2023-03-31

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Received: 6 April 2022 | Revised: 2 February 2023 | Accepted: 8 March 2023

DOI: 10.1111/jan.15652

ORIGINAL RESEARCH: EMPIRICAL RESEARCH - QUANTITATIVE

JAN Leading Global Nursing Research WILEY

A nurse-led comprehensive geriatric assessment intervention in primary care: A feasibility cluster randomized controlled trial

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Funding information
National Institute for Health Research, Grant/Award Number: ICA-CDRF-2016-02-018

Abstract

Aim: To determine the feasibility of a nurse-led, primary care-based comprehensive geriatric assessment (CGA) intervention.

Design: A feasibility cluster randomized controlled trial.

Methods: The trial was conducted in six general practices in the United Kingdom from May 2018 to April 2020. Participants were moderately/severely frail people aged 65 years and older living at home. Clusters were randomly assigned to the intervention arm control arms. A CGA was delivered to the intervention participants, with control participants receiving usual care. Study outcomes related to feasibility of the intervention and of conducting the trial including recruitment and retention. A range of outcome measures of quality of life, function, loneliness, self-determination, mortality, hospital admission/readmission and number of prescribed medications were evaluated.

Results: All pre-specified feasibility criteria relating to recruitment and retention were met with 56 participants recruited in total (30 intervention and 26 control). Retention was high with 94.6% of participants completing 13-week follow-up and 87.5% ($n = 49$) completing 26-week follow-up. All outcome measures instruments met feasibility criteria relating to completeness and responsiveness over time. Quality of life was recommended as the primary outcome for a definitive trial with numbers of prescribed medications as a secondary outcome measure.

Conclusion: It is feasible to implement and conduct a randomized controlled trial of a nurse-led, primary care-based CGA intervention.

Impact: The study provided evidence on the feasibility of a CGA intervention for older people delivered in primary care. It provides information to maximize the success of a definitive trial of the clinical effectiveness of the intervention.

Patient or Public Contribution: Patient and public representatives were involved in the study design including intervention development and production of participant-facing documentation. Representatives served on the trial management and steering committees and, as part of this role, interpreted feasibility data. ISRCTN Number: 74345449.

KEYWORDS
cluster trial, comprehensive geriatric assessment, feasibility, frailty, nurse-led, older people, primary care

1 | INTRODUCTION

The world's population is ageing and, whilst this is undoubtedly a success for improved public health and welfare leading to longer life expectancy, it brings with it the challenge of meeting the health and social care needs of higher numbers of older people. Remaining life expectancy at age 65 is currently 18 years for men and 21 years for women. However, on average, we can expect to experience about 10 years of diminished quality of life at the end of life, due predominantly to limiting disability and illness (Mortimer & Green, 2015). Much of this disability and loss of function can be attributed to the development of frailty. Frailty is a clinical syndrome associated with older age, which features deterioration across multiple body systems and is accompanied by increased vulnerability to adverse health outcomes (Clegg et al., 2013). Becoming frail can be a devastating consequence of ageing. Older people who live with frailty experience higher death rates, falls, care home admissions and are lonelier than those who are not frail (Kojima et al., 2016).

1.1 | Background

Most frailty research has been conducted in higher-income countries and a variety of definitions of frailty used (Hoogendijk et al., 2019), therefore, accurate estimates of global frailty prevalence are not available. One systematic review combined findings from 61,500 participants aged 65 years and over and found a weighted average estimate of 11% frailty prevalence but noted a variation of between 4% and 59% across studies (Collard et al., 2012). With so many people affected as they age, poor outcomes associated with frailty are costly to older individuals and health and social care services. The World Health Organization have promoted the concept of "ageing in place" where older people are supported to live independently and comfortably at home regardless of the severity of frailty (World Health Organization, 2015). This ethos has been internationally adopted, with health systems working towards home-based frailty care with access to comprehensive geriatric assessment (CGA) available not just in hospital, but in primary care (Imison et al., 2017). It remains unclear, however, how this move from specialist care to generalist services delivered in low-intensity settings can be achieved (Hoogendijk et al., 2019).

A holistic, individualized approach is the founding principle of a CGA, which is often described as the gold standard intervention for the management and prevention of deterioration in frailty (Gladman, 2016). The most widely accepted definition of CGA is:

> 'a multidimensional, multidisciplinary process which identifies medical, social and functional needs, and the development of an integrated/co-ordinated care plan to meet those needs'.
>
> (Parker et al., 2018).

Within specialist hospital settings, CGA is the gold standard care with a strong evidence base (Ellis et al., 2011). With its ease of accessibility, established relationships between general practitioners and their patients and access to a multidisciplinary team, primary care has been promoted as an ideal setting for the management of frailty (Drubbel et al., 2013). However, the efficacy of primary care delivered CGA is not well established and there is minimal evidence to support a positive association between this care model and improved clinical outcomes (Imison et al., 2017). Furthermore, there is little evidence to indicate that the acute hospital CGA framework is immediately transferable to primary care, or that primary care clinicians possess the specialist skills and knowledge to deliver this care. Thus, implementation of CGA in primary care remains problematic, with reports that this may be seen as burdensome for general practitioners within an already challenging workload (Reeves et al., 2018) leading to the suggestion that other practitioners such as nurses could implement CGA.

Whilst the principles of CGA may be appropriate for primary care delivery, the practicalities of its implementation, including whether the process can be led by nurses, rather than general practitioners, require further exploration. Studies have demonstrated that appropriately skilled nurses can substitute for doctors in primary care but not specifically in the field of frailty management (Horrocks et al., 2002; van der Biezen et al., 2016). The literature to date has demonstrated the challenges of evaluating primary care interventions for frail older people with ill-defined mechanisms of effect, multiple and confused outcome measures and interventions that are often poorly reported and, therefore, not replicable (Gardner et al., 2017). An overview of studies of nine proactive primary-care programs in The Netherlands called for further research into the target population, outcomes, intervention content and training/skills of the nurses delivering the intervention (Smit et al., 2018). There is little consensus from these studies as to the specific outcomes that can be impacted by CGA, however, in 2018 a standard set of outcome measures for older persons was published (Akpan et al., 2018), which established a minimum set of outcomes for evaluating healthcare for older people. These include functioning, loneliness and quality of life as key characteristics of frailty development.

