

BMJ Open Integrating post-fracture care into the primary care setting (interFRACT): Protocol for a mixed-methods study to co-design a care program to improve rates of osteoporosis and fracture treatment

Jason Talevski ,^{1,2,3} Alison Beauchamp ,^{3,4} Stefanie Bird,^{1,5} Robin M Daly ¹

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For numbered affiliations see end of article.

Correspondence to

Dr Jason Talevski;
j.talevski@deakin.edu.au

ABSTRACT

Introduction Despite evidence showing that timely diagnosis and appropriate pharmacological treatment of osteoporosis reduces subsequent fracture rates, osteoporosis remains significantly underdiagnosed and undertreated. The large and ongoing treatment gap for osteoporosis and associated fragility fractures could be addressed by considering systematic approaches for post-fracture care in the primary care setting. This study will develop the Integrating Post-Fracture Care into Primary Care (interFRACT) care program that aims to enhance diagnosis and treatment of osteoporosis and improve initiation and adherence to fracture prevention strategies for older adults in the primary care setting.

Methods and analysis This mixed-methods study will follow an established co-design approach that involves six steps; the first three aim to gain an understanding of the consumer experience and needs, while the latter three focus on how to improve that experience through design and action. This will include: development of a Stakeholder Advisory Committee to provide guidance on all aspects of study design, including implementation, evaluation and dissemination; interviews with primary care physicians to explore beliefs and attitudes towards osteoporosis and fracture treatment; interviews with consumers (older adults with a diagnosis of osteoporosis and/or fragility fracture) to identify current needs for osteoporosis treatment and fracture prevention; a series of co-design workshops to develop the components of the interFRACT care program based on published guidance and findings from interviews; and a feasibility study with primary care physicians to determine the usability and acceptability of the interFRACT care program.

Ethics and dissemination Ethical approval was obtained from Deakin University Human Research Ethics Committee (approval number: HEAG-H 56_2022). Study results will be published in peer-reviewed journals, presented at national and international conferences, and collated in reports for participating primary care practices.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This study will provide much-needed knowledge for the development and implementation of evidence-based systematic approaches for post-fracture care in the primary care setting.
- ⇒ By utilising the principles of co-design, we will form a research partnership with consumers and key stakeholders and work together on all aspects of intervention development. This will increase acceptance, uptake, long-term adherence and satisfaction of the final intervention.
- ⇒ A post-fracture care program (interFRACT) embedded within the primary care setting will guide primary care physicians with evidence-based treatment plans for osteoporosis and secondary fracture prevention and may have the potential to eliminate the persistent underdiagnosis of osteoporosis and address the care gaps in secondary fracture prevention.
- ⇒ A limitation of this study is the research will be conducted in primary care centres across Australia, so it is possible that the relevance of our intervention may vary across different contexts and geographical locations (eg, internationally).

INTRODUCTION

Osteoporosis represents one of the greatest global health risks for older adults. It is one of the most prevalent types of musculoskeletal conditions among people aged ≥50 years and results in a fragility fracture occurring every 3 seconds globally.¹ Given that our ageing population is rising exponentially, it is estimated that 500 million people aged ≥50 years worldwide will have osteoporosis by 2025 resulting in approximately 13.5 million fractures annually.² The burden that osteoporosis has on patients is primarily due to its associated fractures. Fragility fractures are

the most severe clinical outcome of osteoporosis and can lead to long-term functional impairment, loss of independence, reduced quality of life and premature mortality.^{3–6} In addition to their physical and psychological impacts, osteoporosis and fractures also carry significant economic consequences for both the healthcare system and the individuals themselves.^{5 7 8}

