Participant Information Sheet (Patient)

Study Title: The Frail2Fit Study: Online Nutrition and Exercise Support for Older Adults with Frailty

Researcher: Dr Stephen Lim

This project has been reviewed by the Wales REC 7 Research Ethics Committee. REC Reference: 22/WA/0155

You are being invited to take part in the above research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part in this research. You may like to discuss it with others but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.

What is the research about?

I am a doctor specialising in the Care of Older People with an interest in improving the health of older people. This study aims to see if we can train volunteers to encourage older adults to exercise in a group and to provide them with nutrition support after being discharged from hospital. We also want to know if this is acceptable to them, and their family members. We will see if the exercise and nutrition support have an impact on the health of those taking part. This study is funded by the University Hospital Southampton Research and Development grants scheme and has been submitted to the NHS Health Research Authority research ethics committee for approval.

Why have I been asked to participate?

You have been asked to take part in this study because you are due to be discharged from the University Hospital Southampton NHS Foundation Trust and you meet the eligibility criteria for this study. The inclusion criteria for this study are: anyone older than age 65, identified as frail,

who can participate safely in the exercise programme, are able to walk at least a few steps upon hospital discharge, and are able to give consent.

What will happen to me if I take part?

Online exercise and nutrition support

When you get home, you will be encouraged by volunteers to join in online home-based seated exercise and group nutrition support for twelve weeks. The volunteers delivering the programme have been trained by health professionals. In the first month you will be offered the opportunity to participate in 3 online sessions per week. Over time the number of sessions per week will reduce as you become more independent and learn how to complete the exercises.

The exercises are done seated. They are simple to complete and are designed to maintain or improve your muscle strength. It is important that you move to where you feel comfortable and at your own pace. As you get a bit fitter the volunteers can offer you a resistance band. This is a long elastic band to get your muscles safely working a bit harder. The exercise is done online in a group with your peers.

The nutrition support will involve friendly group discussion about diet and eating. The volunteers are not dieticians but they will be able to offer you direction to information that could help with eating well and feeling good.

If you struggle to access the support online, we have an iPad (computer) you can borrow. We can also show you how to use the iPad and how to access the online sessions. Our research staff will be here to help you throughout the programme. If you do not feel comfortable using the online support then you can opt for telephone support instead.

Evaluating the programme

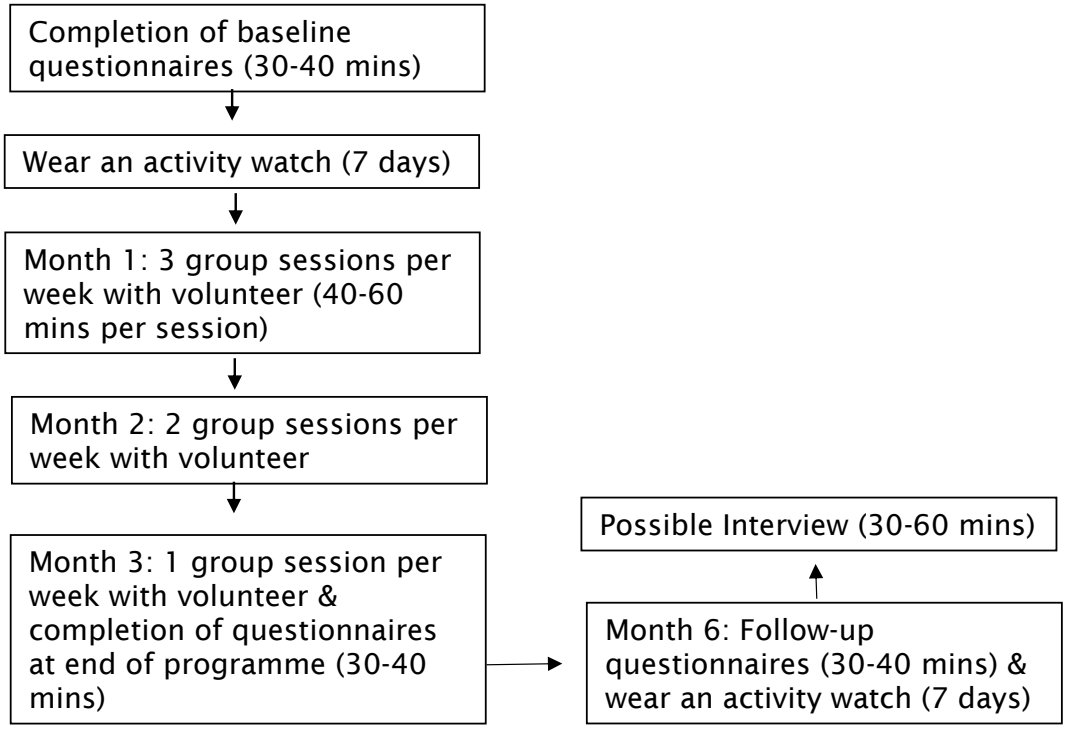
To find out if the online support works, we would like to learn about your health and well-being. We might also ask you some questions about your experiences participating in the programme.

