Implementation of a frailty intervention in the transition from hospital to home: a realist process evaluation protocol for the FORTRESS trial

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ABSTRACT

Introduction Frailty in Older people: Rehabilitation, Treatment, Research Examining Separate Settings (the FORTRESS study) is a multisite, hybrid type II, stepped wedge, cluster, randomised trial examining the uptake and outcomes of a frailty intervention. The intervention is based on the 2017 Asia Pacific Clinical Practice Guidelines for the Management of Frailty and begins in the acute hospital setting and transitions to the community. The success of the intervention will require individual and organisational behaviour change within a dynamic health system. This process evaluation will examine the multiple variables at play in the context and mechanism of the frailty intervention to enhance understanding of the outcomes of the FORTRESS study and how the outcomes can be translated from the trial into broader practice.

Methods and analysis The FORTRESS intervention will recruit participants from six wards in New South Wales and South Australia, Australia. Participants of the process evaluation will include trial investigators, ward-based clinicians, FORTRESS implementation clinicians, general practitioners and FORTRESS participants. The process evaluation has been designed using realist methodology and will occur in parallel to the FORTRESS trial. A mixed-method approach will be used with qualitative and quantitative data collected from interviews, questionnaires, checklists and outcome assessments. Qualitative and quantitative data will be examined for CMOCs (Context, Mechanism, Outcome Configurations) and programme theories will be developed, tested and refined. This will facilitate development of more generalisable theories to inform translation of frailty intervention within complex healthcare systems.

Ethics and dissemination Ethical approval for the FORTRESS trial, inclusive of the process evaluation, has been obtained from the Northern Sydney Local Health District Human Research Ethics Committees reference number 2020/ETH01057. Recruitment for the FORTRESS trial uses opt-out consent. Dissemination will be via publications, conferences and social media.

Trial registration number ACTRN12620000760976p (FORTRESS trial).

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This process evaluation employs a realist methodology combined with implementation theory to facilitate a deep and detailed analysis of the implementation of the frailty guidelines.
⇒ The process evaluation involves mixed methods and data from a range of stakeholders including implementation staff, ward-based clinicians, intervention participants and carers.
⇒ Findings will explore how the different sites vary in terms of their responsiveness to implementation of frailty guidelines.
⇒ The process evaluation protocol outlines the methods of evaluation prior to results being known to enhance transparency of approach, as well as validity and credibility of the final findings.
⇒ Information from general practitioners about the frailty intervention will be obtained indirectly (rather than directly) and this is a potential limitation of this process evaluation.

INTRODUCTION

Frailty is a common and reversible condition in older people characterised by unintentional weight loss, low muscle strength, fatigue, reduced gait speed and reduced physical activity capacity.1 It is defined as a clinical state with multiple causes which increases an older person’s vulnerability for increased dependency, morbidity and mortality when exposed to a stressor.2 There is a high prevalence of frailty within older people in inpatient hospital settings, with Richards et al3 reporting 49% of adult inpatients classified as frail, and prior studies reporting frailty prevalence rates of between 27% and 80% in hospitalised older patients.4 5 While illness and hospitalisation can exacerbate frailty, hospital admissions are an important opportunity for identification of frailty and intervention.
The Asia-Pacific Clinical Practice Guidelines for the Management of Frailty were developed by a clinical expert panel and reported using the GRADE (Grading of Recommendations, Assessment, Development and Evaluation) methodology to evaluate available scientific evidence and form recommendations. The guidelines recommend (1) using validated tools to identify frailty, (2) physical activity incorporating resistance training, (3) addressing polypharmacy, (4) screening for reversible causes of fatigue, (5) screening and considering protein and caloric supplementation/fortification and (6) vitamin D supplementation.

While there is evidence of the benefits of integrated multidisciplinary care for the management of frailty, less attention has been given to the implementation of frailty treatment guidelines in scientific research. Translation of recommendations from guidelines to real-world clinical practice within a complex health system is rarely straightforward. Although guidelines recommend that older Australians are screened for frailty, there is currently no single frailty-screening tool that is routinely implemented into clinical practice in Australia. While there is also increasing recognition of the need for community intervention for frailty reduction, changes to policies and programmes are required to ensure this happens and there is currently variation in how exercise and nutritional interventions for older people are delivered across hospital and community settings.

