener transcripts. We will use these codes to  
42 develop acceptability categories and themes. Codes and themes will be  
43 reviewed with a third researcher experienced in qualitative methodology to  
44 promote rigour.  
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48 We will create joint displays (i.e., side-by-side comparison tables) of  
49 ranking results for the screening tools and qualitative comments about  
50 screener impressions of the tools to facilitate data integration.  
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#### 54 3) Acceptability to consumers

55 We will present consumer ratings for each tool (Likert scaled) as frequency  
56 tables, along with reporting the mean, range and proportion in each group.  
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3 We will use a joint display to add indicative qualitative comments about  
4 these results, aiming to represent the range of opinion for each tool.  
5 Against each tool, we will also present summary descriptive data based on  
6 the whole sample describing refusal rates and reason for refusal.  
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### 10 **Interpretation**

11 We will structure our discussion of the results by each dimension of  
12 feasibility/acceptability, noting the extent of convergence between the  
13 qualitative and quantitative data sources where appropriate. Where  
14 divergence occurs, we will discuss potential causes and implications.  
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### 18 **Ethics and Dissemination**

#### 19 **Ethics and Informed Consent**

20 The study has been approved by the Torrens University Higher Research  
21 Ethics Committee. Written informed consent will be obtained from all  
22 participants and screeners prior to participation. Where informed consent  
23 cannot be obtained due to cognitive impairment, consent will be sought  
24 from an attendant person responsible for the participant and co-signed by  
25 the general practitioner.  
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#### 31 **Participant Safety**

32 At each site the health service provider will do a brief safety analysis prior  
33 to commencement to ensure it is safe to proceed. We will offer participants  
34 the right to refuse participation in physical tests they deem unsafe.  
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#### 38 **Dissemination**

39 We will publish our findings within peer-reviewed journals and present at  
40 relevant conferences within the field. Separate publications will address  
41 findings for the diagnostic test accuracy and psychosocial research  
42 objectives. At no time will participants be identifiable within the research  
43 dissemination process.  
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#### 48 **Authors' contributions**

49 The research question, concept and design were formulated by RA, JB, RV,  
50 SY, TS, JK, MC, MA and AK. Preparation of the manuscript was completed  
51 by RA. RA, JB, RV, TS, SY, JK, MC, MA, and AK reviewed and edited the  
52 manuscript. All authors have read and approved the final version of the  
53 manuscript.  
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## Competing interests

The authors declare that they have no competing interests. The views expressed in this article are those of the authors and do not necessarily represent the official viewpoint of their organisations.

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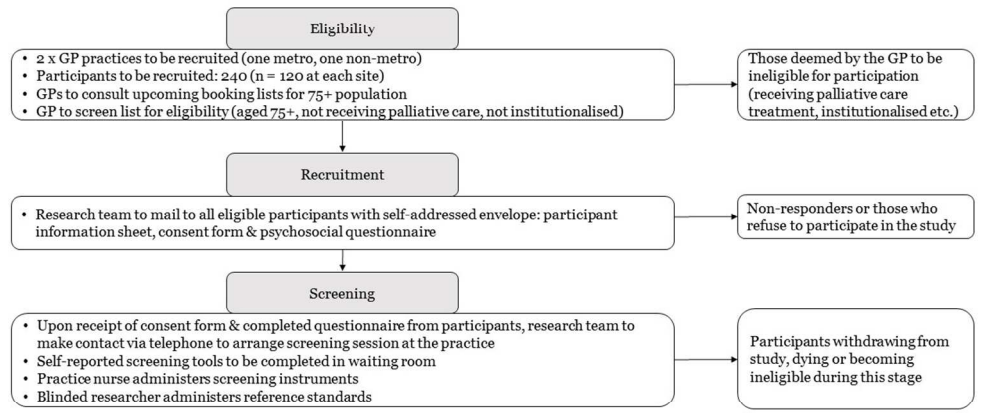
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# BMJ Open

## Feasibility, Acceptability and Diagnostic Test Accuracy of Frailty Screening Instruments in Community-Dwelling Older People within General Practice Settings: A Study Protocol

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-016663.R1
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<b>Primary Subject Heading</b>:	General practice / Family practice
Secondary Subject Heading:	Geriatric medicine
Keywords:	Frailty, General practice, Older people, Diagnostic test accuracy, Feasibility

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## Title

Feasibility, Acceptability and Diagnostic Test Accuracy of Frailty Screening Instruments in Community-Dwelling Older People within General Practice Settings: Study Protocol

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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, 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.

## Keywords

Frailty, General practice, Older people, Diagnostic test accuracy, Feasibility, Sensitivity and specificity

## Strengths and Limitations of this Study

### Strengths

- 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.

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- The acceptability component of our study will measure acceptability of screening instruments to both health service providers (general practitioners and practice nurses) and consumers.

### Limitations

- 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 health care 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+, although results vary widely [13]. Applying even this conservative rate to the future Australian population aged 65+ would result in a projection of over one million frail Australians by 2061 [14], a significant challenge for the health care 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. Further, there remains extensive disagreement among the experts over how extensive screening should be



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3 [21–23]. Regardless of the extent of screening, GPs and their teams will  
4 need accurate screening instruments to effectively identify those who are  
5 frail or at risk [24,25], and if translation into busy practices is to be  
6 successful, also instruments that are logistically feasible and acceptable to  
7 health service providers and consumers.  
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### 11 **Australian Care Context and Purpose for Screening**