Before you leave hospital a research assistant, who is a healthcare professional, will collect some basic information about you. This will include measurements of your physical health, eating habits and activity levels with questionnaires. You will also be given an activity watch

(accelerometer) to wear for 7 days when you get home. This watch will accurately measure your activity levels. After three months and six months, we will contact you again to repeat the measurements to determine the impact of the exercise and nutrition support on your health. The repeat data collection process will be done at your own home over the telephone and activity watches will be posted to you with a return pre-paid envelope.

You may be invited to attend an interview to share your views and experiences on the exercise and nutrition support programme. Interviews will take place over the phone, or online (e.g., Zoom) depending on your preference. Interviews will be audio-recorded. If you do participate in an interview your details will be anonymised (non-identifiable participant information), which means that no one outside the research team will know your name. People will read about the things you say to us, but they will not know who said those things.

Timeline



Are there any benefits in my taking part?

Studies have shown that exercise training and nutrition support are beneficial in improving physical function of older people. One of the benefits of taking part in this study is that you will be taught evidence-based exercises and nutrition advice which will be conducted in group online sessions. Exercising in an online group can also be a positive experience as the social aspect of group exercises has been shown to be a source of motivation.

By taking part in this study, you will also be contributing to further research to improve the health of older people.

Are there any risks involved?

The risks involved in this study are minimal. Common injuries that may occur during exercises include muscle strain and back pain. To reduce the chances of any injuries you will be encouraged to exercise at your own pace to a level you feel comfortable with. The exercises are gentle seated movements and will be shown to you by friendly volunteers who have been trained by health professionals.

Less commonly, is the risk of falls. However, the exercise programme is likely to help promote improvement in balance and muscle strength, which may help reduce the risk of falling. This study does not involve any invasive procedure.

What will happen in case of an emergency?

The volunteers will be taught how to deliver the support sessions safely. However, in the unlikely event that you require immediate medical attention (e.g., collapse) the volunteer will contact the emergency services. If you experience an adverse event (e.g., a muscle strain) then the volunteer will let us know (the study team) and we will get in contact with you to escalate the situation further, if required. Feel free to contact us if you have any worries or concerns during the programme.

What data will be collected?

We will collect basic information such as your gender, date of birth, age, physical function status, and cognitive status. Using validated questionnaires, we will measure your physical activity levels, eating habits and well-being. These questionnaires will take approximately 30-40 minutes to complete with assistance from one of the research team. We will also measure your activity levels using an activity watch (accelerometer). These measures are important as it will help determine if the exercise and nutrition programme had a positive impact on your health. You may be invited to an interview to explore your views and experiences about the exercise and nutrition programme. Interviews will be recorded using a digital audio-recorder.

Your contact details will be recorded to allow the research team to contact you at 3 and 6 months to re-do questionnaires. Your address will be recorded in case of an emergency during the exercise session. This will enable volunteers to notify the emergency services of where you are if needed.

Your information will be anonymised (made non-identifiable) during the data analysis process and published data will not include any identifiable participant information.

Will my clinical care team know if I want to participate in the study?

If you decide to volunteer for the study, we will send a letter to your clinical care team to let them know that you are participating in the research if you consent to this in the consent form.

Will the online sessions continue when the study has finished?

The online support sessions will last 12 weeks during the study. There will be no further online support sessions when the study has finished. However, you will be given resources, including booklets and access to online videos to continue with your exercise and nutrition changes at home in your own time.

Will my participation be confidential?

Your participation and the information we collect about you during the course of the research will be kept strictly confidential.

Only members of the research team and responsible members of the University of Southampton may be given access to data about you for monitoring purposes and/or to carry out an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential.

