PLAIN LANGUAGE STATEMENT AND CONSENT FORM

TO: Participants

Plain Language Statement

Date:	6th April, 2022
Full Project Title:	TeleFFIT - A personalized, telehealth exercise and lifestyle risk factor management program to reduce falls and fracture risk in older adults: A hybrid effectiveness-implementation trial.
Principal Researcher:	Professor Robin Daly
Associate Researcher(s):	Prof Kim Bennell, A/Prof David Scott, Prof Peter Ebeling, Prof Andrea Maier, Prof Lora Giangregorio, Prof Rana Hinman, A/Prof Jennifer Watts, Dr Harriet Koorts, Dr Catherine Milte, Prof Lilian Orellana, Prof Ralph Maddison, Dr Jonathan Rawstorn, Dr Helen Brown, Dr Jenny Gianoudis, Belinda De Ross, Dr Shalika Bohingamu Mudiyanselage, Dr Tosin Olaluwoye.

This Plain Language Statement and Consent Form is **16** pages long. Please make sure you have all the pages.

1. Your Consent

You are invited to take part in this research project as you have been identified as aged 60 years or over, have access to a smart device and have osteoporosis or low bone density with various risk factors for falls/fracture. This research project will investigate the effectiveness of a telehealth-based exercise and lifestyle risk factor management program relative to usual care for reducing the risk of falls and/or fracture in older adults. This Plain Language Statement contains detailed information about the research project. Its purpose is to explain to you as openly and clearly as possible all the procedures involved in this project before you decide whether or not to take part in it.

Please read this Plain Language Statement carefully. Feel free to ask questions about any information in the document. You may also wish to discuss the project with a relative or friend or your local health worker or doctor. Feel free to do this.

Once you understand what the project is about and if you agree to take part in it, we will ask you to provide your Consent online at your first appointment with a research team member. There are two consent forms (one related to the main study and the other to access your Medicare Benefits Schedule (MBS) and/or Pharmaceutical Benefits Scheme (PBS) information (please refer below for further information). By signing the Consent Forms online, you indicate that you understand the information and that you give your consent to participate in the research project.

You will be given a copy of the Plain Language Statement to keep as a record.

Participation in this study 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. Your decision whether or not to participate will not affect your relationship with Deakin.

2. Purpose and Background

Age-related declines in muscle strength and mobility have been associated with an increased risk of falls, which when combined with low bone density or osteoporosis, can increase the risk of fracturing a bone. While various pharmaceutical agents are often prescribed as the first line of defence to treat osteoporosis and prevent fractures, current guidelines also endorse the use of exercise and nutritional approaches with lifestyle risk factor management to reduce both falls and fracture risk. However, uptake and adherence to traditional community-based activity programs is often low/poor, and not personalized to meet individuals' needs, preferences, financial and social resources.

Digital health technologies (telehealth) offer an equitable, inexpensive and accessible opportunity to meet the needs of a greater number of people with osteoporosis or at an increased risk for falls and fractures. Telehealth also has the added advantage of being able to deliver personalized programs and information and ensure timely patient to practitioner communication anywhere at any time. Therefore, the aim of this **TeleFFIT** study (**Tele**-health for **F**alls and **F**racture Prevention **I**mplementation **T**rial) is to evaluate the clinical and cost-effectiveness of a telehealth model of service delivery that will involve a smart device exercise app, health coaching, self-directed learning, and nutrition and peer support to improve self-management strategies to optimise bone and muscle health and mobility to reduce falls and fracture risk.

The specific study aims are to evaluate: 1) the long-term effectiveness of the TeleFFIT program for older adults at risk of falls/fracture on the two key clinical outcomes in the pathway to fracture –falls and hip bone mineral density (BMD) - compared to usual health care; and 2) the barriers and facilitators to implementing the TeleFFIT program in the real-life setting. A total of **386** men and women aged 60 years and over will participate in this project.

You are invited to participate in this research project because you are:

- 60 years of age or over
- Have access to a smart device
- Have osteoporosis or low bone density with some risk factors for falls or fracture
- Free of any serious health conditions that might limit your participation in an exercise program

This is a government funded study supported by a grant from the Medical Research Future Fund – Preventive and Public Health Research Initiative. It has been initiated by Professor Robin Daly, the Principal investigator of the study. There are no costs to you associated with participating in this research project, nor will you be paid.