12 In Australia, opportunities for comprehensive assessment for older people  
13 in general practice through the 75+ Health Assessment and associated care  
14 planning receive government rebates under the Medical Benefits Scheme  
15 (MBS) [26]. Through chronic disease and management health plans, older  
16 people can then access rebated allied health (although limited) and  
17 psychology services. General practitioners are also able to refer to specialist  
18 geriatricians for Comprehensive Geriatric Assessment for which also there  
19 is a specialist rebate. Access to medical services might vary by geographical  
20 region.  
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23 Means tested but publicly funded Aged Care Services that provide for home  
24 case support services and some therapy services are accessible through the  
25 centralised portal, My Aged Care. A brief assessment of multiple domains is  
26 undertaken but where care needs are identified as high, a more  
27 comprehensive assessment occurs through the Aged Care Assessment  
28 Program. The older person might then be approved for more coordinated in  
29 home care and support or residential aged care. Some service providers  
30 provide for day therapy services. At all times, older people are also able to  
31 access therapy and support services privately and when acute care is  
32 required, older people might access specialist geriatrics, rehabilitation and  
33 palliative care service through both the public hospital and private hospital  
34 systems although in some regions, these services might be limited.  
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37 Therefore, screening for frailty risk in general practice might allow the  
38 general practitioner to identify earlier those aged 75 years and older who  
39 might benefit from a comprehensive assessment via the 75+ Health  
40 Assessment, following which a management plan including further  
41 investigation and referral to various services might occur in a proactive  
42 rather than a reactive approach. The relative 'safety net' provided by the  
43 MBS-funded items has important implications for how we approach the  
44 issue of accuracy within this study. The most important consideration for  
45 Australian GPs is likely to be avoiding false negatives, so as to avoid missing  
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3 people who actually are frail. In contrast, the consequences of false  
4 positives are less significant given the options for subsequent follow-up. We  
5 are thus emphasising sensitivity over specificity in our study.  
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9 Aside from accuracy, feasibility and acceptability will also be critical factors  
10 in the selection of screening instruments. The feasibility and acceptability  
11 of frailty screening instruments within general practice has been  
12 significantly under-researched [16]. Consequently we have drawn on  
13 several feasibility studies addressing the introduction of non-frailty  
14 instruments in developing our approach [27], along with early results from  
15 focus groups on frailty conducted with Australian GPs. We will assess the  
16 feasibility and acceptability of the index tests from three perspectives: 1)  
17 Feasibility of implementation within the context of a busy general practice  
18 environment; 2) Acceptability to health service providers; 3) Acceptability  
19 to consumers.  
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26 Within health research, passive case-finding (using medical records, for  
27 example), has been promoted as potentially advantageous over active case-  
28 finding due to lower cost and burden on study participants [28]. It  
29 therefore could be viewed as a viable alternative to the active and rather  
30 intensive screening approach adopted in our study. However, passive case-  
31 finding is unviable within this context given that routinely collected medical  
32 records would be unlikely to capture the range of data required to detect  
33 frailty (with the possible exception of the construction of a frailty index)  
34 and are subject to high variability, a globally observed finding [28]. These  
35 factors suggest an insufficiently reliable basis for its inclusion within our  
36 study.  
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43 In the absence of an Australian policy directive on frailty screening,  
44 screening will likely be directed to the most appropriate perceived  
45 candidates rather than to all persons of a given age. Preliminary findings  
46 from an aligned study of Australian GP perspectives on frailty and frailty  
47 screening [29] indicate that in identifying potential candidates, it is  
48 probable that psychosocial factors may play a key role in GP considerations.  
49 For example, people who live alone, suffer depression or who have few  
50 social supports could potentially be at more risk from the impacts of frailty  
51 than those who have greater personal resources. The association of  
52 psychosocial factors with frailty is an emerging trend that has been  
53 reported within the research literature [30–35] although results to date  
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3 have been mixed [36]. Consequently, in order to better characterise those  
4 diagnosed as frail, we will also collect a range of psychosocial measures  
5 from our sample.  
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### 8 **Objectives**

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10 Our study is designed to: assess the (1) feasibility (2) acceptability (to  
11 health service providers and consumers) and (3) diagnostic test accuracy of  
12 a number of frailty screening instruments within the context of Australian  
13 general practice. A fourth objective will be to explore the association of a  
14 range of psychosocial measures with frailty.  
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## 18 **METHODS AND ANALYSIS**

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20 We will employ a prospective, cross-sectional and observational research  
21 design. We have reviewed our study design against the Standards for  
22 Reporting of Diagnostic Accuracy (STARD) and QUADAS-2 criteria. The  
23 study will be conducted between July 2017 and June 2018.  
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### 27 **Setting**

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29 We will conduct the study within 2 general practice sites within South  
30 Australia, one metropolitan and one non-metropolitan. We will select  
31 practices based on purposive sampling.  
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34 Four practice nurses (registered nurses working in general practice) – 2 at  
35 each site - will be contracted to administer the index tests. Potential  
36 screeners will sign a consent form to enrol in the study. The screeners will  
37 attend training prior to commencement.  
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### 41 **Participants**

#### 42 **Eligibility**

##### 43 **Inclusion Criteria**

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45 We will employ convenience sampling to recruit our sample. Patients will  
46 be eligible if they were aged 75+ years as at 30<sup>th</sup> June 2016 and booked to  
47 attend at the study sites for an upcoming appointment over a pre-specified  
48 period during 2017.  
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53 Patients with dementia will be included as participants if written, informed  
54 consent is given by a responsible person who is available to attend with  
55 them at the study sessions. Inclusion will be discussed on a case by case  
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3 basis with the patient's doctor. Doctors will co-sign all consent forms  
4 involving patients with impaired ability to consent.  
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7 We will endeavour to include participants with limited English proficiency  
8 wherever possible, but will exclude those with insufficient English to fully  
9 participate in the study.  
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### 12 Exclusion Criteria

13 We will exclude from the study those patients too ill to be assessed (i.e.  
14 undergoing palliative care treatment or currently hospitalised), resident  
15 within residential care facilities or whose English is insufficient to fully  
16 participate.  
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## 20 Substudy 1: Diagnostic Test Accuracy