Despite major advances in our understanding of the pathogenesis and treatment of osteoporosis, recent evidence suggests that only 20–25% of patients with a fragility fracture are being actively treated or diagnosed for osteoporosis.^{9–11} This is referred to as the ‘osteoporosis care gap’ and represents a missed opportunity for secondary fracture prevention. More than half of hip fracture patients aged ≥50 years have had a previous fragility fracture,¹² and of these individuals, approximately 50% are unaware that they are at a higher risk for another fracture.¹³ Applying appropriate secondary prevention measures for these patients could prevent an estimated 25% of hip fractures per year¹⁴ and reduce annual healthcare system costs in Australia by over \$250 million (AUD).⁷ Several effective interventions for secondary fracture prevention have been established, the most notable being the development of the Fracture Liaison Service.¹⁵ These multidisciplinary clinical care programs are a coordinator-based, secondary fracture prevention service and have been implemented worldwide by healthcare systems to ensure that patients aged ≥50 years receive targeted and coordinated treatment for fragility fractures.⁹ Within this hospital-based model, Fracture Liaison Service staff members identify fracture patients, arrange for appropriate investigations to be undertaken, and then either initiate osteoporosis treatment, if appropriate, or leave the initiation of osteoporosis treatment to the primary care provider who is commonly alerted that their patient has sustained a fracture and that further assessment is required. High-quality research has shown that Fracture Liaison Services are highly effective at increasing rates of osteoporosis diagnosis and treatment initiation,^{16 17} improving health-related quality of life and physical function,¹⁸ and decreasing subsequent fractures and fracture-related mortality.¹⁷ However, almost all of these programs are hospital-based or require referral from hospital, therefore not capturing a large percentage of the population at risk of fragility fracture. Furthermore, these programs are scarce in some areas of the world, meaning that the burden of osteoporosis management commonly lies within primary care. In the absence of a robust osteoporosis and fracture care service in the primary care setting, a ‘Catch-22’ scenario prevails whereby orthopaedic surgeons or geriatricians rely on GPs to manage fractures in the community, but GPs only do so if advised by these expert clinicians. This ‘disconnect’ in communication within the healthcare system is no doubt a major contributor to the ‘osteoporosis care gap’.

GPs are generally the first point of contact for health-related concerns in Australia and are the most trusted

source of health information for most people.¹⁹ However, there are gaps in GPs’ knowledge when it comes to post-fracture care in older adults,²⁰ especially in the light of relatively newer osteoporosis medications, with 70–90% of GPs wishing to be more informed about the management of osteoporosis and fragility fractures.^{21–23} The prevalence of fragility fractures is high within the primary care setting, with studies reporting 17–30% of adults aged ≥ 50 years present to primary care centres with their first fragility fracture,^{24 25} and of these patients, approximately 70% will not have been admitted to hospital due to the fracture.²⁵ Yet, there is a lack of evidence on appropriate and effective fracture management programs in the primary care setting.^{18 26 27} A recent cross-sectional study across eight European primary care centres found a large treatment gap for women aged ≥70 years, whereby 75% of women with an increased risk of a fragility fracture were not receiving any form of osteoporosis medication.²⁸ Even among patients with prior vertebral or hip fractures the treatment gap was high, with 42% and 64%, respectively, not receiving osteoporosis treatment. The treatment gap however was much smaller in those with diagnosis of osteoporosis (30.9% vs 74.6% in women at increased risk of fragility fracture),²⁸ highlighting an urgent need to improve the diagnosis of osteoporosis in the primary care setting.²⁹ A post-fracture care program embedded within the primary care setting may have the potential to eliminate the persistent underdiagnosis of osteoporosis and address the care gaps in secondary fracture prevention.

Aims and hypotheses

GPs should play a critical role in secondary fracture prevention, even if the initial fracture management was initiated in a previous setting, and we hypothesise that the ‘osteoporosis care gap’ could be addressed by considering evidence-based systematic approaches for post-fracture care in the wider primary care setting. Therefore, this study aims to develop a new post-fracture care program for the primary care setting to enhance diagnosis and treatment of osteoporosis and improve initiation and adherence to fracture prevention strategies in older adults. Specific objectives are to:

1. Conduct interviews with primary care physicians—referred to as general practitioners (GPs) in Australia—to explore beliefs and attitudes toward osteoporosis treatment and fracture prevention and determine barriers and enablers to implementation of interventions in the primary care setting;
2. Undertake interviews with individuals with a recent diagnosis of osteoporosis and/or fragility fracture (hereafter referred to as ‘consumers’) to identify current needs in osteoporosis treatment and fracture prevention within the primary care setting;
3. Design the components of the Integrating Post-Fracture Care into Primary Care (interFRACT) care program in a series of co-design workshops with consumers and relevant stakeholders; and

4. Undertake a feasibility study with GPs to determine the usability and acceptability of the interFRACT care program.

Following the principles of co-design, at this stage it is unknown what the final care program developed in this study will consist of. However, the interFRACT care program will be tailored to the primary care setting to assist GPs in making decisions about who is eligible for osteoporosis diagnostic testing and to help communicate the risks and benefits of fracture prevention treatment for patients registered within the practice who present with their first fragility fracture, irrespective of whether initial fracture management takes place in the practice itself or has been initiated in another setting. The intervention may range from a completely innovative idea through to a simple modification of existing services, for example: the introduction of a modified Fracture Liaison Service for the primary care setting; an education program addressing GP knowledge gaps and providing easier access to information regarding anti-osteoporotic agents, engagement in falls/fracture prevention strategies such as calcium/vitamin D supplementation and structured exercise programmes, and/or clear referral pathways to appropriate healthcare professionals (exercise physiologists, endocrinologists, etc); or exploration of potential uses of new technologies (eg, electronic reminder prompt system; a clinical decision support tool).

METHODS AND ANALYSIS

This mixed-methods study will follow a co-design approach described by Boyd *et al.*³⁰ There are two phases comprising six steps in this approach; the first three aim to gain an understanding of the consumer experience and needs, while the latter three focus on how to improve that experience through design and action (figure 1).

Phase 1: exploratory phase

Step 1: engage

A Stakeholder Advisory Committee will be established comprising consumers and stakeholder groups relevant to this project. The main purpose of the Stakeholder Advisory Committee will be to provide overall guidance throughout all aspects of study design, implementation, evaluation and dissemination, and to ensure consumer/stakeholder perspectives and co-design are central to all activities. More specifically, the Stakeholder Advisory Committee will provide input on the research questions and prioritisation/agenda setting and be responsible for informing intervention development and tailoring based on factors impacting feasibility.

The committee will be led by the principal investigator (JT) and will include six consumers and six stakeholder representatives to avoid biased representation (total of 13 members). We will aim to include an equal representation of gender and representatives from at least three states/territories of Australia. Consumers will be defined as older adults aged ≥ 50 years with a current diagnosis of



Figure 1 Phases and steps of co-design in the Boyd *et al* framework.

osteoporosis, are undergoing treatment for osteoporosis and/or have suffered a fragility fracture in the previous 5 years. Stakeholders will be defined as individuals who have a professional interest in this research project or are affected by the outcomes of this research such as, but not limited to: GPs with experience in treating osteoporosis/fragility fractures; representatives of key organisations for improving bone health and reducing fracture risk (eg, Healthy Bones Australia; Musculoskeletal Australia); and subject matter experts in fracture care (eg, geriatricians, endocrinologists or fracture liaison service providers). Given the aim is to develop a care program for the primary care setting, at least two GPs will be included in the committee, however, representatives from other clinical settings are important to include for collaborative contribution of other relevant elements to post-fracture. All Stakeholder Advisory Committee members will be aged 18 years and over, be fluent in the English language, and have the ability to provide informed written consent.

Potential committee members will be identified through established links and networks from previous collaborations or recommendations from leading researchers/academics in this field in Australia. Individuals will be invited to join the Stakeholder Advisory Committee through an expression of interest process circulated via email and printed flyers throughout numerous health services. This will include advertising through currently established consumer advisory boards and organisations such as Musculoskeletal Australia, Healthy Bones Australia and the Health Issues Centre. Those who indicate an interest in joining the committee will be followed up via phone call. Consumer and stakeholder members will be remunerated for their time at the Deakin University recommended rates per hour.