3. Procedures – what you will be asked to do

If you decide to participate in this study, you will be asked to sign this Participant Information and Consent Form.

To participate in this study, you must have passed the initial telephone screening test conducted by one of the research staff. You must also have passed a pre-exercise health screen to make sure that you do not have any medical conditions that could affect your participation in this study or received clearance from your doctor to participate.

Upon entry into the study, you will be randomly allocated to one of two study groups: the TeleFFIT program or usual care group. For every five people, three will be randomly allocated to TeleFFIT and two to usual care. You cannot choose which group you want to be in. This is called randomisation. This is a standard research method used to ensure that the results of a study are true and correct.

What is the TeleFFIT program?

If you are allocated to the TeleFFIT program, you will be asked to take part in a 12-month home-based exercise program (at no cost to you). The program involves undertaking three 30-minute home training sessions (with the option of splitting them into 10 or 15 minute exercise 'snacking' sessions) each week, using an exercise application (app) which we will teach you how to use. The exercise program will include a warm-up and cool-down, balance exercises, moderate intensity muscle strengthening exercises for the legs, arms and back, and postural (spinal) and core strengthening exercises. You will be provided with some equipment (e.g. resistance bands, stepping box, foam mat, dumbbells) to support your program. You will also be asked to incorporate 30 to 120 daily functional weight-bearing step, dance or jumping type movements into your daily life activities (e.g. stomping during TV commercials), and from week 17 you will be instructed to perform some aerobic-type activity (such as walking) twice a week. The total time commitment for the 12 months of training will be approximately 1.5 hours per week.

All your training will be monitored by a qualified exercise practitioner (EP; exercise physiologist or physiotherapist) who will conduct an initial one-on-one consultation with you (either in person or via Zoom) prior to starting the program, to discuss your exercise preferences, health and medical history and devise a personalised program for you to complete. You will also have a video consultation with a dietitian to discuss a healthy eating plan. Throughout the 12-month program you will have regular video sessions with your EP and dietitian to monitor your progress, and you will receive regular messages (text/email) from the EP/research team to remind you to exercise and maintain your healthy eating plan, and to provide tips for you to improve self-management behaviours to improve bone/muscle health and mobility. Finally, you will also be provided with a number of online (video) self-directed education sessions around falls and fracture prevention as well as the opportunity to engage with the researchers and your fellow participants regularly throughout the program via online forums, should you choose to.

What is the usual care group?

If you are allocated to the usual care group, you will receive usual care from your doctor as well as additional exercise and falls prevention education material (online information/handouts) throughout the 12-month study.

Testing procedures

For participants living in Victoria who are able to travel to Deakin University (Burwood) for testing, you will attend campus 3-4 times over a ~12-month period:

- **Visit 1 (Baseline - prior to commencing the study):** Total time approximately 3.5 hours and will involve completing the measures shown under the heading "Study Measures" below.
- **Visit 2 (Mid-point – week 26):** Total time approximately 2 hours and will involve completing some of the measures performed at the baseline appointment.
- **Visit 3 (Final):** Will follow the same format as visit 1. This visit will take place after the intervention at around **week 52**.

For participants living interstate, you will be asked to perform a battery of tests at home at the above 3 timepoints (Baseline, Mid-point and 12-month Follow-up) via Zoom.

Study Measures

We will collect health, medical and lifestyle related information from you and conduct a number of tests throughout the study. These tests will be conducted at Deakin University (and some of you will complete tests at home under the supervision of the researchers via Zoom instead). At your testing

appointments at Deakin University prior to, at the mid-point and at the end of the study (week 52), you will undergo the following test measures:

- Total body and regional (arms and legs) body composition (amount of muscle and fat) will be measured using a non-invasive method referred to as dual energy X-ray absorptiometry (DXA). This test involves lying on a bed for approximately 8 minutes whilst a scanning arm moves along the length of your body above you.
- The same DXA machine will be used to measure your bone mineral density at the hip and spine, as well as the presence of any vertebral fractures through a lateral scan. These scans will take approximately 20-30 minutes in total.
- NB. You may be asked to come into Deakin University for a hip DXA scan as part of screening to determine your bone mineral density (and therefore your eligibility for the study). You will be asked to sign the consent form below prior to these scans, acknowledging that, should you not meet the eligibility criterion for bone mineral density, you will not be able to participate in the study.
- Your body composition and body water levels will also be assessed via a quick and simple, non-invasive test, called Bioimpedance Spectroscopy, to complement the DXA scan results. Bioimpedance measurements are taken by sending a painless electrical current through the body. The procedure is extremely safe and provides highly accurate information on body tissue composition and fluid levels.
- You will be required to undergo some simple tests to measure your muscle function such as walking speed, stair climbing and dynamic balance. We will also assess your leg, back and grip muscle strength.
- We will assess your thoracic spine posture by getting you to stand against a wall and using a small device that automatically measures the range of motion of your joints, called an inclinometer.

For participants living interstate, you will be asked to perform a battery of tests at home (via Zoom) to assess your physical functional including balance, mobility, strength and calf girth.

In addition to the above tests, all participants will be required to complete some other tests and questionnaires throughout the study. You will be asked to complete most of these questionnaires via our secure online platform.

- You will be asked to complete a general lifestyle/health questionnaire which will ask you for information on education history, marital status, past employment history, ethnic origin, skin type/sun exposure habits, medical, menstrual (women) and smoking history, alcohol consumption, and use of prescription and non-prescription medications. You will also be asked to complete a series of questionnaires related to falls efficacy, depression/anxiety, quality of life, technology proficiency/acceptance, bone/muscle health self-management behaviours and your normal physical activity and activities of daily living.
- For those of you allocated to the TeleFFIT group, you will also be asked to complete some questionnaires related to factors that might influence your physical activity and the usability and usefulness of the TeleFFIT program and study material (e.g. website, educational videos).
- Throughout the study we will ask you to record any falls each day, adverse health events or visits to any health care providers/services every 4 weeks.
- We will use an online questionnaire and ask you to record/recall all your food intake over 24 hours (1 day) at baseline and 52 weeks. Each food record will take approximately 30 minutes to

complete. This can be completed on paper if you prefer. We will also ask you to complete a dietary behaviours questionnaire at baseline, 13, 26, 39 and 52 weeks.

- We will ask you to report on your typical sun exposure habits and changes to any medications through an online questionnaire at baseline, 13, 26, 39 and 52 weeks.
- We will be measuring your normal physical activity habits over a week period at baseline, 26 and 52 weeks. To do this, you will be fitted with two small lightweight devices called an accelerometer and inclinometer. These devices store information on your general physical activity habits. The accelerometer / inclinometer will be worn on the wrist and thigh, respectively, during waking hours but not during aquatic activities. We will ask you to wear these two devices for seven consecutive days and to fill in a daily logbook telling us whenever you put on/took off the devices.
- In order to determine the cost-effectiveness of the TeleFFIT intervention (and any potential cost benefit to our health-care system) we would like to request access to your complete Medicare Benefits Schedule (MBS) and/or Pharmaceutical Benefits Scheme (PBS) data from Services Australia for the 12 months that you are in the study. Medicare collects information on your doctor visits and the associated costs, while the PBS collects information on the prescription medications you have filled at pharmacies.

Services Australia is not involved in the conduct of this study other than to release your Medicare Benefits Schedule (MBS) and/or Pharmaceutical Benefits Scheme (PBS) claims information. You will be asked to sign a separate 'Services Australia Participant Consent Form' (page 12 below) authorising the study to access your complete MBS and/or PBS information as outlined here in the Plain Language Statement. The consent of your Services Australia personal information to the study is completely voluntary and there will be no cost to you. If you do not want to consent to the release of your Services Australia personal information you do not have to. You should feel under no obligation to consent to this aspect of the study and choosing not to participate will not affect your current and future medical care in any way.

Power of Attorney or Guardianship Orders provide people the legal authority to act on behalf of someone else. If you are unable to provide consent for yourself or you are consenting for someone over the age of 14 years, Power of Attorney or Guardianship Order may be accepted. Services Australia will only accept a certified copy of an original Power of Attorney (Enduring or Medical), Guardianship order. Services Australia cannot provide the research team with participant information without supplied evidence. Statutory declarations will not be accepted.

- Some of you will be invited to participate in interviews with the study researchers at the end of the study to provide your opinion/feedback on the TeleFFIT program to assist us in developing the most effective and enjoyable program in the future. These sessions will be audio-recorded with your permission. It is possible that you may feel embarrassed or uncomfortable about being recorded but all audio-recordings of interviews will be de-identified.