In 2005, advanced practitioner nurses with advanced diagnostic and prescribing skills known as Community Matrons (CMs) were introduced in England to provide case management for very high-intensity service users (Chapman et al., 2009). The CMs have not specifically focussed on the needs of older people who live with frailty, but it would appear that their specific skill set would be appropriate to manage their care. This study used CMs to deliver the intervention who

were employed by the National Health Service Community Health Organization and based on general practices. They worked alongside community nursing teams but did not share a caseload with them.

A further methodological challenge, identified in several studies, is how best to identify and diagnose frailty (Pialoux et al., 2012). A systematic review by Clegg, Rogers, et al. (2015) evaluated screening tools that had been validated in clinical trials for their application in primary care. They concluded that no one test is superior to diagnose frailty in primary care. Given concerns about primary care capacity and workload (Shaw et al., 2018), there has been a move in recent years to provide easy and rapid approaches to frailty identification (Ruiz et al., 2020). This has led to the development of automated tools that can be populated by information from the clinical record and provide lists of frail people within a general practice population. One such tool is the electronic frailty index (eFI; Clegg et al., 2016). The eFI is a computerized algorithm developed using data from 900,000 older people's UK primary care records. It is based on the principles of the cumulative deficit model of frailty (Rockwood et al., 2005) and calculates a frailty score based on the occurrence of up to 36 deficits, taking information from the primary care clinical record (Alharbi et al., 2020). Frailty scores are then categorized into four levels of frailty severity: fit, mildly frail, moderately frail and severely frail. The eFI is fully automated and, therefore, is time-efficient and does not require any clinical knowledge to produce a full list of frail patients within a general practice population. It has robust predictive validity for mortality, hospitalization and care home admission (Clegg et al., 2016).

This feasibility randomized controlled trial addressed the limitations of previous research by using an automated, systematic method of frailty diagnosis and participant identification using the eFI and used specifically trained, advanced-level nurses to deliver the intervention. It enabled the evaluation of outcome measures and testing of feasibility parameters to maximize recruitment and retention to a future definitive trial.

2 | THE STUDY

2.1 | Aim

The aim of this study was to determine the feasibility of delivering a CGA-based intervention, led by nurses in primary care, to older people who live with frailty. The trial objectives concerning the feasibility of delivering the trial in primary care and to determine outcome measures for a definitive trial were:

- To assess compliance with the holistic assessment and care planning intervention (HAPPI).
- To verify that proposed outcome measurement and follow-up schedules are feasible to collect.
- To determine achievable targets for recruitment and follow-up rates.
- To evaluate methods of recruitment using the eFI.
- To evaluate characteristics and feasibility of the proposed outcome measures and to determine suitable outcome measures for the definitive trial.
- To assess the availability of clinical data and the time needed to analyse data required for numeric outcome measures.
- To explore factors that will enable future economic evaluation alongside the main trial (availability of data to complete the EQ-5D-5L).

2.2 | Design

A cluster feasibility randomized control trial (fRCT) with general practices as the unit of randomization was conducted from May 2018 to April 2020 in the UK. General practices were recruited and set up as clusters from May to October 2018 and participant recruitment opened in November 2018. The trial (ClinicalTrials.gov identifier: ISRCTN 74345449) was the second phase of a mixed-methods study of a nurse-led holistic assessment and care planning in partnership intervention (HAPPI study). The content of the intervention was determined using a Delphi survey in phase one (Lyndon et al., 2021). The study protocol was published (Lyndon et al., 2019) and approved by the UK's National Health Service Research Ethics Committee (NHS REC reference number: 18/LO/1354; IRAS project ID: 229210). Six general practices were recruited as study clusters following eligibility assessment, with three randomly assigned to the intervention and three to the control arm. Computer-generated randomization was conducted by the Clinical Trials Unit. Study reporting has been informed by the CONSORT Statement (Schulz et al., 2010) and a completed CONSORT checklist is available in Supplementary Information 1.

2.3 | Participants

All moderately and severely frail patients aged 65 years and over within the general practice's population were identified using the eFI. Each patient was assigned a trial number and a list of trial numbers was sent to the Clinical Trials Unit for sampling. A stratified random sampling method was used with two strata: moderately frail (n = 3183) and severely frail (n = 565), with 45 selected from the moderately frail cohort and 45 from the severely frail cohort. The 90 trial numbers were sent back to the general practice who could then identify them. This provided the randomly sampled 90 potential participants without patient identifiable information leaving the general practice without consent. The following additional study eligibility criteria were then applied:

- Frailty confirmed by PRISMA7 instrument (Raiche et al., 2008).
- Able to give informed consent.
- Living in own home/supported living accommodation.

Patients in receipt of palliative care with limited life expectancy, those who lack the mental capacity to give informed consent or if they are already on the caseload of a CM were excluded from the study. Eligible people were invited to participate and with, their consent, names of interested patients were passed to the research team to make contact.

As a feasibility study, a formal sample size calculation based on considerations of power was not performed (Thabane et al., 2010). Recruitment numbers were based on the planned recruitment of six general practices (clusters), with a total population of 491,000. It was anticipated that following initial screening using eFI, approximately 9000 (1500 per cluster) potential participants would be identified and from these 540 (90 per cluster) sampled for second screening (PRISMA7) and eligibility. Following the second screening, it was estimated that around 20% of eligible participants would consent to participate. The follow-up rate of consented participants was estimated at 70%, which would provide follow-up outcome data on a minimum of 76 participants across the six sites. A recruitment target was set at 60 participants which was felt to be achievable within the resource and time constraints of the study.