### 21 Data Collection

22 Figure 1 outlines the overall data collection process for the diagnostic test  
23 accuracy aspect of the study.  
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27 <Figure 1 to go here>  
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### 30 Recruitment

31 We will mail eligible participants an invitation letter, consent form, and  
32 participant information sheet. We will ask potential participants to sign a  
33 consent form (or if unable to consent, a family member will be asked to sign  
34 on their behalf) to be returned to the research team via self-addressed  
35 envelope. Participants will be given the right to withdraw from  
36 participation should they wish to, as well as to opt out of completing  
37 individual instruments. We will collect demographic information (age, sex)  
38 from those electing not to participate in order to compare participants with  
39 non-participants.  
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45 Upon receipt of the consent form, we will telephone the participant to make  
46 an appointment to attend the screening session within two weeks to ensure  
47 information currency.  
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50 Recruitment will conclude upon successful achievement of the required  
51 sample size (n=120 from each practice).  
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### 54 Screening session

55 On arrival, we will ask participants to complete a questionnaire including  
56 standard demographic information along with a select number of  
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3 psychosocial instruments. They will then complete two self-reported index  
4 tests, returning each test as completed so that time to complete can be  
5 recorded. The practice nurse will then administer 5 administered index  
6 tests in random order. A blinded researcher (RA) will then administer the  
7 two reference standards. The total estimated duration of the appointment  
8 will be between 45 and 60 minutes.  
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### 13 Follow-Up

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

#### 21 Index Tests: Overview

22 Following a literature review, we shortlisted 14 frailty screening  
23 instruments as candidates for inclusion as index tests, further reducing the  
24 list based on clinical advice, validity and reliability, appropriateness to the  
25 study population and context, time to implement and delivery method. We  
26 ultimately selected the following instruments for inclusion: FRAIL  
27 Screening Instrument; Groningen Frailty Index; PRISMA-7; Edmonton  
28 Frail Scale; Gait Speed; Reported Edmonton Frail Scale and Kihon  
29 Checklist.  
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#### 35 Index Tests: Administered by Practice Nurse

##### 36 *FRAIL Screening Instrument*

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38 The FRAIL Screening instrument is a 5-item instrument addressing five  
39 aspects of frailty: fatigue, resistance, ambulation, illness, and loss of weight  
40 [37]. Each component is allocated one point and all components are  
41 summed, resulting in a scale from 0 to 5. The original cut-points will be  
42 used in this study and were: frail (3-5), pre-frail (1-2), and robust (0) health  
43 status.  
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##### 48 *Groningen Frailty Indicator*

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50 The Groningen Frailty Indicator is a multi-domain frailty instrument found  
51 to be reliable and valid in a Dutch community-dwelling population [38,39].  
52 It has 15 items, resulting in a summed score from 0 to 15, with the frailty  
53 cut-point - also used in this study - set at 4 or more points.  
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##### 57 *PRISMA-7*

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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].

### 11 *Edmonton Frail Scale*

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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].

### 24 *Gait Speed*

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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  $\leq 0.8$  m/s cut-off point for frailty in our study.

### 36 *Index Tests: Self-Reported*

#### 37 *Reported Edmonton Frail Scale*

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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.

#### 48 *The Kihon Checklist*

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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 7 or more 'yes' questions.

## Reference Standards

We consulted prior research for potential reference standards, identifying three commonly used candidates [25,41]: Comprehensive Geriatric Assessment (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 inter-disciplinary 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], make 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 Fried et al's original formulation, as shown below [7:M156].

- *Shrinking* (unintentional weight loss of  $\geq 10$  pounds in the prior year or, at follow-up, of  $\geq 5\%$  of body weight in the prior year by direct measurement of weight), as assessed by the question: “*In the last year, have you lost more than 10 pounds unintentionally (i.e., not due to dieting or exercise)?*”

*Weakness*: We will measure grip strength with a hand-held Jamar dynamometer, assessing maximal grip strength (kilograms) in the dominant hand (average of 3 measures). Fried's cut-points are shown in Table 1 and will be used in this study:

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

<b>Men</b>		<b>Women</b>	
<i>BMI</i>	<i>Cut-off (kg)</i>	<i>BMI</i>	<i>Cut-off (kg)</i>
$\leq 24$	$\leq 29$	$\leq 23$	$\leq 17$
24.1–26	$\leq 30$	23.1–26	$\leq 17.3$
26.1–28	$\leq 30$	26.1–29	$\leq 18$
$> 28$	$\leq 32$	$> 29$	$\leq 21$

- *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:  $\geq 7$  seconds (men of



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3 height  $\leq$  173 cm and women  $\leq$  159 cm), and  $\geq$  6 seconds (men of  
4 height  $>$  173 cm and women  $>$  159 cm).  
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8 • *Low physical activity level:* Measured by the short-form Minnesota  
9 Leisure Time Activity questionnaire [56]. The questionnaire is used to  
10 derive a weighted score of kilocalories expended/week, with the  
11 following cut-points: men  $<$  383 and women  $<$  270 kcals/week.  
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14 The frailty cut points specified in the original model and used within this  
15 study were that 3 or more components meeting the criteria indicate frailty.  
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### 18 19 20 *Adelaide Frailty Index*

21 The second reference standard is the Adelaide Frailty Index (AFI), a 42-  
22 item variant of a standard frailty index based on the methodology reported  
23 in Searle et al [57]. It was developed by Mr. Mark Thompson as part of  
24 ongoing work within the regional geriatric health service (Thompson et al,  
25 unpublished)[58]. The frailty cut point for the AFI, also applied within this  
26 study, is a score of 9 or more (i.e. 21% or more).  
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29 The AFI includes elements drawn from the following frailty risk factors:  
30 Shrinking, Exhaustion, Low Energy Expenditure, Slowness, Weakness,  
31 Cognitive Impairment, Falls and Balance, Urinary Incontinence,  
32 Polypharmacy, Oral Health, Pain, Mental Health and Chronic Conditions.  
33 Several questions within the AFI were derived from validated screening  
34 instruments in common use within those domains. The AFI intentionally  
35 excludes disability items, in recognition of the distinction between  
36 disability and frailty [59].  
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### 39 *Psychosocial Instruments*

