

PLAIN LANGUAGE STATEMENT AND CONSENT FORM

TO: Participants

PLAIN LANGUAGE STATEMENT

Date:	13 June 2022
Full Project Title:	<u>Integrating Post-Fracture</u> Care into Primary Care (interFRACT): Development of a Post-Fracture Care Pathway for the Primary Care Setting
Principal Researcher:	Dr Jason Talevski
Associate Researchers:	Professor Robin Daly (Deakin University); Dr Alison Beauchamp (Monash University)

You are invited to take part in this research project titled “*Integrating Post-Fracture Care into Primary Care (interFRACT): Development of a Post-Fracture Care Pathway for the Primary Care Setting*”. You are being invited to take part in this research because we feel that your experience as a healthcare professional can contribute to our understanding and knowledge of local health practices.

This form will provide you with all **the information you need about this research project**. It explains what the research project will involve, why we are undertaking this research, and what your participation in this research will involve. All this information is given to you to help you decide whether you would like to take part in this research, so please read it carefully.

Your **participation in this study is completely voluntary** and there will be no cost to you. If you do not want to take part in this study, you should feel under no obligation to participate. Non-participation or withdrawal will not affect your relationship with Deakin University or any of the researchers. Before you decide if you want to take part in our research project, you can ask any questions you may have about the project by contacting Dr Jason Talevski on **(03) 9244 5116** or via email at j.talevski@deakin.edu.au

If you want to take part in this research project, please sign the consent form at the end of this document. By signing the form, you are telling us that you:

1. Understand what you have read
2. Consent to take part in the research project
3. Consent to the use of your personal information as described

1. What is the purpose of this research?

Osteoporosis represents one of the greatest global health risks for older individuals. It is estimated that 500 million people aged >50 years worldwide will have osteoporosis by 2025 resulting in approximately 13.5 million fractures annually.

Post-fracture care pathways – defined as a coordinator-based, secondary fracture prevention service implemented by healthcare systems for the treatment of older patients with a fragility fracture – have been developed and implemented across Australia, with high-quality research showing they are highly effective at improving treatment initiation and decreasing subsequent fractures and mortality post-fracture. However, the majority of post-fracture care pathways in Australia are hospital-based, even though more than 60,000 fracture patients a year do not present to hospital, therefore missing a large percentage of the population at risk of fracture.

The aim of this research is to understand current clinical practices and experiences with osteoporosis treatment and secondary fracture prevention in the primary care setting. The findings from this research project will help us develop a post-fracture care pathway designed specifically for GP clinics that can enhance detection of osteoporosis and improve initiation and adherence to fracture prevention strategies in older adults.

2. What does taking part in this research involve?

Your participation in this project will involve completing one audio-recorded interview with a member of the research team. Interviews will be conducted preferably in-person, however, can be conducted over the telephone or via videoconferencing if you prefer. Once you have returned the signed consent form, a member of the research team will contact you to ask your preferred days and times for the interview, and preferred platform.

At the agreed time and day, your interview will be conducted by a member of the research team – no one else but the interviewer will be present. Once you are ready, the researcher will let you know when they have started audio-recording. If you use a videoconferencing program, only the audio of the interview (e.g., what you say) will be recorded. During the interview, you will be asked questions about:

- Your views about selection of osteoporosis medicines and use of different treatments;
- Your beliefs and perceived role in secondary fracture prevention;
- Potential barriers and enablers to the implementation of a post-fracture care pathway in your clinic; and
- What you think a successful and feasible secondary fracture prevention intervention would look like in your clinic

If you do not wish to answer any of the questions during the interview, you may say so and the interviewer will move on to the next question. The expected length of the interview will be approximately **30 minutes**.

3. Can I withdraw from the study after agreeing to participate?

Participation in any research project is voluntary. If you do not wish to take part, you are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. People withdraw from studies for various reasons, and you do not need to provide a reason. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with Deakin University.

If you decide to withdraw from this project, please notify a member of the research team or complete and return the Withdrawal of Consent Form attached. If you withdraw from the study, you will be able to choose whether the study can use the information it has collected about you. Where both boxes are ticked in error or neither box is ticked, the study will not use any of the information it has collected about you. You can withdraw from this project up to one year after the conduction of your interview.

If you decide to withdraw from the study, please complete the withdrawal of consent form attached at the end of this form and return it to Dr Jason Talevski at the following address:

Dr Jason Talevski
Institute for Physical Activity and Nutrition, Deakin University
Melbourne Burwood Campus
221 Burwood Highway
Burwood VIC 3125

4. What are the possible benefits of taking part in this research?

We cannot guarantee or promise that you will receive any benefits from this project other than the opportunity to talk about your experiences. However, we are hoping that research into this topic will allow for more informed and improved procedures in the future in terms of post-fracture care in the primary care setting.

