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Being Your Best: protocol for a feasibility study of a codesigned approach to reduce symptoms of frailty in people aged 65 years or more after transition from hospital

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ABSTRACT

Introduction The population is ageing, with increasing health and supportive care needs. For older people, complex chronic health conditions and frailty can lead to a cascade of repeated hospitalisations and further decline. Existing solutions are fragmented and not person centred. The proposed *Being Your Best* programme integrates care across hospital and community settings to address symptoms of frailty.

Methods and analysis A multicentre pragmatic mixed methods study aiming to recruit 80 community-dwelling patients aged ≥65 years recently discharged from hospital. *Being Your Best* is a codesigned 6-month programme that provides referral and linkage with existing services comprising four modules to prevent or mitigate symptoms of physical, nutritional, cognitive and social frailty. Feasibility will be assessed in terms of recruitment, acceptability of the intervention to participants and level of retention in the programme. Changes in frailty (Modified Reported Edmonton Frail Scale), cognition (Mini-Mental State Examination), functional ability (Barthel and Lawton), loneliness (University of California Los Angeles Loneliness Scale-3 items) and nutrition (Malnutrition Screening Tool) will also be measured at 6 and 12 months.

Ethics and dissemination The study has received approval from Monash Health Human Research Ethics Committee (RES-19-0000904L). Results will be disseminated through peer-reviewed journals, conference and seminar presentations.

Trial registration number ACTRN12620000533998; Pre-results.

Strengths and limitations of this study

- *Being Your Best* is the first study to develop and pilot a codesigned holistic frailty programme for discharged older hospital patients.
- This study will provide evidence for the feasibility and acceptability of a holistic approach to reduce symptoms of frailty.
- Based on scientific reasoning, we postulate that participant choice of interventions that are meaningful and relevant will increase compliance, adherence and improve outcomes.
- The feasibility study design is not powered to determine intervention effectiveness.
- Results will inform the design and conduct of a future multicentre randomised controlled trial of postdischarge education and community services linkage to reduce symptoms of physical, nutritional, cognitive and social frailty.

INTRODUCTION

Frailty refers to increased vulnerability and decreased resilience, with multiple causes and contributors including physical, psychological, social or a combination of factors.[1] Consequently, frailty may encompass reduced functional capacity and ability to partake in activities of daily living (ADL). It can also lead to reduced energy levels, cognitive impairment, poor health outcomes and susceptibility to ill health or stressors that otherwise could be tolerated. Individuals can be characterised as robust (non-frail), prefrail (susceptible to the impact of frailty) or frail.[2–4] Prevalence figures vary, with reports estimating 6%–21% of Australians aged ≥65 years meet the criteria for frailty; with 38%–48% being prefrail.[1 2] The differences in prevalence are likely due to differences in the screening tool used, namely deficit accumulation (frailty index) or a phenotype approach.[2] From a population perspective, this means that at a minimum, almost half of people aged ≥65 years are prefrail or frail[3]; that is, approximately 1.63 million Australians.

Frailty is associated with multimorbidity, polypharmacy, falls and cognitive and functional impairment. It is also associated with reduced quality of life, longer hospital stays, difficulty recovering from illness and surgery, institutionalisation and increased risk of mortality.[5–7] People who are frail are more likely to require acute hospital admission, and more likely to require community referral to home nursing, community services or rehabilitation.[8] Rose *et al* explored the associations between age, hospital length of stay, discharge destination and mortality.[9] Age was associated with increasing levels of frailty, and increasing frailty was associated with more complex discharge arrangements, contributing to longer length of hospital stay. As frailty increased in severity, fewer older people returned home or to their original level of care, and more older people changed residence, received palliative care or died.[10]

Frailty can be considered a dynamic process, with potential for change in an individual's frailty status, as well as a spectrum of vulnerability, where increasing levels of frailty are associated with greater negative impact on the individual.[11] Both frailty and prefrailty have been found to be modifiable.[12–15] A systematic review of the effectiveness of interventions in a range of settings, designed to prevent the progression of frailty and prefrailty in adults aged ≥65 years, found that group-based physical exercise was effective in reducing or postponing frailty.[16]