2.4 | Intervention and control

The intervention consisted of a programme of visits conducted in the participant's home by CMs possessing advanced assessment and non-medical prescribing skills. The intervention was entirely person-centred, not standardized and prescribed so that each participant's intervention was personalized and novel. It consisted of a holistic assessment based on a conversation between the participant and the nurse. A standardized suite of evidence-based assessment tools (available at: https://www.plymouth.ac.uk/research/the-holistic-assessment-and-care-planning-in-partnership-intervention-study-happi) was used as appropriate for the individual, their healthcare needs, long term conditions and personal preferences. A personalized plan of care and support was developed in partnership with the participant and referrals made to other services as required. The maximum dose of the intervention was one assessment and six care planning visits conducted over a 12-week period. Participants in the control group received standard primary care for frailty. Approaches to care of older people with frailty is variable primary care (British Geriatrics Society et al., 2014) and may include the management of long-term conditions, referrals to other services, prescribing of medications and routine vaccinations delivered by a general practitioner or other primary care clinician.

2.5 | Data collection

Case report forms were completed consisting of three sections relating to intervention delivery, participant outcome measures and data from the clinical record. Participant outcomes included physical and emotional health and mobility (SF-36; Brazier et al., 1996), health-related quality of life (EQ-5D-5L; EuroQuol, 2019), loneliness (UCLA-3) (Velarde-Mayol et al., 2016), function (Barthel Index) (Mahoney & Barthel, 1965) confidence in own ability to manage health (LTC-6; Health Foundation, 2013), numbers of prescribed medication and numbers of hospital admissions/readmissions, days spent in hospital and deaths In addition, a screening log was completed by the general practices, detailing numbers of participants screened, those eligible, responses to recruitment letters and numbers who progressed to consent or declined to participate. Data were entered into a customized database by the general practices and the research team.

2.6 | Outcome measures

Study outcomes related to feasibility of the intervention, feasibility of conducting the trial and the assessment of outcomes measures for a future trial are presented in Figure 1. An additional participant-reported

Feasibility of Conducting the Trial

1. Number of clusters/sites expressing an interest in participating
2. Number of clusters/sites screened for selection and reason for non-selection
3. Number of clusters/sites withdrawing from the study and reason for withdrawal
4. Numbers of participants screened as eligible, recruited, consented and followed up
5. Numbers of participants identified using the electronic frailty index (eFI)
6. Number of and timing of participant withdrawals
7. Number of completed interventions
8. Number of referrals made

Evaluation of Outcome Measures

1. Number of outcome measures completed at baseline and follow-up intervals
2. Number of missing items at each time-point
3. Assessment of the following outcome measure instruments:
   - Health-related quality of life (EQ-5D-5L)
   - Levels of loneliness (UCLA 3-Item Loneliness Scale)
   - Physical health and mobility, level of pain, mood and emotional health and health-related quality (SF-36)
   - Functional independence (Barthel Index)
   - Confidence in own ability to manage health (Health Foundation LTC6)
   - Mortality (date and cause of death)
   - Number of hospital admissions
   - Total number of days spent in hospital
   - Number of medications prescribed

FIGURE 1 Trial outcome measures.

outcome measure (Barthel Index) was included in the study protocol but omitted in error from the protocol publication (Lyndon et al., 2019). The results of this outcome measure are reported in this paper. Initially, the numbers of falls were included as an outcome measure, but this was later withdrawn in a protocol amendment as it was impossible to record and measure accurately using self-reporting or from the clinical record. A priori feasibility criteria relating to the recruitment and retention of clusters and participants were agreed upon by the Trial Steering Committee to assess whether it was feasible to progress to a definitive trial. Participant and general practice reported outcome measures were collected at baseline, 13 and 26 weeks post-intervention. Participant-reported outcome measures were collected by a blinded assessor at the participant's home. The Chief Investigator could not be blinded to allocation as she provided training to the nurses delivering the intervention, similarly, the nurses could not be blinded. General practices were blind to allocation until participant identification and recruitment processes were complete. General practice-reported outcome measures were entered onto a bespoke trial database by the practice team.

2.7 | Ethical considerations

The study protocol was approved on 16th October 2018 by the National Health Service Research Ethics Committee (REC reference: 18/LO/1354; IRAS project ID: 229210). Protection of participants and researchers from harm was paramount. The study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice, and the UK Policy Framework for Health and Social Care Research.

2.8 | Data analysis

Statistical analyses were undertaken using Statistical Package for the Social Sciences (SPSS) version 24. As a feasibility study, it was inappropriate to test treatment effects, therefore, the statistical analyses were descriptive in design and detailed in the a priori statistical analysis plan. The mean difference was reported in order to adhere to changing policies of the funder (National Institute of Health and Care Research) who require feasibility studies to demonstrate the potential promise of the proposed intervention and provide at least a confidence interval of the feasibility data. All analyses and data summaries were conducted on the intention-to-treat population (Figure 2).

2.9 | Validity, reliability and rigour

Feasibility of outcome measures including the Instruments properties (SF-36, EQ-5D-5L, UCLA-3, Barthel Index and LTC-6) were valid and reliable.

3 | RESULTS

3.1 | Recruitment and retention

General practices were deemed suitable to participate if they had the eFI embedded into clinical record systems and had a CM attached to the general practice who was willing to deliver the HAPPI intervention. Out of 14 general practices approached to participate, eight expressed an interest in participation and six progressed as clusters. Eight general practices did not meet eligibility, four had no CM in post to deliver the intervention and four did not have the eFI within their electronic clinical notes systems. No clusters withdrew from the study prior to completion. All clusters completed screening and eligibility processes in line with the trial protocol (BLINDED FOR PEER REVIEW). Target recruitment was 60 participants in 10 months with 56 participants recruited. Delays in receiving approvals slowed initial recruitment but higher than anticipated recruitment rates were noted across all clusters, with an average of 9.3 participants per month achieved. The demographic and clinical characteristics of participants are reported in Table 1.