Step 2: plan

The first meeting of the Stakeholder Advisory Committee will be held to plan all study steps. This hybrid-model meeting will include a mixture of in-person and remote attendees (via the virtual meeting platform Zoom) and will involve discussing and refining the overall purpose and scope of the study and the key principles underpinning its delivery; defining the target audience for the intervention and sampling plan for the next 'exploring' phase; and finalising the structure and topics for interviews. Study documentation (eg, study protocol, interview guides) and a meeting agenda will be circulated to all committee members prior to the meeting to prepare any questions or further ideas they may have about the study.

Step 3: explore

This step will involve learning about and understanding the experiences and needs of primary care services through interviews with a convenience sample of consumers and GPs; and a systematic review of the literature.

Consumer interviews

Approximately 20 community-dwelling older adults will be recruited for one-on-one interviews. To be included, participants must be ≥ 50 years of age; have suffered a minimal trauma fragility fracture in the previous 24 months, received a diagnosis of osteoporosis or received treatment for osteoporosis in the previous 24 months; and be proficient in the English language. Participants will be ineligible if they are unable to give informed consent (eg, cognitive impairment). Potential consumer participants will be identified through a variety of health services and musculoskeletal health-related organisations. Individuals will be invited to participate via written invitation or an email that will prompt interested individuals to get in touch with the principal investigator (JT) for participation. Potential participants will then be screened before providing written consent to participate in the project to ensure they meet the above inclusion criteria.

Semi-structured interview guides will be developed using Normalisation Process Theory³¹ which characterises key mechanisms that promote the implementation,

Box 1 Example vignette used to prompt discussion

A female patient in her early 60s saw her GP after falling down in the garden and injuring her wrist. The GP sent her for an X-ray and found that she had broken her wrist. After placing her in a cast, the GP thought that she might have osteoporosis and gave her some information about the condition. The patient was quite concerned to hear something might be wrong with her, but when the doctor asked if she had any questions, she couldn't think of anything to ask. She felt there was a lot of new information to try and take in during the visit, and left the appointment not really clear about she was supposed to do next.

embedding and integration of new and complex health interventions. Interviews will be conducted in-person, through telephone or via videoconferencing (Zoom), and will run for approximately 30 minutes. The interviews will be divided into three components:

1. The first component of the interview will include open-ended questions about consumer perceptions (understanding, beliefs, attitudes) and experiences of fragility fractures; engagement with clinicians across all healthcare settings; post-fracture treatment programs (including in-hospital care, Fracture Liaison Services, primary care); and facilitators/barriers to fracture prevention activities. To provide context for participants, short 'vignettes' will be written describing challenges that a consumer might face during consultations with their GP about osteoporosis and fragility fractures. These vignettes will be used to prompt discussion about barriers and enablers to post-fracture care (box 1).
2. In the second part of the interviews, participants will be provided with examples of current post-fracture care interventions and be asked for suggestions about the design and delivery of a potential new intervention for secondary fracture prevention.
3. At the end of the interview, osteoporosis knowledge of consumers will be assessed using the validated Osteoporosis Patient Knowledge Questionnaire (OPQ)³² to explore the knowledge profile of this population-based sample of older adults.

Interviews will be audio recorded, transcribed verbatim and analysed with deductive and inductive coding being applied using NVivo12. A reflexive thematic analysis using Braun and Clarke's approach³³ will be undertaken to identify themes within the data that could be used to inform content for the intervention. We will undertake an iterative analysis process, and if data saturation has not been met, we will continue recruiting participants until saturation is achieved. OPQ data will be analysed separately with a process of triangulation applied at the interpretation stage of the analysis to determine whether findings were convergent, complementary, or contradictory.

GP interviews

A total of 15 GPs will be recruited from primary care practices to participate in semi-structured interviews to elucidate information regarding their current clinical

practices and experiences with osteoporosis treatment and secondary fracture prevention. They must be current practicing GPs who have treated a patient with osteoporosis or a fragility fracture during the previous 12 months. Potential GP's will be identified through established links and networks of study investigators from previous collaborations (eg, Victoria Primary Health Networks, The Royal Australian College of General Practitioners). GPs will be invited to participate in interviews via email or advertising newsletters which will prompt interested GPs to contact the principal investigator (JT) for participant screening and obtaining written consent. Interviews will be conducted in-person, via telephone or via video-conferencing (Zoom) and will run for approximately 30 minutes.