A randomised controlled trial (RCT) based in a community setting in Singapore of physical, nutritional and cognitive interventions found that these interventions (alone and in combination) significantly reduced frailty levels in predominantly prefrail community-dwelling adults aged ≥65 years. Cognition improved with training, nutrition and physical interventions. Frailty was also reduced in the control group, who received a placebo nutritional supplement, standard healthcare and visits from the intervention nurses, suggesting that strategies beyond physical activity are important in addressing frailty in older people. The trial provided structured, purpose-designed group training and controlled for the effect of increased social interactions on frailty scores.[6] This study highlights the importance of reducing the impact of frailty and prefrailty on older person outcomes and the broader health system.

OBJECTIVES

This study will test, in an Australian cohort, the feasibility and acceptability of *Being Your Best*, a holistic, person-centred, codesigned, intervention programme informed by a large international evidence-based study. This study will be conducted in two phases: (1) a codesign phase to inform the intervention component; and (2) an intervention phase in which the codesigned modules will be offered to older people recently discharged from hospital. It is hypothesised that the *Being Your Best* programme will lead to a reduction in frailty and build resilience in older people who are frail, leading to less hospital admissions, and escalation of further care requirements.

METHODS

Study design and setting

Being Your Best is a pragmatic mixed methods study comprising a two-phase programme which integrates care transitions of community-dwelling patients from three emergency departments (ED) at The Alfred, Cabrini and Monash Health-Dandenong hospitals to home; and for recently hospitalised community-dwelling patients receiving home-based nursing support from Bolton Clarke. All hospitals are large tertiary referral healthcare providers, two of which are service public patients, with one servicing private patients in the inner south-east suburbs of Melbourne, Australia; and Bolton Clarke is a national provider of community and aged care services.

Phase 1 will involve a codesign partnership between researchers, community members and clinicians from the four healthcare providers, where intervention strategies will be discussed, identified and chosen.

Phase 2 will recruit frail and prefrail older community-dwelling adults in hospital. *Being Your Best* comprises: (1) needs assessment, (2) education, (3) targeted needs-based management driven by patient choice, empowerment and goal setting, (4) community-based or home-based intervention modules that integrate physical, cognitive, social and nutritional strategies to address frailty, (5) telephone follow-up to cultivate resilience and review behaviour change and goals, and (6) reassessment at 6 months. Primary outcomes are feasibility and acceptability of the programme, and secondary outcomes include measurement of changes in frailty status.

PHASE 1: CODESIGN OF *BEING YOUR BEST* PROGRAMME

Being Your Best builds on the existing evidence of interventions shown to moderate frailty by incorporating self-determination and codesign elements. It has been shown that by promoting self-determination to enhance competence and confidence, higher adherence to the programme will occur.[17] Codesign engages key stakeholders, involving them in the decision process of the intervention phase.[18] This process has been shown to support sustainability of programmes in the healthcare sector ensuring they are fit to purpose, acceptable, valuable and enduring.[19] *Being Your Best* builds on evidence-based strategies that will be presented for discussion in the codesign sessions. To reduce costs and support sustainability of the programme, *Being Your Best* will use existing community activities within the four frailty modalities (physical, cognitive, social, nutritional). Community activities will include exercise groups, tai chi, meals on wheels, library groups, language classes, and so on.

PATIENT AND PUBLIC INVOLVEMENT

Participants and sample size

One to two codesign sessions will be planned with up to eight members from each of the four participating health service Community Partnership Groups (CPG). CPG members will be current or former patients, family members or clients of health services who are motivated to help improve service delivery and patient, client and family experience. This process will help ensure diverse representation for input in the codesign process, to ensure the interventions will meet the needs of a broad range of frail or prefrail older people attending these healthcare providers.