Retention across all clusters was high with 94.6% ($n = 53$) participants completing 13-week follow-up and 87.5% ($n = 49$) completing 26-week follow-up. Retention was similar in both groups with 96.7% of intervention participants completing 13-week follow-up and 86.7% completing 26-week follow-up compared to 92.3% and 88.5% respectively in the control group. Failure to complete three and 6-month follow-up was, in all seven cases, due to withdrawal from the trial. All withdrawals were initiated by the individual participants themselves.

3.2 | Adherence to and refinement of the intervention

Adherence to the intervention was good with 84.6% of intervention participants receiving at least the minimum intervention dose. All the 32 assessment tools included in the intervention pack were used during the intervention but not with all participants. The most frequently used assessment tool was the medication review summary, followed by the conversation guide, the clinical frailty scale, and the personalized care plan templates. All participants who did not withdraw completed the intervention with a personalized care and support plan in place. Referrals to other services did occur but were lower than anticipated. Most referrals ($n = 31$) were to general practitioners, with fewer referrals to physiotherapy ($n = 7$), voluntary services ($n = 7$), dementia services ($n = 6$) and district nurses ($n = 4$).

3.3 | Assessment of outcome measures

To assess feasibility, outcome measures were compared for completeness, ease of administration and acceptability. At baseline, 30 study participants (100%) completed the outcome measure

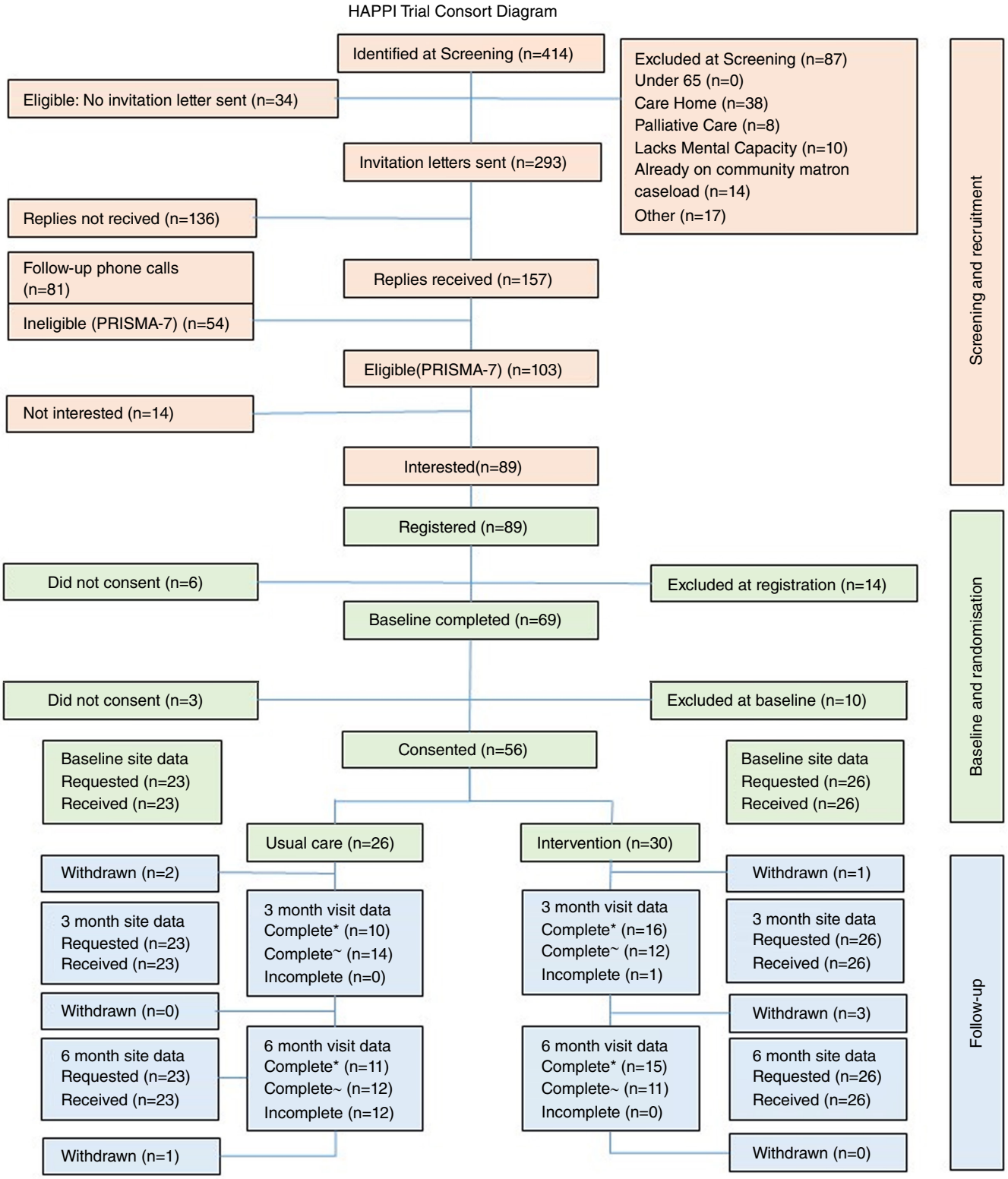

FIGURE 2 Consort flow diagram.

questionnaires in the intervention group and 26 (100%) completed in the control group. At 13 weeks, one participant had withdrawn from the intervention group and 16 (53.3%) participants completed the questionnaires within the protocol window, at 26 weeks there were three further withdrawals, and 15 (50.0%) study participants completed the questionnaires within the protocol window. In the control

TABLE 1 Demographic and clinical characteristics of participants.