The interview guide will be developed using Normalisation Process Theory³¹ and will include open-ended questions that explore GP views about selection of osteoporosis medications and use of different treatments; beliefs and perceived role in secondary fracture prevention; the scale and key role of coordination between all related management services for fragility fractures across different healthcare settings (eg, collaborative information from existing Fracture Liaison Services, Orthogeriatric Services or Falls Prevention Services); and potential barriers and enablers to post-fracture care in their setting (eg, access to diagnostic support). GPs will also be asked what they think a successful and feasible secondary fracture prevention intervention would look like in their clinics. Interviews will be audio recorded, transcribed verbatim and analysed with deductive and inductive coding being applied using NVivo12. A reflexive thematic analysis using Braun and Clarke's approach³³ will be undertaken to identify themes within the data that could be used to inform intervention content. We will undertake an iterative analysis process, and if data saturation has not been met, we will continue recruiting participants until saturation is achieved.

Systematic review

A systematic review of academic literature will be undertaken with the aim of identifying any interventions in osteoporosis and fracture prevention that were developed specifically for the primary care setting, and to identify best-practice strategies for secondary fracture prevention.

Step 4: develop

A hybrid-model co-design workshop (in-person and Zoom attendees) with the Stakeholder Advisory Committee will be held to establish intervention ideas for the interFRACT care program. Findings from the interviews and systematic review will be presented and discussed. Any identified barriers and enablers to osteoporosis and fracture care in the primary care setting will be discussed, and ideas for strategies to address these within the intervention will be sought. Intervention content, design and implementation techniques will be proposed and prioritised. After this workshop, the research team will develop

several intervention prototype drafts based on the priorities discussed during the workshop.

Step 5: decide

In a second co-design workshop with the Stakeholder Advisory Committee, several intervention prototypes will be presented and discussed, and a final prototype of the interFRACT care program will be developed based on the following criteria: likelihood of addressing barriers identified in Step 3; feasibility and resources required to develop and implement the intervention; potential to be delivered by GPs (as opposed to external researchers); and potential for improving diagnosis of osteoporosis and initiation of fracture prevention strategies in older adults.

Step 6: change

A pilot feasibility study to assess acceptability and usability will be conducted for the final intervention. We will elicit feedback on the intervention from approximately 15 GPs recruited via an invitation letter sent out to a number of GP clinics (GPs who had participated in the initial consultation phase will also be invited). Two approaches for measuring feasibility will be used:

1. Semi-structured interviews with GPs will be held (approximately 30 minutes each) and will involve the researchers going through each component of the interFRACT care program and asking GPs to comment on functionality of the intervention and recommendations for any revisions.
2. An online survey (via Qualtrics) of acceptability where GPs will be asked to rate ease of use and the potential value and efficacy of the intervention using a 5-point Likert scale (from strongly disagree to strongly agree). GPs will be asked if they believe the intervention could potentially improve the incidence of osteoporosis diagnosis testing (eg, Dual-energy X-ray Absorptiometry scans) and uptake and adherence of osteoporosis treatment/fracture prevention strategies (eg, bisphosphonate use, vitamin D/calcium use, exercise) in their patients with fragility fracture.

A fourth and final co-design meeting with the Stakeholder Advisory Committee will be held to discuss findings from this step and make any final changes to the care program. This will include discussion about future research that aims to test the effectiveness, implementation and future scalability of the interFRACT care program in a randomised clinical trial. The study processes are summarised in [figure 2](#).