The aim of the FORTRESS (Frailty in Older people: Rehabilitation, Treatment, Research Examining Separate Settings) trial is to implement and evaluate an evidence-based frailty intervention in hospital and community settings for ‘frail’ older people by examining the effectiveness and uptake of frailty interventions. Details of the trial are presented elsewhere. This protocol describes the methodology of the process evaluation which will occur concurrently.

Process evaluations are used to describe and guide the process of translating evidence into practice. There is increasing recognition of their importance, particularly when the trial intervention is complex and/or occurs across different settings. The UK Medical Research Council (MRC) guidance for evaluating complex interventions recommends conducting process evaluations to better explain the impact of context, any discrepancies between expected and observed outcomes and to ultimately provide insights that can aid implementation. Process evaluations can assist in interpreting outcomes, barriers and facilitators to implementation as well as more thoroughly understanding components of the intervention. Through thorough analysis, the process evaluation can help to explore reasons for any variations in trial outcomes to allow an enhanced understanding of how frailty intervention can be translated from the trial into broader practice.

**Theoretical underpinnings—a realist process evaluation**

Realist evaluation will be used to guide the process evaluation based on the methodology proposed by Pawson and Tilley. This approach was chosen to frame the process evaluation as it aims to explore ‘what works (or does not), for whom and under what conditions’. It is well suited to in-depth analysis of the implementation of an intervention within the complex healthcare system.

Realist evaluation theoreies that complicated interventions act within open systems which interact with personal, interpersonal and environmental factors within and external to the intervention. These can only be understood through systematic investigation of the contexts in which events occur, underlying causal mechanisms, and the outcomes produced. This inter-relationship of domains is expressed as Context+Mechanism = Outcome. Context is the pre-existing environment and microsystem and macrosystem the intervention is implemented within. Mechanisms include the actions and behaviours generated by the intervention. Outcomes are the result of the interactions between the Context and the Mechanisms which can be analysed at individual, organisation, structural and societal levels. Context–Mechanism–Outcome Configurations (CMOC) are central to building and refining theories of implementation.

There are multiple implementation theories which differ by their level of abstraction and the range of specific instances to which they can apply. This process evaluation will be centred on the development and refinement of programme theories to propose and test middle-range theories (see figure 1).

The development of middle-range theories in this process evaluation can be conceptualised as a three-stage process. Stage 1 involves identification of the specific objectives relevant to this study, development of the initial programme theories (IPTs) and design of the study. Stage 2 involves data collection, analysis, synthesis and programme theory refinement. Refined programme theories are synthesised and retested, attempting to identify ‘demiregularities’ (semipredictable patterns or pathways of programme functioning) which can assist to identify potentially transferrable theories. As theories are tested, middle-range theories may be developed (stage 3) to explain programme theories and identified demiregularities. The middle-range theories operate at a higher level of abstraction from the programme theories and may be useful to inform implementation in other settings.

**Initial programme theory**

The ‘programme theory’ in realist studies is the hypothesis of how and why the implementation of the intervention is expected to work. The development of the IPT for this process evaluation involved analysis of the study protocol, wider academic literature and discussion with trial investigators and consumers.

IPT (presented as provisional CMOCs):

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1. Clinician knowledge of frailty and engagement in the identification of frailty during hospital admission (C) will result in implementation of targeted frailty interventions and the codevelopment of a frailty management plan (M) ensuring that the frail older person has the knowledge and skills to address their frailty after discharge (O).

2. Through implementing individualised frailty interventions in the acute and community setting (C), individuals will gain physical strength and increase their engagement in functional activities (M) resulting in improved health outcomes and quality of life (O).

3. When the Frailty Management Plan is individualised, explained to the participant and given to the GP practice (C), there will be improved continuity and integration of care (M) which will result in improved quality of care for people with frailty (O).