40 In recognition of the complex relationship between psychosocial factors  
41 and frailty, we will administer five psychosocial instruments within the self-  
42 complete questionnaire. Depression is associated with frailty among older  
43 people [34] and is measured here via the commonly used GDS-15 (short  
44 form of the Geriatric Depression Scale) [60]. Social isolation will be  
45 measured by an abbreviated version of the Lubben Social Network Scale  
46 (the LSNS-6), which has been widely used worldwide to measure isolation  
47 among older people [61,62]. A measure relating to sense of perceived  
48 control, as originally conceptualised and validated by Lachman and Weaver  
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[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 (BAP-Q) [65]. Lastly, a specific measure of older people's quality of life will be measured using the 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 de-identified study data on a password-protected drive.

### Statistical Methods

#### Sample Size

We derived a sample size estimate using a methodology reported in 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+ respectively (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

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3 screening appointment while also allowing for the possibility of a lower  
4 than estimated prevalence of frailty in the population.  
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### 7 Analysis

8 We will examine the distribution of quantitative variables visually and by  
9 using the Shapiro-Wilk test for normality [70]. Categorical variables will be  
10 described as frequencies. Quantitative variables will be displayed as  
11 mean±SD where normally distributed or as medians with 25th and 75th  
12 percentiles where asymmetrically distributed. Where the results for an  
13 index test or reference standard are indeterminate or incomplete, results  
14 for that participant will be excluded. No imputation will be performed for  
15 missing data.  
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21 Our accuracy analysis will compare the results of each index test against  
22 each reference standard. We will construct variables reflecting each frailty  
23 instrument and define the presence of frailty according to the specified cut-  
24 points. We will create standard 2 x 2 tables for each index test against each  
25 reference standard, and calculate sensitivity and specificity with their  
26 corresponding 95% confidence intervals (95% CI), along with positive and  
27 negative predictive values and likelihood ratios. We will determine the  
28 extent of agreement between the index tests and reference standards by  
29 calculating Cohen's kappa.  
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35 To analyse the relationship between the psychosocial variables and frailty,  
36 we will define the presence of frailty as a binary variable (frail/not frail)  
37 according to the Fried criteria as measured in the Frailty Phenotype. We  
38 will use binomial (binary) logistic regression to analyse the association  
39 strength (odds ratio) for the frail state with the psychosocial variables using  
40 the non-frail state as the comparison category. We will consider a value of  $p$   
41  $< 0.05$  to be statistically significant. The data will be analysed using the  
42 latest available version of the SPSS statistical software (SPSS Inc., Chicago,  
43 Illinois, USA).  
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49 To test inter-rater reliability, 8 subjects tested by each screener (32 in all)  
50 will be asked to repeat the index test session including self-reported tests  
51 with a second blinded screener within 48 hours after the initial rating.  
52 Given the binary nature of the outcome (i.e. frail/not frail) and multiple  
53 raters, the kappa coefficient will be used to ascertain agreement, with the  
54 minimum acceptable value set to 0.6. We will ask every third participant  
55 participating at each research site in the main study to participate in the  
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3 inter-rater reliability component, proceeding until such time as the site and  
4 screener quota is reached.  
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## 7 **Substudy 2: Feasibility and Acceptability**

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9 We will apply a convergent parallel mixed methods approach to the analysis  
10 of feasibility and acceptability. We define mixed methods research,  
11 following Johnson et al, as a type of research combining “elements of  
12 qualitative and quantitative research approaches ... for the broad purposes  
13 of breadth and depth of understanding and corroboration.” [71:123] Mixed  
14 methods have increasingly been applied within the health sciences in recent  
15 years where a more complete understanding of an issue than is allowed by  
16 quantitative or qualitative approach alone is sought [72].  
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### 22 **Data Collection and Management**

#### 23 **1) Feasibility**

24 We will measure the feasibility of the index tests by collecting the following  
25 information about each test:  
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#### 28 ***Noted by research team prior to data collection:***

- 29 • Education or training required to administer each test
- 30 • Special equipment/devices required
- 31 • Physical space required

#### 32 ***Collected by practice nurse during session:***

- 33 • Time to administer each instrument
- 34 • Instrument completion by respondents (Include any reasons for non-  
35 completion)

#### 36 **2) Acceptability to health service providers**

37 We will ask the screeners to complete a standardised form to capture initial  
38 impressions of the instruments during the data collection period. We will  
39 also request that screeners participate in an interview conducted within a  
40 week after data collection has concluded to gather their overall impressions  
41 of the instruments. We will rate each instrument against a 1-10 Likert scale  
42 measuring ease of implementation as well as including a number of open-  
43 ended questions. We will ask screeners to rank the instruments in order of  
44 preference.  
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### 3) 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 (2008) 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 tool and record the response. We will also ask participants to complete a 1 - 10 Likert-scaled questionnaire measuring perceived ease in completing each tool. 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 de-identification procedures as specified under Diagnostic Accuracy.

#### Data Analysis

##### 1) 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.

##### 2) 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 (i.e., side-by-side comparison tables) of ranking results for the screening tools and qualitative comments about screener impressions of the tools to facilitate data integration.

### 3) Acceptability to consumers

We will present consumer ratings for each tool (Likert scaled) 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 tool. Against each tool, 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 co-signed by the general practitioner.