There will be continual review and monitoring during your participation in this research study to enable the early detection of any problems that you may experience. You will have regular video/email/text message contact with your exercise practitioner, and they will be in regular contact with the researchers to provide updates about your progress and any concerns. Furthermore, the researchers will be contactable via phone or email if you ever have any queries/concerns at any time throughout the study.

4. Possible Benefits

We cannot guarantee or promise that you will receive any benefits from this project.

For some people, by participating in this project you may experience improvements in bone density, muscle mass, muscle strength, mobility, and performance of a number of physical function tests. The program may also reduce your risk and fear of falling, as well as your health-related quality of life. We also expect that the findings from this study will make an important contribution to the development of safe, practical and widely accessible exercise and nutrition intervention programs for reducing falls and fracture risk in older adults with or at risk of osteoporosis and fractures.

5. Possible Risks

Possible risks, side effects and discomforts related to this study include the following:

- The exercise program will involve resistance (strength) and muscle toning training, and you may experience some minor and transient muscle soreness initially following the sessions or following the muscle and functional testing. However, this form of training has been shown to be safe and acceptable. Precautions have been taken to minimise the risk of physical injury to you, but as with all types of exercise there are some risks involved, such as muscle strain. You will be given advice on how to avoid this from occurring and how to recognise if there might be a problem. It is important that you report any pain or discomfort to your exercise practitioner within the exercise app so they can monitor your progress/safety and ensure you are getting the most out of your exercise program.
- This research study involves exposure to a very small amount of radiation from the DXA scans of your body. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose you will receive from all the DXA scans of your body in this study will be approximately 0.025 mSv. At these dose levels, no harmful effects of radiation have been demonstrated, as any effect is too small to measure. The risk is believed to be minimal.

If you have been involved in any other research studies that involve radiation, please inform us. Please keep this Plain Language Statement and Consent Form that includes information about your exposure to radiation in this study for at least five years. You will be required to provide this information to researchers of any future research studies involving exposure to radiation.

There may be additional unforeseen or unknown risks that the researchers do not expect or do not know about. Please tell the research team and your doctor immediately about any new or unusual symptoms that you experience.

6. What are the alternatives to participation?

You do not have to take part in this research project. Other options available for improving your falls and fracture risk include following your GP/health providers' advice. You can discuss this with your doctor/GP before you decide whether or not to take part in this research project.

7. Other Treatments Whilst on Study

It is important to tell your doctor and the research staff about any treatments or medications you may be taking, including non-prescription medications, vitamins or herbal remedies and any changes to these during your participation in the study.

8. Privacy, Confidentiality and Disclosure of Information

Any personal information provided by you to the researchers involved with this project will remain confidential. It will only be disclosed with your permission, subject to legal requirements.

All collected information will be labelled with a unique study code, and not with your name or any other identifying information, which will be kept separate from the information collected. All online information collected from you will be collected via a secure platform (program) and transferred to

computer files that are password protected on a secure Deakin University server. Any paper copies of this information will be kept in a locked filing cabinet in the researcher's office at Deakin University. The information collected from this study will be kept until the end of the project and then placed in archives for 15 years from the publication of findings. All data will be kept in a database stored on a computer which will be password-protected and only accessible to the research staff involved in this study and may be used in future research which is closely related to this project. In the future, we may also wish to share some non-identifiable aggregate research data with other groups that obtain relevant ethics approval that are not immediately involved in this project, but your information will remain non-identifiable.

For those of you allocated to the TeleFFIT program, we will be required to enter your name and date of birth in the exercise application (app) so that we can send you your exercise program. All your exercise data will be stored online. The information contained in our TeleHab account will not be visible or shared with third parties. All data stored in TeleHab is encrypted and secure to prevent breaches against the confidentiality of data.

Your Medicare Benefits Schedule and Pharmaceutical Benefits Scheme data will only be used for the purpose of this research project, these data cannot be used in future research outside of this approved project. However, future research projects that are extensions of or closely related to this project may use other information collected for this project. This information will only be disclosed with your permission, except as required by law. Further, your consent is only specific to participation in this and closely related research projects and does not involve the establishment of a databank.