	Intervention	Control	All
Mean age in years (*SD*) [range]	80.0 (7.3) [67–95]	85.1 (6.8) [67–100]	82.4 (7.4) [67–100]
Gender, *n* (%)			
Male	15 (50.0)	10 (31.5)	25 (44.6)
Female	15 (50.0)	16 (68.5)	31 (55.4)
Relationship status, *n* (%)			
Single	1 (3.3)	2 (7.7)	3 (5.4)
Married/civil partnership	19 (63.3)	15 (57.7)	34 (60.6)
Divorced/civil partnership dissolved	2 (6.7)	1 (3.8)	3 (5.4)
Widowed/surviving civil partner	8 (26.7)	8 (30.8)	16 (28.6)
Living arrangements, *n* (%)			
Alone	10 (33.3)	11 (42.4)	21 (37.5)
Spouse/Partner	19 (63.4)	14 (53.8)	33 (59.0)
Parent/s	0 (0.0)	0 (0.0)	0 (0.0)
With children under 18	0 (0.0)	0 (0.0)	0 (0.0)
With children over 18	0 (0.0)	1 (3.8)	1 (1.75)
Other family	1 (3.3)	0 (0.0)	1 (1.75)
Non-family	0 (0.0)	0 (0.0)	0 (0.00)
Frailty severity, *n* (%)			
Moderately frail	18 (60.0)	18 (69.3)	36 (64.2)
Severely frail	12 (40.0)	7 (26.9)	19 (34.0)
Missing	0 (0.0)	1 (3.8)	1 (1.78)

Abbreviation: SD, standard deviation.

group, there were two withdrawals at 13 weeks and 10 (38.5%) participants completed within the protocol window, at 26 weeks there had been no further withdrawals and 11 (42.4%) participants completed within the protocol window.

Completeness of the data is an important feasibility parameter for all outcome measures as it can be used to inform the likely pattern of missing data in a full-scale trial. If a considerable amount of outcome data was missing, this may suggest a need to reconsider the choice of outcome measures and will provide an insight into how missing data can be avoided in the subsequent full trial. Numbers of missing data were low in this study which indicated that outcome measures instruments were acceptable to participants and easy to administer. The proportion of participants data missing at each outcome is summarized for each allocated group and at each time point (Table 2).

The mean and standard deviation for each measure at each time point were reported to demonstrate that the appropriate data could be collected and analysed (Table 3). Outcome measures were assessed for responsiveness over time, but this finding should be interpreted with caution because this fRCT was not powered for this purpose. The mean difference is reported to demonstrate that it is feasible to collect the data required to calculate this in a definitive trial. Mean scores and mean differences are reported with 95% confidence intervals for all outcome measures for the intervention and control groups at 26 weeks (Table 4). Progression to full trial was assessed against the a priori feasibility recruitment and retention criteria and results indicated all criteria were achieved (Table 5).

3.4 | Assessment of sample size for a definitive trial

Standard deviation for all outcome measures was reported to inform the sample size for a definitive trial (Table 3). In addition, in order to assess the effect of cluster randomization, the intracluster correlation coefficient (ICC) was cautiously estimated to be 0.05 and it was agreed that the future definitive trial would aim to test the intervention with 5% significance and 90% power. Assuming an ICC of 0.05 and cluster size of 10 in a future trial (as in this trial), this yields a design effect 1.45. The numbers required to detect a given effect size for a definitive trial are summarized in Table 6. Based on recruitment data from this fRCT it would seem feasible for a future trial to recruit 200–300 participants in this population and a modest effect size of 0.2 could be detected at 5% significance with 90% power from centres with an ICC of 0.05.

3.5 | Adverse effects

Safety was assessed by comparing the number and nature of serious adverse events and adverse events in both the intervention

TABLE 2 Missing outcome measures by group.

Outcome measure	Intervention group (*n*=) (%)			Control group (*n*=) (%)		
Time point	Baseline	13 (±1) weeks	26 (±1) weeks	Baseline	13 (±1) weeks	26 (±1) weeks
SF-36						
Physical functioning	0 (0.0)	3 (10.0)	4 (13.3)	1 (3.8)	2 (7.7)	3 (11.5)
Role-physical	0 (0.0)	4 (13.3)	4 (13.3)	0 (0.0)	2 (7.7)	2 (7.7)
Bodily pain	0 (0.0)	3 (10.0)	4 (13.3)	0 (0.0)	2 (7.7)	3 (11.5)
General health	0 (0.0)	4 (13.3)	5 (16.7)	0 (0.0)	3 (11.5)	4 (15.4)
Vitality	1 (3.3)	3 (10.0)	5 (16.7)	0 (0.0)	2 (7.7)	3 (11.5)
Social functioning	0 (0.0)	3 (10.0)	4 (13.3)	0 (0.0)	2 (7.7)	3 (11.5)
Role-emotional	0 (0.0)	3 (10.0)	4 (13.3)	0 (0.0)	2 (7.7)	3 (11.5)
Mental health	0 (0.0)	3 (10.0)	6 (20.0)	1 (3.8)	2 (7.7)	3 (11.5)
Reported health transition	0 (0.0)	3 (10.0)	4 (13.3)	0 (0.0)	2 (7.7)	3 (11.5)
LTC-6	0 (0.0)	3 (10.0)	6 (20.0)	0 (0.0)	2 (7.7)	3 (11.5)
UCLA-3	0 (0.0)	4 (13.3)	4 (13.3)	0 (0.0)	3 (11.5)	3 (11.5)
Barthel Index	1 (3.3)	4 (13.3)	5 (16.7)	0.0 (0.0)	2 (7.7)	4 (15.4)
EQ-5D-5L						
Mobility	0.0 (0.0)	4 (13.3)	4 (13.3)	0.0 (0.0)	2 (7.7)	3 (11.5)
Self-care	0.0 (0.0)	4 (13.3)	4 (13.3)	0.0 (0.0)	2 (7.7)	3 (11.5)
Usual activities	0.0 (0.0)	4 (13.3)	4 (13.3)	0.0 (0.0)	2 (7.7)	3 (11.5)
Pain/discomfort	0.0 (0.0)	4 (13.3)	4 (13.3)	0.0 (0.0)	2 (7.7)	3 (11.5)
Anxiety/depression	0.0 (0.0)	4 (13.3)	4 (13.3)	0.0 (0.0)	2 (7.7)	3 (11.5)
EQ-5D-5L VAS	0.0 (0.0)	4 (13.3)	4 (13.3)	0.0 (0.0)	3 (11.5)	3 (11.5)
Number of hospital admissions	0.0 (0.0)	3 (10.0)	4 (13.3)	1 (3.8)	3 (11.5)	3 (11.5)
Number of hospital readmissions	0.0 (0.0)	3 (10.0)	4 (13.3)	1 (3.8)	3 (11.5)	3 (11.5)
Total number of days spent in hospital	0.0 (0.0)	3 (10.0)	4 (13.3)	1 (3.8)	3 (11.5)	3 (11.5)
Number of prescribed medications	0.0 (0.0)	3 (10.0)	4 (13.3)	1 (3.8)	3 (11.5)	3 (11.5)

and control group; none were reported for the duration of the trial.