##### **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.

## Authors' contributions

The research question, concept and design were formulated by RA, JB, RV, SY, TS, JK, MC, MA and AK. Preparation of the manuscript was completed by RA. RA, JB, RV, TS, SY, JK, MC, MA, and AK reviewed and edited the manuscript. All authors have read and approved the final version of the manuscript.

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## Competing interests

The authors declare that they have no competing interests. The views expressed in this article are those of the authors and do not necessarily represent the official viewpoint of their organisations.

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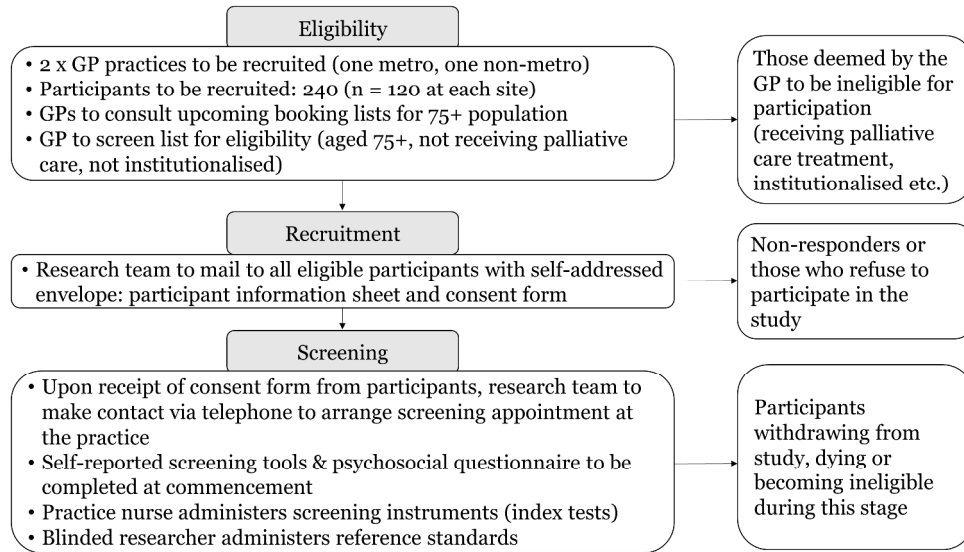
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Figure 1 Study Flow Diagram (Diagnostic Test Accuracy component)



Study Flow Diagram (Diagnostic Test Accuracy component)

338x190mm (300 x 300 DPI)

review only

# BMJ Open

## 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

Journal:	<i>BMJ Open</i>
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Keywords:	Frailty, General practice, Older people, Diagnostic test accuracy, Feasibility and acceptability, Sensitivity and specificity

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## Title

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, 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.

## Keywords

Frailty, General practice, Older people, Diagnostic test accuracy, Feasibility, Sensitivity and specificity

## Strengths and Limitations of this Study

### Strengths

- 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.

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- The acceptability component of our study will measure acceptability of screening instruments to both health service providers (general practitioners and practice nurses) and consumers.

### Limitations

- 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 health care 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+, although results vary widely [13]. Applying even this conservative rate to the future Australian population aged 65+ would result in a projection of over one million frail Australians by 2061 [14], a significant challenge for the health care 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. Further, there remains extensive disagreement among the experts over how extensive screening should be

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3 [21–23]. Regardless of the extent of screening, GPs and their teams will  
4 need accurate screening instruments to effectively identify those who are  
5 frail or at risk [24,25], and if translation into busy practices is to be  
6 successful, also instruments that are logistically feasible and acceptable to  
7 health service providers and consumers.  
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### 11 **Australian Care Context and Purpose for Screening**

12 In Australia, opportunities for comprehensive assessment for older people  
13 in general practice through the 75+ Health Assessment and associated care  
14 planning receive government rebates under the Medical Benefits Scheme  
15 (MBS) [26]. Through chronic disease and management health plans, older  
16 people can then access rebated allied health (although limited) and  
17 psychology services. General practitioners are also able to refer to specialist  
18 geriatricians for Comprehensive Geriatric Assessment for which also there  
19 is a specialist rebate. Access to medical services might vary by geographical  
20 region.  
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23 Means tested but publicly funded Aged Care Services that provide for home  
24 case support services and some therapy services are accessible through the  
25 centralised portal, My Aged Care. A brief assessment of multiple domains is  
26 undertaken but where care needs are identified as high, a more  
27 comprehensive assessment occurs through the Aged Care Assessment  
28 Program. The older person might then be approved for more coordinated in  
29 home care and support or residential aged care. Some service providers  
30 provide for day therapy services. At all times, older people are also able to  
31 access therapy and support services privately and when acute care is  
32 required, older people might access specialist geriatrics, rehabilitation and  
33 palliative care service through both the public hospital and private hospital  
34 systems although in some regions, these services might be limited.  
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37 Therefore, screening for frailty risk in general practice might allow the  
38 general practitioner to identify earlier those aged 75 years and older who  
39 might benefit from a comprehensive assessment via the 75+ Health  
40 Assessment, following which a management plan including further  
41 investigation and referral to various services might occur in a proactive  
42 rather than a reactive approach. The relative 'safety net' provided by the  
43 MBS-funded items has important implications for how we approach the  
44 issue of accuracy within this study. The most important consideration for  
45 Australian GPs is likely to be avoiding false negatives, so as to avoid missing  
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3 people who actually are frail. In contrast, the consequences of false  
4 positives are less significant given the options for subsequent follow-up. We  
5 are thus emphasising sensitivity over specificity in our study.  
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9 Aside from accuracy, feasibility and acceptability will also be critical factors  
10 in the selection of screening instruments. The feasibility and acceptability  
11 of frailty screening instruments within general practice has been  
12 significantly under-researched [16]. Consequently we have drawn on  
13 several feasibility studies addressing the introduction of non-frailty  
14 instruments in developing our approach [27], along with early results from  
15 focus groups on frailty conducted with Australian GPs. We will assess the  
16 feasibility and acceptability of the index tests from three perspectives: 1)  
17 Feasibility of implementation within the context of a busy general practice  
18 environment; 2) Acceptability to health service providers; 3) Acceptability  
19 to consumers.  
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26 Within health research, passive case-finding (using medical records, for  
27 example), has been promoted as potentially advantageous over active case-  
28 finding due to lower cost and burden on study participants [28]. It  
29 therefore could be viewed as a viable alternative to the active and rather  
30 intensive screening approach adopted in our study. However, passive case-  
31 finding is unviable within this context given that routinely collected medical  
32 records would be unlikely to capture the range of data required to detect  
33 frailty (with the possible exception of the construction of a frailty index)  
34 and are subject to high variability, a globally observed finding [28]. These  
35 factors suggest an insufficiently reliable basis for its inclusion within our  
36 study.  
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43 In the absence of an Australian policy directive on frailty screening,  
44 screening will likely be directed to the most appropriate perceived  
45 candidates rather than to all persons of a given age. Preliminary findings  
46 from an aligned study of Australian GP perspectives on frailty and frailty  
47 screening [29] indicate that in identifying potential candidates, it is  
48 probable that psychosocial factors may play a key role in GP considerations.  
49 For example, people who live alone, suffer depression or who have few  
50 social supports could potentially be at more risk from the impacts of frailty  
51 than those who have greater personal resources. The association of  
52 psychosocial factors with frailty is an emerging trend that has been  
53 reported within the research literature [30–35] although results to date  
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3 have been mixed [36]. Consequently, in order to better characterise those  
4 diagnosed as frail, we will also collect a range of psychosocial measures  
5 from our sample.  
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### 8 9 **Objectives**