(C=Context, M=Mechanism, O=Outcome)

The above IPTs informed the development of methods for this process evaluation. These theories will be used, tested and refined throughout the analysis of the study data and new theories may be developed iteratively.

METHODS AND ANALYSIS

The process evaluation has been designed to be run in conjunction with, and in parallel to, the main FORTRESS trial. The research team is involved in both studies. There will be information that is shared between the main FORTRESS study and the process evaluation. The integration of the primary study and the process evaluation allows any important and relevant information to be shared, including any quality or process issues that may be impacting the trial.

Overview of FORTRESS trial

The FORTRESS trial is a stepped wedge, cluster randomised trial involving six wards in Hornsby Ku-ring-gai Hospital in New South Wales, Australia and Southern Adelaide Local Health Network in South Australia, Australia. The study was approved by the Northern Sydney Local Health District Human Research Ethics Committee. The trial involves an opt-out approach to participant consent. Each ward introduces the intervention at 4 month intervals. An overview of the stepped wedge design is presented in figure 2.

The trial utilises a hybrid type II approach, which is designed to allow testing of the implementation strategy while observing outcomes and effectiveness. As portrayed in figure 2, there is an initial period of 4 months where
no clusters (sites) are exposed to the intervention. By the end of the study all clusters have been exposed (trial intervention due for completion June 2023).

Participants: people aged 75 years and over admitted to the participating hospital wards will be screened using the FRAIL scale\(^\text{16}\) and those with a score of 3 or more will be considered to be ‘frail’ and eligible to participate in the study. Other inclusion criteria include living at home (not in a residential aged care facility), a Mini Mental State Examination score of ≥24/30 and being able to cooperate with the intended intervention. People who were not independently mobile prior to admission, have an estimated life-expectancy of <12 months, or who are admitted with stroke are excluded.

Intervention: the implementation of the frailty guidelines begins in hospital wards where the person is assessed. All patients who fit the inclusion criteria and are admitted to the study ward are automatically given the intervention unless they ‘opt out’. A frailty management plan is developed and discussed with the participant and family by ward-based therapists. The frailty management plan consists of an individualised exercise programme with a resistance training component, assessment of nutritional status (with interventions if indicated) and pharmacist review (with recommendations as appropriate). On discharge from the hospital, the frailty management plan is sent with the participant, forwarded to a community implementation facilitator (an allied health professional) and sent to the participant’s regular General Practitioner (GP). The community implementation facilitator supports continuation of the plan through liaison with the participant, the GP and significant others.

Outcome assessment: all participants will be followed up by phone by an outcome assessor blinded to allocation at 5 months and 12 months postdischarge; the primary outcome is length in days of non-elective hospital admissions over 12 months post recruitment.

Process evaluation of the FORTRESS trial
Study design and data collection methods
Study design
The study setting for the process evaluation is the same as the FORTRESS trial (as detailed above). Participants in the process evaluation will include trial investigators, ward-based clinicians, FORTRESS implementation clinicians, GPs and FORTRESS participants.

The study will be guided by the RAMESES II (Realist and Meta-narrative Evidence Synthesis: Evolving Standards) guidelines for reporting realist evaluations.\(^27\) The process evaluation will use mixed methods with data collected from multiple sources. The data sources chosen will provide insights into contexts and mechanisms that will allow programme theories to be tested and refined. Both qualitative and quantitative data will be used to identify CMOCs which will be synthesised into programme theories.

The individual data sources will each contribute to refinement of the IPTs, and to the development of potential new programme theories. Table 1 identifies the primary component/s of the CMOC that each data source will contribute information to.

Data collection methods
The individual data collection methods and measures used for this process evaluation are:

Frailty knowledge and perceptions interviews
The knowledge and perceptions of frailty by ward-based hospital staff during the intervention period at each site is an important contextual factor and will be measured through semistructured interviews. This will be used to test IPTs 1 and 2. The interviews may be conducted in person or phone call and written consent will be obtained prior to interview. Interviews were chosen over focus groups due to potential impact of COVID-related meeting restrictions.