4 | DISCUSSION

This trial achieved the pre-determined feasibility criteria and demonstrated that it is feasible for a nurse-led, CGA-based intervention to be implemented in primary care and that it is possible to conduct a randomized controlled trial. However, it has also provided important learning to improve the design of a future definitive trial. Previous research has found that recruiting and retaining general practices in clinical trials is challenging (Wilson et al., 2000; Yallop et al., 2006), therefore, this was an important feasibility parameter providing data on how to maximize engagement and overcome barriers. In the UK, contracts for general practices were amended in 2017 to include the mandatory identification of severely frail patients (NHS England, 2017). Consequently, most general practices approached and invited to join the study, were keen to participate because of their interest in frailty and its management. Strategies to improve retention of general practices in clinical trials include effective communication, easy data-collection methods and payment upon meeting pre-agreed targets (Dormandy et al., 2008), these were useful in this trial.

Participant recruitment and retention targets in this fRCT were achieved, however, there were challenges in various aspects of the recruitment process, and their resolution provided important learning for the definitive trial. The rate of recruitment was significantly influenced by having capacity at the sites to complete the initial identification, invitation and screening procedures. In one cluster, support was provided by the research team who applied eligibility criteria and compiled a list of people to be invited to participate. This accelerated the process and demonstrated that, with targeted support, initial procedures could be completed within the specified time frame. There is evidence of under-recruitment of older people to research studies, particularly RCTs (Clegg, Rogers, et al., 2015). Studies

TABLE 3 Participant and site-reported outcome measures.

Outcomes	Intervention group			Control group		
	Mean (*SD*)			Mean (*SD*)		
Time point	Baseline	13 (±1) weeks	26 (±1) weeks	Baseline	13 (±1) weeks	26 (±1) weeks
SF-36: Physical functioning	30.5 (24.2)	29.2 (22.3)	27.1 (23.5)	31.4 (27.5)	29.8 (23.1)	27.8 (26.3)
SF-36: Role-physical	20.7 (13.2)	18.1 (11.8)	21.6 (13.3)	19.1 (14.8)	18.3 (15.3)	20.6 (14.2)
SF-36: Bodily pain	9.4 (5.6)	8.5 (5.1)	10.1 (6.0)	12.0 (6.3)	12.8 (6.8)	11.5 (6.2)
SF-36: General Health	21.6 (10.5)	18.8 (11.5)	18.7 (11.2)	20.1 (9.6)	22.3 (10.1)	21.1 (9.6)
SF-36: Vitality	13.4 (7.0)	12.8 (8.6)	11.8 (9.0)	12.9 (6.7)	13.8 (9.6)	14.0 (8.3)
SF-36: Social functioning	12.3 (7.3)	13.6 (6.9)	10.3 (2.0)	12.7 (5.98)	13.4 (6.2)	8.6 (3.4)
SF-36: Role-emotional	21.7 (9.1)	22.9 (9.0)	26.4 (5.8)	20.2 (10.4)	20.4 (11.9)	25.1 (7.0)
SF-36: Mental health	34.8 (11.8)	35.3 (10.5)	43.2 (20.4)	36.7 (8.5)	39.5 (8.1)	39.3 (7.5)
SF-36: Reported health transition	36.6 (21.5)	35.2 (18.7)	38.6 (27.9)	33.6 (25.4)	42.7 (23.9)	38.9 (24.7)
LTC-6	9.5 (5.4)	11.5 (5.3)	11.4 (4.7)	12.5 (4.3)	11.7 (6.1)	13.6 (4.3)
UCLA-3	4.6 (2.0)	4.6 (2.1)	4.6 (2.1)	4.2 (1.7)	3.9(1.1)	3.9 (2.1)
Barthel Index	15.8 (2.8)	18.0 (2.5)	17.7 (2.7)	15.5 (2.9)	17.5 (4.2)	17.3 (3.8)
EQ-5D-5L Index Values	0.50 (0.29)	0.59 (0.24)	0.58 (0.31)	0.58 (0.28)	0.61 (0.26)	0.64 (0.22)
EQ-5D-5L VAS	61.5 (20.8)	59.9 (19.2)	60.1 (19.5)	60.9 (15.3)	64.7 (19.7)	63.0 (19.5)
Number of deaths	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)
Number of hospital admissions	0.10 (0.3)	0.11 (0.3)	0.15 (0.4)	0.16 (0.4)	0.22 (0.5)	0.39 (0.8)
Number of hospital readmissions	0.00 (0.0)	0.00 (0.0)	0.04 (0.2)	0.00 (0.0)	0.00 (0.0)	0.09 (0.2)
Total number of days spent in hospital	0.08 (0.3)	0.31 (1.2)	0.65 (1.7)	0.09 (0.3)	0.23 (0.5)	3.14 (7.5)
Number of prescribed medications	11.8 (6.0)	9.9 (3.62)	9.3 (3.50)	10.7 (3.1)	13.5 (8.2)	10.6 (3.5)

Abbreviation: SD, standard deviation.

have reported high participant exclusion and refusal rates, especially in trials recruiting older people with frailty (Azad et al., 2008). These issues did not appear to affect recruitment to the HAPPI trial since, despite some delays, recruitment was completed as anticipated within 10 months, however, the process was sporadic and did not follow the planned study timetable.