10 Our study is designed to: assess the (1) feasibility (2) acceptability (to  
11 health service providers and consumers) and (3) diagnostic test accuracy of  
12 a number of frailty screening instruments within the context of Australian  
13 general practice. A fourth objective will be to explore the association of a  
14 range of psychosocial measures with frailty.  
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## 18 19 **METHODS AND ANALYSIS**

20 We will employ a prospective, cross-sectional and observational research  
21 design. We have reviewed our study design against the Standards for  
22 Reporting of Diagnostic Accuracy (STARD) and QUADAS-2 criteria. The  
23 study will be conducted between July 2017 and June 2018.  
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### 27 28 **Setting**

29 We will conduct the study within 2 general practice sites within South  
30 Australia, one metropolitan and one non-metropolitan. We will select  
31 practices based on purposive sampling.  
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34 Four practice nurses (registered nurses working in general practice) – 2 at  
35 each site - will be contracted to administer the index tests. Potential  
36 screeners will sign a consent form to enrol in the study. The screeners will  
37 attend training prior to commencement.  
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### 41 42 **Participants**

#### 43 44 **Eligibility**

##### 45 **Inclusion Criteria**

46 We will employ convenience sampling to recruit our sample. Patients will  
47 be eligible if they were aged 75+ years as at 30<sup>th</sup> June 2016 and booked to  
48 attend at the study sites for an upcoming appointment over a pre-specified  
49 period during 2017.  
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53 Patients with dementia will be included as participants if written, informed  
54 consent is given by a responsible person who is available to attend with  
55 them at the study sessions. Inclusion will be discussed on a case by case  
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3 basis with the patient's doctor. Doctors will co-sign all consent forms  
4 involving patients with impaired ability to consent.  
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### 7 Exclusion Criteria

8 We will exclude from the study those patients too ill to be assessed (i.e.  
9 undergoing palliative care treatment or currently hospitalised), resident  
10 within residential care facilities or whose English is insufficient to fully  
11 participate.  
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## 14 Substudy 1: Diagnostic Test Accuracy

### 15 Data Collection

16 Figure 1 outlines the overall data collection process for the diagnostic test  
17 accuracy aspect of the study.  
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19 <Figure 1 to go here>  
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### 23 Recruitment

24 We will mail eligible participants an invitation letter, consent form, and  
25 participant information sheet. We will ask potential participants to sign a  
26 consent form (or if unable to consent, a family member will be asked to sign  
27 on their behalf) to be returned to the research team via self-addressed  
28 envelope. Participants will be given the right to withdraw from  
29 participation should they wish to, as well as to opt out of completing  
30 individual instruments. We will collect demographic information (age, sex)  
31 from those electing not to participate in order to compare participants with  
32 non-participants.  
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35 Upon receipt of the consent form, we will telephone the participant to make  
36 an appointment to attend the screening session within two weeks to ensure  
37 information currency.  
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40 Recruitment will conclude upon successful achievement of the required  
41 sample size (n=120 from each practice).  
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### 44 Screening session

45 On arrival, we will ask participants to complete a questionnaire including  
46 standard demographic information along with a select number of  
47 psychosocial instruments. They will then complete two self-reported index  
48 tests, returning each test as completed so that time to complete can be  
49 recorded. The practice nurse will then administer 5 administered index  
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3 tests in random order. A blinded researcher (RA) will then administer the  
4 two reference standards. The total estimated duration of the appointment  
5 will be between 45 and 60 minutes.  
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### 8 9 **Follow-Up**

10 Where either of the reference standards indicates frailty, the participant  
11 will be offered a follow-up appointment with their GP. The research team  
12 will not collect data at this appointment.  
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### 14 15 **Test methods**

#### 16 17 **Index Tests: Overview**

18 Following a literature review, we shortlisted 14 frailty screening  
19 instruments as candidates for inclusion as index tests through discussion  
20 with the clinician members of the research team. We considered validity  
21 (sensitivity at least 0.6), appropriateness to context (in English,  
22 transferable to Australia) time to implement ( $\leq 20$  minutes) and delivery  
23 method (administered, i.e. not solely records-based) in our deliberations.  
24 We ultimately selected the following instruments for inclusion: FRAIL  
25 Screening Instrument; Groningen Frailty Index; PRISMA-7; Edmonton  
26 Frail Scale; Gait Speed; Reported Edmonton Frail Scale and Kihon  
27 Checklist.  
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#### 30 31 **Index Tests: Administered by Practice Nurse**