5. What are the possible risks or disadvantages of taking part in this research?

Participation in the study is not expected to have any risks for interviewees. You will be able to control the direction of the conversation and you do not need to answer any questions you don't want to. If you become upset or uncomfortable because of any of the questions, we can arrange counselling or other appropriate support for you (this will be free of charge). If you require immediate counselling for emotional discomfort, please call LifeLine (13 11 141) or Beyond Blue services (1300 22 4636).

6. New information arising during the project

Although highly unlikely, during the research project, new information about the risks and benefits of the project may become known to the researchers. If this occurs, you will be told about this new information. This new information may mean that you can no longer participate in this research.

7. Storage, retention, and destruction of your information

By signing the consent form, you consent to the research team collecting and using your personal information for research purposes. The information recorded is confidential, and no one else except the researchers of this study will have access to the information documented during your interview.

Paper-based information will be stored in a locked filing cabinet in an office at Deakin University in Australia. Electronic information will be stored in password-protected files on secure computer servers at Deakin University, and only accessible by the researchers named in this information sheet. The entire interview will be tape-recorded, but no one will be identified by name on the recording. At the beginning of the interview, you will be reminded not to provide any identifying information about yourself or a third party (e.g. name, date of birth). The audio recording will be professionally transcribed by an external transcribing organisation, with no identifying information included. Audio files and transcripts will be kept on secure computer servers at Deakin University.

Seven years after publication of the findings, all your data will be destroyed by securely shredding paper documents and deleting electronic files from the Deakin University server. Data from this study will not be used in any future research outside of this approved study.

8. What happens when the research project ends?

Findings from this research project will be reported to Deakin University, presented at national/international conferences, and published in scientific journals. The findings will be presented about the whole group of people who took part in the project, so you will not be identified in any reports, nor will there be the possibility of being identified in the future. When using quotes from interviews in all research outputs, pseudonyms will be generated for participants to ensure participant confidentiality and anonymity. All results will be combined, and individual responses will not be shown.

If you would like to know about the results of this project, you can contact Dr Jason Talevski on **(03) 9244 5116** or via email at j.talevski@deakin.edu.au.

9. Future research

If you are interested in taking part in other future health-related research projects at Deakin University, we will ask you to tick the relevant box on the consent form at the end of this form, stating you agree to being contacted again in the future. However, this is optional and you are under no obligation to take part in any further research undertaken at Deakin University.

10. Who is organising and funding the research project?

This research is being conducted by Dr Jason Talevski from Deakin University. Other investigators are listed on the first page of this form. The research is funded by Deakin University, Amgen, and Healthy Bones Australia.

11. Who has reviewed the research project?

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007 - updated 2018) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

The ethical aspects of this research project have been approved by the Deakin University Human Research Ethics Committee (HEAG-H 56_2022).

12. Who can I contact for more information?

If you would like more information about this research project, you can contact:

Name:	Dr Jason Talevski
Position:	Postdoctoral Research Fellow, Deakin University
Phone:	(03) 9244 5116
Email:	j.talevski@deakin.edu.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then you may contact:

The Human Research Ethics Office, Deakin University
221 Burwood Highway
Burwood VIC 3125
Telephone: (03) 9251 7129
research-ethics@deakin.edu.au

Please quote project number: HEAG-H 56_2022

Thank you for reading the project information sheet. The consent form will follow this section.

PLAIN LANGUAGE STATEMENT AND CONSENT FORM

TO: Participants

CONSENT FORM

Date: 13 June 2022

Full Project Title: Integrating Post-Fracture Care into Primary Care (interFRACT):
Development of a Post-Fracture Care Pathway for the Primary
Care Setting

Reference Number: HEAG-H 56_2022

- I have read and I understand the attached Plain Language Statement.
- I freely agree to participate in this project according to the conditions in the Plain Language Statement.
- I have been given a copy of the Plain Language Statement and Consent Form to keep.
- The researcher has agreed not to reveal my identity and personal details, including where information about this project is published, or presented in any public form.
- I agree for my interview to be audio-recorded and transcribed without revealing my identity and any personal details.

Participant's Name
(please print)

Signature **Date**

I am interested and willing to be contacted again to learn about and/or participate in further health-related research being conducted at Deakin University:

Yes, I agree

No, I do not agree

PLAIN LANGUAGE STATEMENT AND CONSENT FORM

TO: Participants

WITHDRAWAL OF CONSENT FORM

Date: 13 June 2022

Full Project Title: Integrating Post-Fracture Care into Primary Care (interFRACT):
Development of a Post-Fracture Care Pathway for the Primary
Care Setting

Reference Number: HEAG-H 56_2022

I hereby wish to WITHDRAW my consent to participate in the above research project and understand that withdrawal WILL NOT jeopardise my relationship with Deakin University. Please tick one of the boxes below to let us know if we can still use the information we have collected about you for research purposes.

NO, do not use any of the information collected about me for this research

YES, you can use the information collected about me for this research

Participant's Name
(please print)

Signature **Date**

Please post or email this form to:

Dr Jason Talevski
Institute for Physical Activity and Nutrition, Deakin University
Melbourne Burwood Campus
221 Burwood Highway
Burwood VIC 3125
j.talevski@deakin.edu.au