Codesign session participants will be recruited through CPG coordinators via expression of interest. The aim of the codesign sessions and how they will be conducted will be explained to them; they will be given time to ask any questions they might have. Furthermore, it will be explained to the participants that the data presented from the codesign group will be deidentified. Finally, they will be asked to provide informed consent. Participation will be supported with taxi transport as required and refreshments.

These codesign sessions will be supplemented by sessions with medical, nursing and allied health clinicians from each site.

Data collection and analysis

Duration of the codesign sessions will be 1–2 hours and will be guided by a research team member. The objectives will be to:

- Generate discussion about what frailty means to participants.
- Explain the evidence for effective strategies for each modality; furthermore, the intensity of the activities will be discussed but will ultimately be adapted to each individual's capabilities.
- Obtain participant perspectives about these strategies; what they should be called and what they should comprise.
- Seek their opinion on examples of affordable community support networks that might address one or more interventions.

Discussions will be audio recorded and transcribed. Findings from the codesign sessions will be used to design the interventions for piloting in phase 2. The CPG participants will be asked if they would like to receive the information obtained from these sessions. The results will be disseminated in paper form or electrically to those who wish to receive them.

PHASE 2: FEASIBILITY AND ACCEPTABILITY OF *BEING YOUR BEST* PROGRAMME

Participants and sample size

It is anticipated that a total of 80 participants will be recruited from the three hospitals and home nursing clients who satisfy inclusion and exclusion criteria. As this is a pragmatic feasibility pilot study, 80 participants were deemed a sufficient number to determine the primary outcomes based on previous work.[20]

Inclusion criteria: Age ≥65 years, able to communicate in English, able to provide written informed consent, community dwelling, hospital attendance to ED in one of the participating hospitals, score ≥6 on Modified Reported Edmonton Frail Scale (Mod-REFS).

Exclusion criteria: resident of an aged care home, surgical or intensive care unit admission, discharged to residential aged care, discharged to rehabilitation (including home-based rehabilitation), receiving terminal or end-of-life care, residing >10 km from recruitment hospital.

Recruitment and consent

Participants will be recruited by a health professional (hospital ED nurse (employed for this project) or Bolton Clarke hospital liaison nurse) at each site just prior to hospital discharge, or for home nursing clients, in their home, within 48 hours of discharge. Potential participants will be approached, and the project will be explained. A cognitive capacity check will be conducted to make sure the person understands the participant information and consent form. The Mini-Mental State Examination (MMSE) scale will be administered to determine eligibility. If no or mild cognitive impairment is determined, the Mod-REFS will then be conducted to ascertain the eligibility regarding frailty/prefrailty (score ≥6). Eligible older people will be invited to participate. Written informed consent will be sought at the time of recruitment. It will be explained to the participants that they can withdraw from participating in the project at any stage; we will ask for the reason of withdrawal to inform future studies. Participants will be telephoned at 1 week after hospital discharge to assent consent and to organise a home visit by a research nurse, within 48 hours of the telephone call. In the event of any unanticipated post-discharge health concerns, the research nurse will liaise directly with the hospital.

Intervention

The *Being Your Best* intervention programme will provide four evidence-based activity modules that are addressing the frailty domains of physical function, cognition, social connection and nutrition through an integrated, coordinated community-based approach.

Activities will be group and community based where possible. Participants will be provided with education about their needs assessment and encouraged, through motivational interviewing, to choose one or more of the four module(s) that appeal to them and to develop personalised goals and action plans. They will be phoned by a member of the research team within 48 hours of the home visit to provide support, encouragement and assistance with commencing their personalised programme. Video-enabled phone calls will also be offered as an option. During the 6-month programme, participants will be telephoned regularly by one of two experienced researchers

to encourage motivation, comprising a minimum of 2–11 follow-up phone calls, each lasting approximately 30 min. The participants will be telephoned at 12 months to assess programme sustainability. An activity calendar will be provided for completion for discussion during the follow-up telephone calls.