Data collected will be entered electronically on the computer and stored on the university's networked storage. Access to this information will be password-protected. Hard copies of participant information will be stored in a locked filing cabinet in a secure office in our research unit and will be accessible only by the research team. Audio recordings for the interviews will be deleted once they have been transcribed. Codes are allocated to each participant to ensure that the data is anonymised. Only the researchers in this study will have access to your data.

In accordance with the regulations we are required to keep your data secure for 10 years.

Your data may be used in future studies by our research team. If this happens, your data will be used anonymously (non-identifiable participant information) so you cannot be identified. Any new research studies using your data will be authorised by the local research ethics committee.

Do I have to take part?

No, it is entirely up to you to decide whether or not to take part. If you decide you want to take part, you will need to sign a consent form to show you have agreed to take part.

Please inform me if you wish to take part in this study and I will be in touch with you to provide you with more information and go through the consent process.

Meredith SJ, *et al. BMJ Open* 2023; 13:e069533. doi: 10.1136/bmjopen-2022-069533

University of Southampton

What happens if I change my mind?

You have the right to change your mind and withdraw at any time without giving a reason and without your participant rights being affected. Please inform the volunteer leading the sessions or me if you wish to withdraw from the study.

If you do not wish to carry on with this study, you can withdraw at any time without giving a reason. If you decide to withdraw we would like to retain the use of anonymised (non-identifiable participant information) routine data and any data already collected which would be important for the overall study results.

What happens if I have given consent but then lose capacity to consent during the study?

You and all your identifiable data collected during the study would be withdrawn from the study. Data which is not identifiable to the research team may be retained.

What will happen to the results of the research?

Your personal details will remain strictly confidential. Research findings made available in any reports or publications will not include information that can directly identify you without your specific consent. The results of the research will be published in scientific journals. Research staff may also present the results at conferences and local meetings, and on a website where it would be available to members of the public. You will not be identified in any report produced.

If you are interested, when we have finished analysing the study data, the research team will phone you to share the results. We will also place the study findings on a website (https://www.arc-wx.nihr.ac.uk/) and point you to any open access research publications. If you are interested but do not have access to the internet we can post the results upon request.

Where can I get more information?

For further information, please contact me (**Dr Stephen Lim)** at s.e.lim@soton.ac.uk, or by telephone 023 8120 6131.

Or you can contact the research assistant Dr Samantha Meredith at s.j.meredith@soton.ac.uk, or by telephone 078 2510 4783.

What happens if there is a problem?

If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions. If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, rgoinfo@soton.ac.uk).

NHS Indemnity Insurance

The University Hospital Southampton NHS Foundation Trust will act as sponsor for this research study and will provide insurance for the study through the NHS indemnity scheme. The insurance will meet the potential legal liability of the sponsor for harm to participants arising from the design of the research and the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research. Moreover, volunteers will be insured by The Liabilities to Third Parties Scheme (LTPS) through NHS Resolutions. This will provide volunteers with employer's liability, public liability, products liability, and professional indemnity cover.

How will we use information about you?

We will need to use information from you for this research project. This information will include your:

- Name
- Age
- Address
- Telephone number
- Gender
- Medical status

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.
Once we have finished the study, we will keep some of the data so we can check the results. We will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed and stored data will be destroyed. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?
You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to sponsor@uhs.nhs.uk, or

by ringing us on +44(0)23 8120 3598.

Thank you for taking the time to read the information sheet and considering taking part in the research.

University of Southampton

Participant Information Sheet (Volunteers)

Study Title: The Frail2Fit Study: Online Nutrition and Exercise Support for Older Adults with Frailty

Researcher: Dr Stephen Lim

This project has been reviewed by the Wales REC 7 Research Ethics Committee. REC Reference: 22/WA/0155

You are being invited to take part in the above research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part in this research. You may like to discuss it with others but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.

What is the research about?

I am a doctor specialising in the Care of Older People with an interest in improving the health of older people. This study aims to see if we can train volunteers to encourage older adults to exercise in a group and to provide them with nutrition support after being discharged from hospital. We also want to know if this is acceptable to them, and their family members. We will see if the exercise and nutrition support have an impact on the health of those taking part. This study is funded by the University Hospital Southampton Research and Development grants scheme and has been submitted to the NHS Health Research Authority research ethics committee for approval.

Why have I been asked to participate?

You have been asked to take part in this study because you are a patient support hub volunteer at University Hospital Southampton NHS Foundation Trust.