Your personal information specified within the consent form will be sent securely to Services Australia to authorise the release of your Services Australia information to the study. Services Australia will retain your consent form for the life of the study as a record of your consent. A copy of your consent form will also be retained by the study for the life of the study. Your Services Australia information will be de-identified and stored securely by the study on servers, or hosted through cloud computing providers, physically located within Australian borders. Your Services Australia information will not be sent outside of Australian jurisdiction and is governed by the Privacy Act 1988.

Your Services Australia information that has been included in de-identified data bases will be securely destroyed after the final publication of the study (15 years). However, if you withdraw from the study you can request the destruction of your Services Australia information, provided it has not been deidentified, analysed and published. All information will be securely destroyed at the completion of the study in a manner appropriate to the security classification of the record content.

For those of you invited to participant in a post-study interview, data will be collected initially in an identifiable format but will be coded prior to analysis to maintain anonymity. All data will be held in confidence and will be stored on a secure, password-protected server at Deakin University with identification numbers only. Your name will NOT be used in any published report, presentation or output. Prior to publication, you will be invited to review any anonymous quotes that are selected for inclusion in any published material.

It is the intention of the researchers to publish the results of this project. In such circumstances your identity will not be disclosed. In all cases, information will be provided in such a way that you cannot be identified. In addition, any information collected will be coded and de-identified, and stored securely in electronic format where only researchers will have access to the data.

The results of this project will be discussed at national and/or international conferences. In all cases your identity and personal information will not be disclosed. Information will be provided in such a way that you cannot be identified. In accordance with the *Freedom of Information Act* 1982 (Vic), you have the right to access and to request correction of information held about you by Deakin University.

9. New Information Arising During the Project

Although 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.

Similarly, as you will be monitored during each testing session, if it appears for any reason that you or the research staff are at risk by your continuing participation in the testing session, the person(s) supervising the research will stop your participation. In all cases you will be offered all available care to suit your needs and medical condition.

10. Results of Project

Upon completion of the project, it is anticipated that the results will be submitted for potential peer-review and journal publication in the field of musculoskeletal and/or telehealth science. The results may also be presented orally to a scientific meeting in Australia or internationally. Upon completion of the study, all participants will be invited to a group presentation conducted by the researchers who will outline the main findings from the study. In addition, all participants will receive a copy (booklet) of their key results.

11. Further Information or Any Problems

If you require further information or if you have any problems concerning this project (for example, any side effects), you can contact the principal researcher or associate researchers.

Contact Person	Telephone Number
Dr Jenny Gianoudis	03 9244 6243
Ms Belinda de Ross	03 9246 8286
Professor Robin Daly	03 9244 6040

12. Complaints / Other Issues

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital. In the event of loss or injury, you may be able to seek compensation through the courts.

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 Manager, Research Integrity, Deakin University, 221 Burwood Highway, Burwood Victoria 3125, Telephone: 9251 7129, research-ethics@deakin.edu.au

Please quote project number [2021-052].

If you have a privacy complaint in relation to the use of your Services Australia information, you should contact the Office of the Australian Information Commissioner. You will be able to lodge a complaint with them.

Website: www.oaic.gov.au
Telephone: 1300 363 992
Email: enquiries@oaic.gov.au
Mail: GPO Box 5218, Sydney NSW 2001

Your personal information Services Australia hold is protected by the Privacy Act 1988 and cannot be given to a third party without your consent or where otherwise permitted by law. For more information about privacy, go to **servicesaustralia.gov.au/privacy**

13. Participation is Voluntary

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.

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. You will also have the option to withdraw your data from the research project if you wish to do so.

Before you make your decision, a member of the research team will be available to answer any questions you have about the research project. You can ask for any information you want. Sign the Consent Form only after you have had a chance to ask your questions and have received satisfactory answers.

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. This notice will allow the research team to inform you if there are any health risks or special requirements linked to withdrawing.

You are under no obligation to continue with the consented release of your Services Australia information. You may change your mind at any time about releasing your information to the Study. People withdraw from studies for various reasons and you do not need to provide a reason.