##### 32 33 ***FRAIL Screening Instrument***

34 The FRAIL Screening instrument is a 5-item instrument addressing five  
35 aspects of frailty: fatigue, resistance, ambulation, illness, and loss of weight  
36 [37]. Each component is allocated one point and all components are  
37 summed, resulting in a scale from 0 to 5. The original cut-points will be  
38 used in this study and were: frail (3-5), pre-frail (1-2), and robust (0) health  
39 status.  
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##### 42 43 ***Groningen Frailty Indicator***

44 The Groningen Frailty Indicator is a multi-domain frailty instrument found  
45 to be reliable and valid in a Dutch community-dwelling population [38,39].  
46 It has 15 items, resulting in a summed score from 0 to 15, with the frailty  
47 cut-point - also used in this study - set at 4 or more points.  
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##### 50 51 ***PRISMA-7***

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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  $\leq 0.8$  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 7 or more ‘yes’ questions.

## Reference Standards

We consulted prior research for potential reference standards, identifying three commonly used candidates [25,41]: Comprehensive Geriatric Assessment (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 inter-disciplinary 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], make 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 Fried et al's original formulation, as shown below [7:M156].

- *Shrinking* (unintentional weight loss of  $\geq 10$  pounds in the prior year or, at follow-up, of  $\geq 5\%$  of body weight in the prior year by direct measurement of weight), as assessed by the question: “*In the last year, have you lost more than 10 pounds unintentionally (i.e., not due to dieting or exercise)?*”

*Weakness*: We will measure grip strength with a hand-held Jamar dynamometer, assessing maximal grip strength (kilograms) in the dominant hand (average of 3 measures). Fried's cut-points are shown in Table 1 and will be used in this study:

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

<b>Men</b>		<b>Women</b>	
<i>BMI</i>	<i>Cut-off (kg)</i>	<i>BMI</i>	<i>Cut-off (kg)</i>
$\leq 24$	$\leq 29$	$\leq 23$	$\leq 17$
24.1–26	$\leq 30$	23.1–26	$\leq 17.3$
26.1–28	$\leq 30$	26.1–29	$\leq 18$
$> 28$	$\leq 32$	$> 29$	$\leq 21$

- *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:  $\geq 7$  seconds (men of

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3 height  $\leq$  173 cm and women  $\leq$  159 cm), and  $\geq$  6 seconds (men of  
4 height  $>$  173 cm and women  $>$  159 cm).  
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- 8 • *Low physical activity level:* Measured by the short-form Minnesota  
9 Leisure Time Activity questionnaire [56]. The questionnaire is used to  
10 derive a weighted score of kilocalories expended/week, with the  
11 following cut-points: men  $<$  383 and women  $<$  270 kcals/week.  
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14 The frailty cut points specified in the original model and used within this  
15 study were that 3 or more components meeting the criteria indicate frailty.  
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### 20 *Adelaide Frailty Index*

21 The second reference standard is the Adelaide Frailty Index (AFI), a 42-  
22 item variant of a standard frailty index based on the methodology reported  
23 in Searle et al [57]. It was developed by Mr. Mark Thompson as part of  
24 ongoing work within the regional geriatric health service (Thompson et al,  
25 unpublished)[58]. The frailty cut point for the AFI, also applied within this  
26 study, is a score of 9 or more (i.e. 21% or more).  
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31 The AFI includes elements drawn from the following frailty risk factors:  
32 Shrinking, Exhaustion, Low Energy Expenditure, Slowness, Weakness,  
33 Cognitive Impairment, Falls and Balance, Urinary Incontinence,  
34 Polypharmacy, Oral Health, Pain, Mental Health and Chronic Conditions.  
35 Several questions within the AFI were derived from validated screening  
36 instruments in common use within those domains. The AFI intentionally  
37 excludes disability items, in recognition of the distinction between  
38 disability and frailty [59].  
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### 44 *Psychosocial Instruments*

45 In recognition of the complex relationship between psychosocial factors  
46 and frailty, we will administer five psychosocial instruments within the self-  
47 complete questionnaire. Depression is associated with frailty among older  
48 people [34] and is measured here via the commonly used GDS-15 (short  
49 form of the Geriatric Depression Scale) [60]. Social isolation will be  
50 measured by an abbreviated version of the Lubben Social Network Scale  
51 (the LSNS-6), which has been widely used worldwide to measure isolation  
52 among older people [61,62]. A measure relating to sense of perceived  
53 control, as originally conceptualised and validated by Lachman and Weaver  
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[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 (BAP-Q) [65]. Lastly, a specific measure of older people's quality of life will be measured using the 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 de-identified study data on a password-protected drive.

### Statistical Methods

#### Sample Size

We derived a sample size estimate using a methodology reported in 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+ respectively (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

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3 screening appointment while also allowing for the possibility of a lower  
4 than estimated prevalence of frailty in the population.  
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### 7 Analysis