Patient and public involvement

Co-design is a relatively new concept within healthcare in which targeted end-users and relevant stakeholders form a partnership with researchers and work together on all aspects of intervention development, from understanding the needs and experiences of end-users through to content development and pilot testing.³⁰ Involving consumers in this way is thought to increase acceptance, uptake, long-term adherence and satisfaction with the

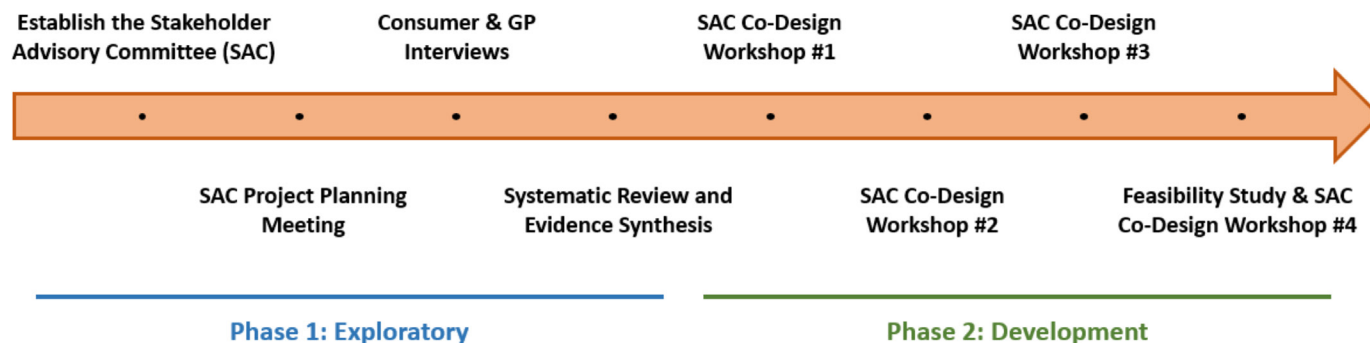


Figure 2 Flowchart of the co-design processes.

intervention, as well as improving the health outcomes of end-users.^{34 35} Patient and public involvement will be integrated throughout all stages of this research. The study will be guided by a Stakeholder Advisory Committee including consumers and stakeholders that will meet four times over the duration of the study. The Stakeholder Advisory Committee will provide overall guidance throughout all aspects of study design, implementation, evaluation and dissemination and ensure consumer/stakeholder perspectives and co-design are central to all activities so the final intervention is developed based on the needs and priorities of the end-users.

Ethics and dissemination

Ethics approval for this study has been received by the Deakin University Human Research Ethics Committee (approval number: HEAG-H 56_2022). We will use a variety of methods to ensure that our work will achieve maximum visibility. Publication of our study protocol provides an important first step in this direction to allow researchers and clinicians to know this work is being undertaken. The study results will be published across multiple manuscripts in peer-reviewed journals and presented at scientific conferences. Findings will also be collated in reports for consumers and GPs. We will use our networks and links to professional bodies to support dissemination of the findings and will use social media to promote the findings via Deakin University's dedicated Twitter and Facebook feeds. No individuals will be identified, and findings will be presented in such a way that identification of participants is not possible.

Author affiliations

¹Institute for Physical Activity and Nutrition Research (IPAN), School of Exercise and Nutrition Sciences, Deakin University, Geelong, Victoria, Australia

²The Australian Institute of Musculoskeletal Sciences (AIMSS), The University of Melbourne and Western Health, St Albans, Victoria, Australia

³School of Rural Health, Monash University, Warragul, Victoria, Australia

⁴Victorian Heart Institute, Monash University, Clayton, Victoria, Australia

⁵Department of Medicine - Western Health, The University of Melbourne, Melbourne, Victoria, Australia

Twitter Jason Talevski @JasonTalevski

Contributors The study concept and design were conceived by JT and RD. JT and SB conducted data collection. Project administration and governance were conducted by JT and SB. Analysis was performed by JT with assistance from AB. JT prepared the first draft of the manuscript. All authors provided edits and critiqued

the manuscript for intellectual content. JT is the guarantor of this work and accepts full responsibility for the finished work and/or the conduct of the study, has access to the data, and controlled the decision to publish.

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ORCID iDs

Jason Talevski <http://orcid.org/0000-0001-9180-8758>

Alison Beauchamp <http://orcid.org/0000-0001-6555-6200>

Robin M Daly <http://orcid.org/0000-0002-9897-1598>

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