You can withdraw your consent to release your Services Australia information by completing and signing the 'Services Australia Participant Withdrawal of Consent Form'. This form is provided at the end of this document, and is to be completed by you and supplied to the research team if you choose to withdraw your consent at a later date. If you withdraw your consent to release your information to the study, you will be able to choose whether the study will destroy or retain your Services Australia information it has collected about you. You should only choose one of these options. Where both boxes are ticked in error or neither box is ticked, the study will destroy all information it has collected about you. If you do withdraw your consent from the study and your information has already been analysed and/or included in a publication, your personal information may not be able to be withdrawn or destroyed. In such circumstances, your personal information will continue to form part of the project study records and results. Your privacy will continue to be protected at all times.

14. Ethical Guidelines

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research* (2007) 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 (EC 2021-052).

Services Australia has confirmed that a Human Research Ethics Committee (HREC) that is registered with the National Health and Medical Research Council (NHMRC), and operates within guidelines set out by the NHMRC has approved this research and any associated documents.

15. Termination of the Study

This research project may be stopped for a variety of reasons. These may include reasons such as unacceptable side effects.

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PLAIN LANGUAGE STATEMENT AND CONSENT FORM

TO: Participants

CONSENT FORM #1

Date: 6th April, 2022

Full Project Title: TeleFFIT - A personalized, telehealth exercise and lifestyle risk factor management program to reduce falls and fracture risk in older adults: A hybrid effectiveness-implementation trial.

Reference Number: [2021-052]

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.

Please do not sign this form before your first testing appointment at Deakin University with a member of the Deakin research team.

Participant's Name (printed) ……

Signature …… Date ……

Witness' Name (printed) ……

Signature …… Date ……

TO: Participants

Services Australia Participant Consent Form

Date: 6th April, 2022

Full Project Title: TeleFFIT - A personalized, telehealth exercise and lifestyle risk factor management program to reduce falls and fracture risk in older adults: A hybrid effectiveness-implementation trial.

Reference Number: [2021-052]

Consent to release of Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) claims information by Services Australia to the Deakin University for the purposes of the "TeleFFIT - A personalized, telehealth exercise and lifestyle risk factor management program to reduce falls and fracture risk in older adults" study.

Important Information (This form is only to be used for participants over 14 years of age)

Complete this form to request the release of your personal Medicare claims information and/or your PBS claims information to TeleFFIT. Any changes to this form must be initialled by the signatory. Incomplete forms may result in the study not being provided with your information.

Rights and Privacy (please tick relevant boxes):

I understand that:

☐ my MBS and PBS information will be disclosed by Services Australia for the purposes of the study.

☐ the results of this research may be published in articles or journals.

☐ my name will never be disclosed by Services Australia, used in the study or published.

☐ my participation in the study is completely voluntary.

☐ I can withdraw my participation in the study at any time (refer to participant information sheet and withdrawal of consent form) and I do not have to provide a reason for my withdrawal.

☐ I understand the information provided to me about the study I am participating in.

☐ I have been given the opportunity to ask questions, and any questions I have asked have been answered to my satisfaction.

Consent (please tick relevant boxes):

☐ I consent to the disclosure by Services Australia of my MBS and/or PBS information to researchers for the purposes of the study.

Participant details

1. Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other ☐

Family name: _____ First given name: _____

Other given name (s): _____

Date of birth: ___ /____/_____
DD / MM / YYYY

Participant details

2. Medicare card number: _____

3. Permanent address: _____

Postal address (if different to above): _____

Authorisation

4. I authorise Services Australia to provide my: ☐ Medicare & PBS claims history

For the period* _____ /_____ /_____ to: _____ /_____ /_____ to TeleFFIT.
DD / MM / YYYY DD / MM / YYYY

Date range is to be completed prior to or at the time of signing the consent form.

*Note: As Services Australia can only extract 4.5 years of data (prior to the date of extraction), the consent period above may result in multiple extractions.

☐ If in the event that I pass away during the study period, I consent to Services Australia providing my claims information to the study.

Declaration

I declare that the information on this form is true and correct.

****NB. Please <u>do not sign this form</u> before your first testing appointment at Deakin University with a member of the Deakin research team****.**

5. Signed: _____ (participant's signature) Dated: ___ /____/_____ OR
DD / MM / YYYY

6. Signed by _____ (full name) _____ (signature) on behalf of participant.

Dated: ___ /____ /_____

☐ Legal guardian** ☐ Power of attorney** ☐ Guardianship order**

* Once a young person has turned 14 years old, they must consent to their own information being released
** Please attach supporting evidence (Power of Attorney document (medical or enduring) or legal guardianship/ guardianship order documents)

Consent forms will not be processed without the relevant supporting evidence.