The intervention modules will address one or more aspects of frailty:

- Physical function: promoting involvement in multicomponent physical activity, through group fitness activities in the community, or educational booklets for home-based intervention.
- Social connectedness: social support by connecting the participant with an existing volunteer conversational phone support service, or existing social community groups.
- Cognitive function: cognitive training through existing community-based group activities, online modules comprising games that improve memory, cognitive abilities and problem-solving skills (eg, Luminosity app; a daily mental training program), or a handbook of cognitive exercises.
- Nutritional support using a healthy eating booklet, alongside connection with existing community groups revolving around food, such as casserole clubs.

If a participant wishes to combine two or more of the modules, *Being Your Best* will offer a pragmatic holistic approach to moderating the effects of frailty.

Appropriate local community services will be chosen by participants, with assistance from a member of the research team using a service map, collated for the region within 10 km of the four service providers. Collation of these services has been conducted through a grey literature search using Council Community Service databases and is updated regularly as services are made available or unavailable. Services may include activities delivered by community neighbourhood houses, senior social groups, alongside community exercise classes, and walking groups, as well as community-based activities for older adults with sensory impairment, such as those offered through Deaf Sports Recreation Victoria, Blind Sports Victoria and Ambleside Tours—Tours for People with Disabilities. All home-based interventions will be individually tailored for each participant, in line with any support required for sensory impairments (ie, large print books or e-books).

Safety considerations

The general practitioner (GP) of each participant will be contacted by the ED or home visiting research nurse before any modality and duration of activity is suggested, with GP clearance before commencement of any activities. The research team will also have regular contact with participants over the telephone, where they can express any concerns they may have. If any participant would like to terminate, or change an activity, or cease their involvement in the study, they are able to do so.

If there are any health concerns, the participants will be advised to contact their GP. Participants will also have access to the research team for advice and support.

Data collection

Demographic data will be collected by the hospital ED nurse. Data will include age, gender, marital status, residential status, comorbidities, use of health services and any hospital admissions in the last 12 months, current use of community services, contact details and GP details. Baseline survey data will be collected at the first home visit, with outcome data collected over the phone at 1, 3, 6 and 12 months after enrolment.

Standardised measurement instruments that demonstrate good psychometric properties and are used in older community-dwelling person research will be applied to all participants. The Mod-REFS is a holistic measure of frailty and prefrailty[21]; the telephone MMSE assesses cognitive function[22]; the Barthel Index measures functional ability to manage ADL[23]; the Lawton Instrumental Activities of Daily Living Scale (IADL) assesses the ability to live independently in the community[24]; the University of California Los Angeles (UCLA) Loneliness Scale-3 items measures loneliness and feelings of social isolation[25]; and the Malnutrition Screening Tool (MST) is a self-assessed scale that identifies risk of malnutrition.[26]

A weekly activity log, including questions specific to the module chosen, will be completed weekly by participants to record details of frequency and time spent on each module. The participants will be provided with a prepaid envelope and asked to send the activity logs to the research team monthly.

A semistructured interview will be conducted with all participants at 6 months after enrolment to ascertain the feasibility of the interventions and their experiences and perceptions. A topic guide will provide prompts that explore participants' experience of the intervention modules and their value, views about the programme and suggestions to enhance effectiveness. A telephone interview will also be conducted at 12 months after enrolment to ascertain sustainability[3] through discussing ongoing engagement with the chosen intervention.

Outcomes

The primary outcome is the feasibility of study processes and acceptability of the codesigned *Being Your Best* intervention. This will include measurement of recruitment, assessment procedures and adherence (and compliance) to the protocol. We will also assess whether the chosen interventions have decreased the baseline Mod-REFS score, that is, whether there an improvement in their frailty symptoms. Admissions to hospital during the programme will also be recorded.

Secondary outcomes include measurements of changes in ADL (Barthel Activities of Daily Living Index) and how independently they can perform these activities (Lawton IADL), cognitive function (MMSE), measure of malnutrition (MST) and level of loneliness (UCLA Loneliness

Scale-3 items). At 12 months after enrolment, we will follow-up all outcomes to ascertain any sustainability.