All interviews will be audio-recorded and transcribed verbatim. Data will be coded by two researchers (using NVivo software) to identify CMOCs. The codes will be developed deductively from the interview guide, and also

![Figure 2](https://example.com/figure2.png)

Figure 2 Stepped wedge design. C, control ward; I, intervention ward.

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<table>
<thead>
<tr>
<th>Data source</th>
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<td>Frailty knowledge and perceptions interviews</td>
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<td>Abbreviated Determinants of Implementation Behaviour Questionnaire (abbreviated DIBQ)</td>
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<td>Participant self-report outcome assessment</td>
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<td>Participant qualitative interviews</td>
<td>C, M, O</td>
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<td>Fidelity assessment</td>
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<td>Interviews with FORTRESS Implementation Clinicians</td>
<td>C, M, O</td>
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<td>GP feedback</td>
<td>C, M</td>
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<td>Timeline analysis</td>
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C, Context; CMOCs, Context, Mechanism, Outcome Configurations; M, Mechanism; O, Outcome.
inductively with codes developed from content within the interview transcripts. We will aim interview 4–5 health professionals from each ward (total approximately n=25) during the intervention period, recruiting until thematic saturation. Similarities and differences between health networks will be explored and analysed in conjunction with intervention outcomes.

Abbreviated Determinants of Implementation Behaviour Questionnaire (abbreviated DIBQ)
An abbreviated and modified version of the DIBQ will assess organisational culture and beliefs that may differ between clusters and influence the context of intervention implementation of the FORTRESS study. This will be used to investigate culture and test IPT 1 and 2. The DIBQ is a questionnaire developed to assess potential implementation behaviour determinants for healthcare professionals.

Verbal consent will be obtained from participants prior to completing the abbreviated DIBQ.

The DIBQ questionnaire used in this study has been reduced from its original version of 93 items assessing 18 domains to 13 items from seven domains—Beliefs about Capability, Beliefs about Consequences, Nature of Behaviour, Organisation, Innovation, Social/Professional Role and Social Influences. Each question is rated on a 7-point Likert scale in keeping with the original questionnaire. The questionnaire was decreased in size to reduce the burden for staff to complete but will still provide information that can be analysed descriptively, compared between sites and considered in relation trial outcomes. Data will be collected from 5 to 6 implementation ward-based staff from each ward (total, n=30–36 participants).

Participant self-report outcome assessment
Phone interviews will be conducted at 3 months and 12 months after the participant has been discharged from hospital and will be conducted by the research outcome assessor. Consent will be opt-out and all participants will complete these outcome assessments unless they opt-out. The interview data will provide outcome data to assist in IPT 1, 2 and 3. An interview guide will be used to guide conversation and include questions as to how much information they were given about the Frailty Management Plan and whether they continued to implement the intervention when at home.

Participant qualitative interviews
During the participant’s 3-month outcome assessment, participants will be asked permission to be contacted for a qualitative interview. Their verbal consent will be documented. The qualitative interview will be conducted via phone at 4–6 months with aim to interview approximately 10% of participants in the FORTRESS intervention group. The interview will assess the participant’s knowledge about frailty and their individual frailty management plan, any recent medical or lifestyle changes and the community resources they access. This will provide information about context, mechanism and outcomes, and will assist in testing IPT 1, 2 and 3. The interviews will audio recorded, transcribed and coded for CMOCs.

Fidelity assessment
The Fidelity and Adherence Scale will be used to assess whether trial participants received intervention as per protocol. The Community Facilitator will record data regarding inpatient care, whether the participant has received a home visit, what resources and education were provided, how adherent and how engaged the participant was throughout the intervention. This will provide information about mechanism and outcome to test IPT 1, 2 and 3.

Interviews with FORTRESS implementation clinicians
All of the FORTRESS implementation clinicians will be interviewed to obtain feedback and insights into GP practice engagement with the Frailty intervention. Their verbal consent will be documented. The implementation clinicians will be able to provide insights and feedback about the intervention, both in the acute and community settings as well as information on interactions with GP practices and participants. This will provide information about context, mechanism and outcome and assist in testing IPT 1, 2 and 3.