Power of attorney – A power of attorney is a document that appoints a person to act on behalf of another person who grants that power. In particular, an enduring power of attorney allows the appointed person to act on behalf of another person even when that person has become mentally incapacitated. The powers under a power of attorney may be unlimited or limited to specific acts.

Guardianship order – A Guardianship order is an order made by a Guardianship Board/Tribunal that appoints a guardian to make decisions for another person. A Guardianship order may be expressed broadly or limited to particular aspects of the care of another person.

SAMPLE OF MEDICARE AND PBS INFORMATION TO BE COLLECTED

A sample of the information that may be included in your Medicare claims history:

Date of service	Item number	Item description	Provider charge	Schedule Fee	Benefit paid	Patient out of pocket	Bill type
20/04/09	00023	Level B consultation	$38.30	$34.30	$34.30	$4.00	Cash
22/06/09	11700	ECG	$29.50	$29.50	$29.50		Bulk Bill

Date of referral	Rendering Provider postcode	Ordering Provider postcode	Hospital indicator	Item category
	2300		N	1
20/04/09	2300	2302	N	2

* Scrambled Provider number refers to a unique scrambled provider number identifying the doctor who provided/referred the service. Generally, each individual provider number will be scrambled and the identity of that provider will not be disclosed.

A sample of the information that may be included in your PBS claims history:

Date of supply	PBS item code	Item description	Patient contribution (this includes under co-payment amounts**)	Net Benefit (this includes under co-payment amounts**)	Pharmacy postcode	Form Category
06/03/09	03133X	Oxazepam Tablet 30 mg	$5.30	$25.55	2560	Original
04/07/09	03161J	Diazepam Tablet 2 mg	$30.85		2530	Repeat

* Scrambled Prescriber number refers to a unique scrambled prescriber number identifying the doctor who prescribed the prescription. Generally, each individual prescriber number will be scrambled and the identity of that prescriber will not be disclosed.
** Under co-payments can now be provided for data after 1 July 2012

Privacy and your personal information

The privacy and security of your personal information is important to us, and is protected by law. We need to collect this information so we can process your applications and payments, and provide services to you. We only share your information with other parties where you have agreed, or where the law allows or requires it. For more information, go to **servicesaustralia.gov.au/privacy.**

PLAIN LANGUAGE STATEMENT AND CONSENT FORM

TO: Participants

Withdrawal of Consent Form

Date: 6th April, 2022

Full Project Title: TeleFFIT - A personalized, telehealth exercise and lifestyle risk factor management program to reduce falls and fracture risk in older adults: A hybrid effectiveness-implementation trial.

Reference Number: [2021-052]

I hereby wish to WITHDRAW my consent to participate in the above research project and understand that such withdrawal WILL NOT jeopardize my relationship with Deakin University.

Participant's Name (printed) ……

Signature …… Date ……

Please mail this form to:
Dr Jenny Gianoudis
School of Exercise and Nutrition Sciences
Deakin University
221 Burwood Highway
Burwood, Victoria 3125

TO: Participants

Services Australia Participant Withdrawal of Consent Form

Date: 6th April, 2022

Full Project Title: TeleFFIT - A personalized, telehealth exercise and lifestyle risk factor management program to reduce falls and fracture risk in older adults: A hybrid effectiveness-implementation trial.

Reference Number: [2021-052]

I wish to WITHDRAW my consent to release my Services Australia information to the study effective from the date below. I request that the study handles the information they have collected about me in the following way (choose one option):

☐ DESTROY all information collected about me to date so it can no longer be used for research

☐ RETAIN all information collected about me to date so it can continue to be used for research

I understand that:

1. no further information about me will be collected for the study from the withdrawal date;
2. information about me that has already been analysed and/or included in a publication by the study, may not be able to be destroyed; and
3. choosing to withdraw from the study will not affect my access to Health Services or Government benefits.

Participant's Name (printed) ……

Signature …… Date ……

Please mail this form to:
Dr Jenny Gianoudis
School of Exercise and Nutrition Sciences
Deakin University
221 Burwood Highway
Burwood, Victoria 3125