McMurdo et al. (2011) report dropout rates of between 5% and 37% in their review of studies that recruited older people. Certain strategies can improve retention in clinical trials, such as the provision of monetary incentives and the use of short-outcome measures and questionnaires (Brueton et al., 2014). This study did not have the finances, or ethical approval, to provide incentives and the outcome measures questionnaires were lengthy and numerous due to the need to test the feasibility of multiple outcome measures. Given the low drop-out rates in this study and high levels of completeness of participant-reported outcome measures, it would appear that the experience of participating was, generally, a positive one. This is borne out by the literature where studies have found that clinicians judge older people as vulnerable and needing protection from research (McMurdo et al., 2011), yet older people themselves display as much, or more willingness to participate as any other sector of the population (Peterson et al., 2002). The research team aimed to enhance the experience of participants. The research nurses were warm and friendly in their approach and all outcome measures were completed at one visit at each time point to reduce the burden. This personal approach, whilst more time-consuming than administering postal questionnaires, contributed to excellent retention rates and is recommended for adoption in the definitive trial.

This study aimed to determine the primary outcome and related outcome measures for a definitive trial. A plethora of outcome measures has been used to evaluate the care of older people (Drouin et al., 2015). Health, self-efficacy, loneliness, function and quality of life are all key features of the development of frailty and concepts often used by older people themselves to describe what frailty means to them (Britain Thinks, 2015). However, the outcomes that could be impacted by a nurse-led CGA-based intervention were unclear at the outset of our study, so a comprehensive evaluation was conducted. All outcome measures evaluated appeared able to detect change over the time. In those relating to quality of life and health status (SF-36 and EQ-5D-5L), ranges were wide and standard deviations were high, which may indicate heterogeneity of participants. Data for moderately and severely frail participants were analysed as

TABLE 4 Mean difference with 95% confidence intervals at week 26.

Outcome	Intervention *n*; mean (*SD*)	Control *n*; mean (*SD*)	Mean difference (95% CI)
SF-36: Physical functioning	26; 27.11 (23.54)	23; 27.83 (26.32)	−7.11 (−15.04, 13.62)
SF36: Role-physical	26; 21.63 (13.32)	23; 20.65 (14.25)	9.82 (−6.9, 8.9)
SF-36: Bodily pain	26; 10.10 (6.02)	23; 11.54 (6.27)	−1.47 (−4.98, 2.09)
SF-36: General Health	25; 18.72 (11.21)	22; 21.11 (9.63)	−2.39 (−8.58, 3.79)
SF-36: Vitality	25; 11.80 (9.02)	23; 14.02 (8.35)	−2.22 (−7.29, 2.84)
SF-36: Social functioning	26; 10.35 (2.14)	23; 8.56 (3.43)	1.78 (1.87, 3.37)
SF-36: Role-emotional	26; 26.44 (5.79)	23; 25.10 (7.05)	1.33 (−2.36, 5.02)
SF-36: Mental health	24; 43.23 (20.40)	23; 39.35 (7.47)	3.88 (−5.22, 1.30)
SF-36: Reported health transition	26; 38.65 (27.88)	23; 38.91 (24.68)	−0.259 (−15.5, 15.0)
LTC-6	24; 11.42 (4.66)	23; 13.65 (4.31)	−2.24 (−4.8, 0.41)
UCLA-3	26; 4.62 (2.16)	23; 3.87 (1.14)	0.75 (−0.24, 1.73)
Barthel Index	25; 17.72 (2.72)	22; 17.32 (3.83)	0.40 (−1.53, 2.34)
EQ-5D-5L Index Values	26; 0.58 (0.31)	22; 0.64 (0.22)	−0.07 (−0.22, 0.09)
EQ-5D-5L VAS	26; 60.15 (22.93)	23; 63.04 (19.52)	−2.89 (−15.22, 9.44)
Number of hospital admissions	26; 0.15 (0.37)	23; 0.39 (0.78)	−0.23 (−0.58, 0.11)
Number of hospital readmissions	26; 0.04 (0.196)	23; 0.09 (0.29)	−0.05 (−0.19, 0.09)
Total number of days spent in hospital	26; 0.65 (1.72)	23; 3.00 (7.37)	−2.35 (−5.59, 0.89)
Number of prescribed medications	26; 9.31 (3.51)	23; 10.61 (3.51)	−1.30 (−3.32, 0.72)

Abbreviations: CI, confidence interval; SD, standard deviation.

TABLE 5 Feasibility criteria results.

Feasibility success criteria	Green	Amber	Red	Trial results
% of general practice sites that were initially approached and progressed to participating in the study	≥50	41–49	≤40	75.0
% of recruitment target achieved (60 participants) in the timescale of 43 weeks (01/11/2018–31/08/2019)	≥50	41–49	≤40	93.3
% of participants completing 3-month follow-up	≥80	51–79	≤50	92.85
% of participants completing 5-month follow-up	≥70	51–59	≤50	87.5
% of consented participants randomized to the intervention group who do not withdraw or die within the intervention period engaging with the minimum "dose" of the intervention	≥75	51–74	≤50	85.5

Note: *Green* indicates the target was achieved. *Amber* indicates the target was not achieved but progression to full trial would be possible with minor protocol amendments. *Red* indicates the target was not achieved and progression to full trial is unlikely to be supported.

one group which may explain the heterogeneity of scores relating to quality of life and health status. It is recommended that in a definitive trial, the two data sets are analysed separately to assess the impact at the different frailty severity levels. Scores relating to physical function and general health domains decreased in both groups over time. This change may be expected in participants who live with moderate and severe frailty and concurs with evidence that function deteriorates as frailty increases in severity (Chen et al., 2007; Milte & Crotty, 2014). It may be that, in a definitive trial, a stabilization of scores could be seen as positive rather than an expectation of improvement.