The interviews will be conducted after the intervention phase is complete and will be audio-recorded and transcribed verbatim. They will be analysed for CMOCs by two researchers independently and programme theories developed by the primary researcher.

GP feedback
General practice visits and education sessions will be conducted by a GP liaison during the FORTRESS trial. Feedback and field notes from these visits and sessions will be collected. This information will be analysed for CMOCs and will provide information regarding context and mechanism to test IPT 3.

Timeline analysis
Analysis of time-based contextual factors impacting on delivery of the intervention will include data collected from fidelity assessment, community implementation facilitator logs and interviews with implementation staff. This analysis will assist in understanding context for all three IPTs.

Data analysis
The process evaluation will involve both qualitative and quantitative data. Where possible, the data analysis will occur prior to the trial outcome being known, with an additional post-hoc analysis conducted once the FORTRESS trial has concluded and the outcomes are available. Possible explanations for trial outcomes will be suggested based on contextual factors and mechanisms identified in the various sites (clusters) and refined into CMOCs and programme theories. The main trial will be analysed independently of the process evaluation findings.
Qualitative data will be analysed for CMOCs and for generative explanation of causation. Audio recordings of interviews will be professionally transcribed in full. Contextual, mechanistic, social and psychological drivers that may influence outcomes will be explored qualitatively through a realist approach to thematic analysis and abductive thinking as guided by Wiltshire and Ronkanen’s model. Experiential, inferential and dispositional themes will be developed with the aim to produce causal explanations and refine programme theories. Analysis of qualitative data will include reflexivity.

Quantitative data will be analysed using descriptive statistics and the SPSS statistical programme. The model will include intervention status and time as fixed effects and site and individuals as random effects. Where appropriate, organisational and individual factors correlated with the outcome will also be included as fixed effects in the model. These may include staff knowledge, organisational culture and other contextual factors identified. Where indicated, linear and logistical regression models may be applied. A secondary analysis will investigate an interaction effect between intervention and time.

The researcher performing the interviews and surveys will not be blinded to intervention site or time point within the trial. Wherever possible, data will be analysed with concealment of intervention group however this will not always be possible, and any outcomes will be reported clearly outlining possible sources of bias. Every effort will be made to minimise missing outcome data and to include a representative non-biased sample of participants.

Patient and public involvement
Two consumer representatives (one from NSW and one from SA) were involved in the FORTRESS trial from the beginning. This included participation in study design, protocol development (for both the FORTRESS trial and the process evaluation), input regarding consumer materials and assessment, as well as contributions to the ethics application. The consumer representatives will be involved in choosing methods for dissemination for outcomes of the FORTRESS trial and the process evaluation.

ETHICS AND DISSEMINATION
Ethical approval has been obtained from the Northern Sydney Local Health District Human Research Ethics Committees reference number 2020/ETH01057. This ethics approval was for opt-out participant consent for the FORTRESS trial, inclusive of the process evaluation.

Dissemination will be via publications, conferences, and social media.

DISCUSSION
The FORTRESS trial involves implementation of frailty intervention according to guidelines. This paper describes the design of a mixed-methods process evaluation aimed at understanding and contextualising the results of the FORTRESS trial. Strengths of this process evaluation protocol include the mixed-methods approach, rich qualitative data from both healthcare staff and older people with frailty and comprehensive intervention fidelity assessment. A limitation is the lack of direct feedback from GPs; however, some data will be obtained indirectly through the GP education session feedback, GP liaison and community implementation facilitator field notes and interviews, as well as the fidelity assessment. Despite this limitation, this process evaluation will contribute to the broader knowledge base around implementing frailty interventions in the acute hospital setting and community after hospital discharge. The realist approach will allow a richly detailed analysis of contextual and mechanistic factors contributing to trial outcomes, thus providing valuable information about frailty knowledge translation and implementation to inform future frailty interventions.

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