Data management

All data will be stored securely on a secure password-protected server and archived for 7 years after study completion. Each participant will be assigned a project-specific identification number. All identifiers will be removed prior to aggregated analyses of the data.

Data analysis

Feasibility of study processes will be assessed including eligibility screening and recruitment strategies, follow-up regime, risk management procedures and level of support required by the participants.

Intervention acceptability to participants will be measured through rates of uptake by eligible people, and retention in the intervention, alongside feedback interviews that consider acceptability from the participants' perspectives. Interview data will be analysed using a qualitative thematic approach. The four subthemes discussed in the codesign sessions (Moving Well, Thinking Well, Connecting Well and Eating Well) will be used as a priori categories, followed by deductive sorting. Data will be systematically scrutinised, charted and sorted into recurrent themes.[27]

Baseline data will undergo descriptive analysis, summarising the sociodemographic, clinical and functional profiles of *Being Your Best* participants. Quantitative data will be presented as proportions, means (SDs) or, for variables that did not conform to a normal or log-normal distribution, medians (IQR). Preintervention and postintervention scores of frailty, functional ability, cognition, loneliness and nutrition will be analysed using paired t-tests, McNemar's test or the Wilcoxon signed-rank test as appropriate. Any preintervention/postintervention differences will be compared with a significance level of p=0.05. Statistical analysis will be performed using STATA (StataCorp. 2017. Stata Statistical Software: Release 15. College Station, Texas: StataCorp).

DISCUSSION

Frailty is a syndrome characterised by reduced physiological reserve and increased vulnerability to adverse outcomes, resulting from cumulative deficits of multiple systems.[28] An increasing number of studies have shown an association between frailty with negative health outcomes including falls, hospitalisation, mortality and loss of independence.

The increasing number and proportion of people aged 60 and over is triggering concerns about increased health and social care costs. Older people with mild frailty or prefrailty are more likely to transition back to a robust state than those who are frail.[29] Health promotion and early intervention present an important opportunity to prevent further decline and dependence and to potentially make gains in health and reductions in disability and need for care. Furthermore, there are studies suggesting a correlation between frailty and polypharmacy, which is more common in older adults.[30]

Being Your Best will build resilience to overcome vulnerabilities arising from frailty using evidence-based, codesigned and person-driven strategies designed to reduce the impact of frailty on older persons.

This programme has the potential to improve quality of life and loss of independence in older people living with frailty or prefrailty. It will also raise awareness of the importance of screening for frailty and prefrailty in healthcare systems. Furthermore, by engaging with GPs, this programme aims to encourage prescribing to already established community services. *Being Your Best* is a holistic approach designed *by* older people *for* older people. It is anticipated that engaging in an intervention of their own choosing may encourage adherence and compliance to the intervention and promote long-term sustainability. It is anticipated that by using one or more of the codesigned interventions, participants will experience decreased frailty and build resilience, leading to fewer hospital admissions, and escalation of further care requirements. The phase 1 part of the programme is aimed to be finalised in the year 2020. Phase 2 will not commence until safe to do so due to COVID-19 pandemic. We are hoping to commence phase 2 in early 2021.

This is the first study to undertake and examine a codesigned approach to mitigate the effects of physical, cognitive, nutritional and social frailty using community-based services. It will enable us to evaluate feasibility of frailty screening in the ED setting, recruitment, delivery of the intervention and outcome measure ascertainment at study conclusion. As participants are limited to community-dwelling older people with frailty, the results may not be generalisable to other populations, such as those with severe cognitive impairment or who reside in aged care homes. The study design is not powered to determine intervention effectiveness; however, the findings will inform the design and conduct of a future multicentre RCT.

The qualitative and quantitative findings of this feasibility study will be used to further expand the intervention programme as well as design a large RCT with the aim to test the effectiveness of the interventions compared with standard care.

ETHICS AND DISSEMINATION

The study has received approval from Monash Health Human Research Ethics Committee (RES-19-0000904L). Results will be disseminated through peer-reviewed journals, conference and seminar presentations.

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