In contrast to other studies, the UCLA-3, did not appear sensitive to change in measuring loneliness (Velarde-Mayol et al., 2016). It may be that this tool is less likely to detect change over a relatively short period of time as in this trial and a definitive trial would require longer follow-up. In addition, personal contact provided as part of the trial may have improved participants' self-perception of their loneliness. The Barthel Index has been widely used in older people and rehabilitation trials and yet its ability to detect a change in highly functional individuals is limited, with a ceiling effect (Quinn et al., 2011). This may be important to note for a definitive trial since many of the moderately frail participants were highly functioning, meaning that this may not be the most sensitive outcome measure. Review of medication is a key component of CGA as certain medications are known to have significant adverse effects in frail older people (Hilmer & Gnjidic, 2017). The nurses in our study reviewed medication regularly as part of the intervention and results demonstrated that

TABLE 6 Estimation of numbers required to detect a given effect size in a definitive trial.

Effect size	Minimum, *n*	Sample size inflated for cluster sizes of 10 patients per practice
0.1	857	1243
0.2	215	312
0.3	96	140
0.4	54	79
0.5	35	51

fewer medications were prescribed at 13 weeks and fewer again at 26 weeks. Numbers of prescribed medication would appear to be a clinically important outcome measure for a definitive trial. Based on this evaluation of outcome measures, the Trial Steering Committee recommended health-related quality of life measured by the EQ-5D-5L as the primary outcome measure for a definitive trial. One of the objectives of this trial was to determine the availability of data to complete the EQ-5D-5L to assess the feasibility of using this outcome measure in a cost-effectiveness evaluation in the future. Given the high levels of completeness, it was recommended that this outcome measure could be used to assess cost-effectiveness in a definitive trial. Secondary outcome measures will include the numbers of prescribed medications and others determined through further stakeholder engagement.

Changes to international policy relating to frailty management in primary care (World Health Organization, 2017) is driving research and findings emerged from other studies conducted concurrently with this study. Four reviews (Frost et al., 2020; Garrard et al., 2020; Travers et al., 2019; Van der Elst et al., 2018) and two studies (Bleijenberg et al., 2017; Lee et al., 2020) provide guidance on methods of identification of frail people, as well as efficacy and content of CGA-based interventions to manage older people with complex conditions in primary care. These demonstrated the scarcity of good quality primary care-based studies and concluded that primary care-based CGA was acceptable but provided variable outcome benefit (Garrard et al., 2020). They also highlighted the difficulty of identifying appropriate frail patients. One review concurred with the findings of our study and reported the positive impact of interventions that included self-management, assessment and care planning procedures and structured care pathways led by more experienced and qualified nurses (Frost et al., 2020). Furthermore, the findings from Travers et al. (2019) related to assessment for function/physical activity and nutritional supplementation will inform the mandatory element of the intervention for a future definitive trial.

4.1 | Limitations

Identification of frail people for research studies is problematic (Clegg, Relton, et al., 2015). The eFI was used for this purpose in our study and it failed to identify enough severely frail people and consequently, after eligibility screening, there were small numbers of severely frail participants. This is a crucial factor for the success of a definitive trial which will require a larger number of participants overall. This limitation meant the study sample was not fully representative and there was heterogeneity of responses from the moderately and the severely frail groups. There were large ranges around the mean scores in all outcome measures as both levels of frailty were analysed as one group. These issues will be addressed in the definitive trial with revised recruitment methods accompanied by consideration of a larger sample size to achieve statistical power. It could then be possible to analyse data from the moderately and severely frail cohorts as separate comparison groups within the study. Bleijenberg et al. (2017) found that a nurse-led intervention had a positive impact on daily functioning in the oldest old population, that is, aged 80 years and over. It would seem appropriate to target this age group as frailty prevalence and severity increases with age (Gale et al., 2015). Another option might be to consider screening for frailty based on gait speed and grip strength, which aims to identify those at the highest risk to poor outcomes. This approach has high levels of sensitivity and specificity and claims to be feasible in primary care practice (Lee et al., 2020).

5 | CONCLUSION

This study has evaluated important feasibility parameters and demonstrated that it is feasible to conduct a RCT of a nurse-led CGA-based intervention in primary care. Whilst this feasibility trial was not designed to test the efficacy of the intervention, it was able to test methods to address methodological deficiencies identified in the current literature with the aim of improving the chances of success of a definitive trial. Conducting the trial has demonstrated that, by adopting a person-centred approach, a holistic assessment can be offered to older people who live with frailty within the time and resource constraints of primary care practice. It is recommended that a definitive randomized controlled trial of the clinical and cost-effectiveness of the intervention is now conducted.

AUTHOR CONTRIBUTIONS

All authors have agreed on the final version and meet at least one of the following criteria (recommended by the ICMJE [https://eur03.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.icmje.org%2Frecommendations%2F&data=05%7C01%7Chelen.lyndon%40plymouth.ac.uk%7C4893c810eb924e66dda08db209494df%7C5437e7eb83fb4d1abfd3bb247e061bf1%7C1%7C0%7C638139594742449623%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=FEZeWNSXxbxktL8OF5SVNiotLmB22%2BeKEMVoooEsaNA%3D&reserved=0]). Substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data. Drafting the article or revising it critically for important intellectual content.

ACKNOWLEDGEMENTS

The authors would like to thank members of the Trial Management Group and Trial Steering Committee including Patient and Public representatives, the Peninsula Clinical Trials Unit, Cornwall Foundation NHS Trust Research Team and the South West Primary Care Clinical Research Network Clinical Support Team.

FUNDING INFORMATION

This study has been funded by the National Institute of Health Research (UK) as part of an Integrated Clinical Academic Clinical Doctoral Research Fellowship award ref: ICA-CDRF-2016-02-018.

CONFLICT OF INTEREST STATEMENT

No conflict of interest has been declared by the authors.

PEER REVIEW

The peer review history for this article is available at https://www.webofscience.com/api/gateway/wos/peer-review/10.1111/jan.15652.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Lyndon, H., Latour, J. M., Marsden, J., & Kent, B. (2023). A nurse-led comprehensive geriatric assessment intervention in primary care: A feasibility cluster randomized controlled trial. *Journal of Advanced Nursing*, *00*, 1–14. https://doi.org/10.1111/jan.15652