What will happen to me if I take part?

You will be trained to deliver online group exercises and nutrition support for older people with frailty. Below we will outline your training and the online programme.

Volunteer Training

The training will be a combination of in-person and online content led by various health professionals specialising in nutrition and exercise for older adults. You will also be given additional resources to support your training including booklets and online videos. Training will take place for half a day in-person at University Hospital Southampton and 3 hours of online training. Also, we are available for any additional one-to-one training sessions that you would like.

The training will be split into 3 main sections:

1) Exercise Training: We will teach you how to safely deliver seated exercises to older adults online, including use of elastic resistance bands (2 hours).
2) Nutrition Training: We will teach you how to engage older adults in conversations about their nutrition and where to signpost older adults for more information about healthy eating (2 hours).
3) Behaviour Change Training: You will be invited to an online course in 'healthy conversation skills' to help you empower older adults to improve their exercise and nutrition (3 hours).

Online Programme for Older Adults with Frailty

The supportive online sessions that you will be delivering to the older adults will last approximately 45-60 minutes and will include 20-30 minutes of exercise and 15-25 minutes of nutrition support. You will also be taught how to motivate lifestyle changes and how to make sure the exercise and nutrition support are safe and enjoyable.

We would like you to deliver the support sessions for 12 weeks to a small group of older adults.

- In the first month (week 1-4) you will deliver 3 sessions per week.
- In the second month (week 5-8) you will deliver 2 sessions per week.

- And in the last month (week 9-12) you will deliver 1 session per week.

You will be teamed up with another volunteer, so you can support each other in the delivery of the sessions. Also, the trainer will support you throughout the project and will organise regular group volunteer meetings to discuss any concerns or feedback.

You may also be invited to attend an interview to share your views and experiences on delivering the online programme. Your details will be anonymised, which means that no one outside the research team will know your name. People will read about the things you say to us, but they will not know who said those things.

Are there any benefits in my taking part?

Studies have shown that resistance exercise training and nutrition support are beneficial in improving physical function. One of the benefits of taking part in this study is that you will be taught evidence-based exercises and dietary advice which will be conducted in group sessions. By doing the exercises yourself, you are also likely to benefit from it. Exercising in a group can also be a positive experience as the social aspect of group exercises has been shown to be a source of motivation. By taking part in this study, you will also be contributing to further research to improve the health of older people.

Are there any risks involved?

The risks involved in this study are minimal. Common injuries that may occur during exercises include muscle strain and back pain. Less commonly, is the risk of falls. However, the exercise programme is likely to help promote improvement in balance and muscle strength, which may help reduce the risk of falling. This study does not involve any invasive procedure.

What will happen in case of an emergency?

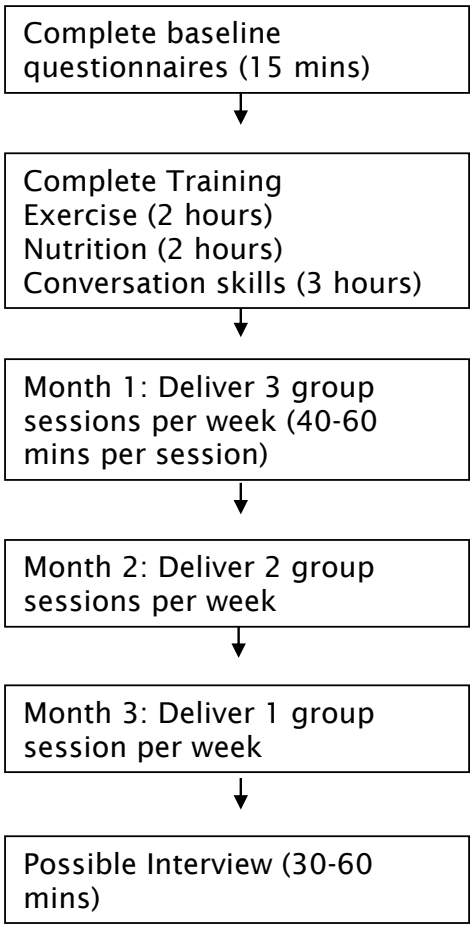
You will be taught how to deliver the support sessions safely. However, in the unlikely event that a participant in your group requires immediate medical attention (e.g., collapse) you will need to call for help (staff will be available in the Patient Support Hub), or contact the emergency services. If a participant experiences an adverse event (e.g.,

a muscle strain) then you will need to let us know (the study team) and we will get in contact with them to escalate the situation further, if required.