8 We will examine the distribution of quantitative variables visually and by  
9 using the Shapiro-Wilk test for normality [70]. Categorical variables will be  
10 described as frequencies. Quantitative variables will be displayed as  
11 mean±SD where normally distributed or as medians with 25th and 75th  
12 percentiles where asymmetrically distributed. Where the results for an  
13 index test or reference standard are indeterminate or incomplete, results  
14 for that participant will be excluded. No imputation will be performed for  
15 missing data.  
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21 Our accuracy analysis will compare the results of each index test against  
22 each reference standard. We will construct variables reflecting each frailty  
23 instrument and define the presence of frailty according to the specified cut-  
24 points. We will create standard 2 x 2 tables for each index test against each  
25 reference standard, and calculate sensitivity and specificity with their  
26 corresponding 95% confidence intervals (95% CI), along with positive and  
27 negative predictive values and likelihood ratios. We will determine the  
28 extent of agreement between the index tests and reference standards by  
29 calculating Cohen's kappa.  
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35 To analyse the relationship between the psychosocial variables and frailty,  
36 we will define the presence of frailty as a binary variable (frail/not frail)  
37 according to the Fried criteria as measured in the Frailty Phenotype. We  
38 will use binomial (binary) logistic regression to analyse the association  
39 strength (odds ratio) for the frail state with the psychosocial variables using  
40 the non-frail state as the comparison category. We will consider a value of  $p$   
41  $< 0.05$  to be statistically significant. The data will be analysed using the  
42 latest available version of the SPSS statistical software (SPSS Inc., Chicago,  
43 Illinois, USA).  
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49 To test inter-rater reliability, 8 subjects tested by each screener (32 in all)  
50 will be asked to repeat the index test session including self-reported tests  
51 with a second blinded screener within 48 hours after the initial rating.  
52 Given the binary nature of the outcome (i.e. frail/not frail) and multiple  
53 raters, the kappa coefficient will be used to ascertain agreement, with the  
54 minimum acceptable value set to 0.6. We will ask every third participant  
55 participating at each research site in the main study to participate in the  
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3 inter-rater reliability component, proceeding until such time as the site and  
4 screener quota is reached.  
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## 7 8 **Substudy 2: Feasibility and Acceptability**

9 We will apply a convergent parallel mixed methods approach to the analysis  
10 of feasibility and acceptability. We define mixed methods research,  
11 following Johnson et al, as a type of research combining “elements of  
12 qualitative and quantitative research approaches ... for the broad purposes  
13 of breadth and depth of understanding and corroboration.” [71:123] Mixed  
14 methods have increasingly been applied within the health sciences in recent  
15 years where a more complete understanding of an issue than is allowed by  
16 quantitative or qualitative approach alone is sought [72].  
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### 22 **Data Collection and Management**

#### 23 1) Feasibility

24 We will measure the feasibility of the index tests by collecting the following  
25 information about each test:  
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#### 28 *Noted by research team prior to data collection:*

- 29 • Education or training required to administer each test
- 30 • Special equipment/devices required
- 31 • Physical space required

#### 32 *Collected by practice nurse during session:*

- 33 • Time to administer each instrument
- 34 • Instrument completion by respondents (Include any reasons for non-  
35 completion)

#### 36 2) Acceptability to health service providers

37 We will ask the screeners to complete a standardised form to capture initial  
38 impressions of the instruments during the data collection period. We will  
39 also request that screeners participate in an interview conducted within a  
40 week after data collection has concluded to gather their overall impressions  
41 of the instruments. We will rate each instrument against a 1-10 Likert scale  
42 measuring ease of implementation as well as including a number of open-  
43 ended questions. We will ask screeners to rank the instruments in order of  
44 preference.  
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### 3) 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 (2008) 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-scaled 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 de-identification procedures as specified under Diagnostic Accuracy.

#### Data Analysis

##### 1) 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.

##### 2) 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 (i.e., 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.

### 3) Acceptability to consumers

We will present consumer ratings for each instrument (Likert scaled) 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 co-signed by the general practitioner.

##### **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.

## Authors' contributions

The research question, concept and design were formulated by RA, JB, RV, SY, TS, JK, MC, MA and AK. Preparation of the manuscript was completed by RA. RA, JB, RV, TS, SY, JK, MC, MA, and AK reviewed and edited the manuscript. All authors have read and approved the final version of the manuscript.

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## Competing interests

The authors declare that they have no competing interests. The views expressed in this article are those of the authors and do not necessarily represent the official viewpoint of their organisations.

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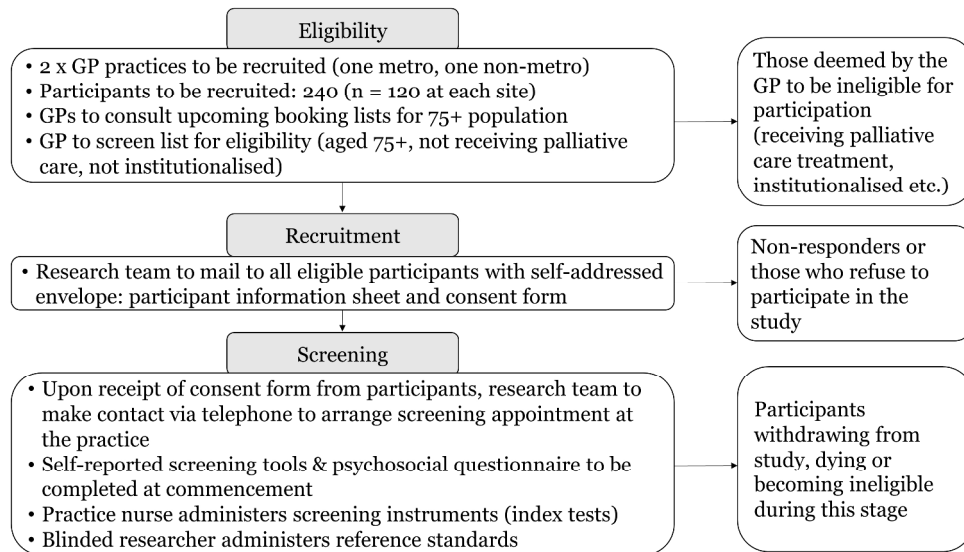


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Figure 1 Study Flow Diagram (Diagnostic Test Accuracy component)



Study Flow Diagram (Diagnostic Test Accuracy component)

338x190mm (300 x 300 DPI)

review only