What data will be collected?

We will be collecting basic information such as your gender, age and ethnicity. You may be interviewed to explore your views and experiences about the exercise programme. Interviews will take place on the telephone, or online (e.g., Zoom) depending on your personal preference. Interviews will be recorded using a digital audio-recorder. Participant information will be anonymised (non-identifiable participant information) during the data analysis process and published data will not include any identifiable participant information.

Timeline



Will the online sessions continue when the study has finished?

The online support sessions will last 12 weeks during the study. There will be no further online support sessions when the study has finished. However, participants will be given resources, including booklets and access to online videos to continue their exercise and nutrition changes at home in their own time.

Will my participation be confidential?

Your participation and the information we collect about you during the course of the research will be kept strictly confidential.

Only members of the research team and responsible members of the University of Southampton may be given access to data about you for monitoring purposes and/or to carry out an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential.

Data collected will be entered electronically on the computer and stored on the university's networked storage. Access to this information will be password-protected. Hard copies of participant information will be stored in a locked filing cabinet in a secure office in our research unit and will be accessible only by the research team. Audio recordings for the interviews will be deleted once they have been transcribed. Codes are allocated to each participant to ensure that the data is anonymised. Only the researchers in this study will have access to your data.

In accordance with the regulations we are required to keep your data secure for 10 years.

Your data may be used in future studies by our research team. If this happens, your data will be used anonymously (non-identifiable participant information) so you cannot be identified. Any new research studies using your data will be authorised by the local research ethics committee.

Do I have to take part?

No, it is entirely up to you to decide whether or not to take part. If you decide you want to take part, you will need to sign a consent form to show you have agreed to take part.

Please inform the researcher if you wish to take part and the research team will be in touch with you to provide you with more information and go through the consent process.

What happens if I change my mind?

You have the right to change your mind and withdraw at any time without giving a reason and without your participant rights being affected. Please inform the researcher if you wish to withdraw from the study.

If you do not wish to carry on with this study, you can withdraw at any time without giving a reason. If you decide to withdraw we would like to retain the use of anonymised (non-identifiable participant information) routine data and any data already collected which would be important for the overall study results.

What happens if I have given consent but then lose capacity to consent during the study?

You and all your identifiable data collected during the study would be withdrawn from the study. Data which is not identifiable to the research team may be retained.

What will happen to the results of the research?

Your personal details will remain strictly confidential. Research findings made available in any reports or publications will not include information that can directly identify you without your specific consent. The results of the research will be published in scientific journals. Research staff may also present the results at conferences and local meetings, and on a website where it would be available to members of the public. You will not be identified in any report produced.

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Or you can contact the research assistant Dr Samantha Meredith at s.j.meredith@soton.ac.uk, or by telephone 078 2510 4783.

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How will we use information about you?

We will need to use information from you for this research project.

This information will include your:

- Name
- Age
- Address
- Telephone number
- Gender
- Medical status

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.
Once we have finished the study, we will keep some of the data so we can check the results. We will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed and stored data will be destroyed. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?
You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to sponsor@uhs.nhs.uk, or
- by ringing us on +44(0)23 8120 3598.

Thank you for taking the time to read the information sheet and considering taking part in the research.

The Frail2Fit study
14th June 2022 Version 1.1 [Ethics/IRAS number 309521]

University of Southampton

CONSENT FORM

Study title: The Frail2Fit Study: Online Nutrition and Exercise Support for Older Adults with Frailty

Researcher name: Stephen Lim **REC Reference:** 22/WA/0155

Participant Identification Number:

Please initial the box(es) if you agree with the statement(s):

I have read and understood the information sheet version _____ dated _____ and have had the opportunity to ask questions about the study.	
I agree to take part in this research project and agree for my data to be used for the purpose of this study.	
I understand my participation is voluntary and I may withdraw (at any time) for any reason without my participation rights being affected.	
I understand that should I withdraw from the study then the information collected about me up to this point may still be used for the purposes of research only.	
I agree to take part in the interview for the purposes set out in the participation information sheet and understand that these will be recorded using video or audio recording.	
I understand that my confidentiality as a participant in this study will remain secure and that the transcript of the interview will not contain my name or identifiable information. I agree for my data to be stored anonymously and that any published quotations or extracts from the research will maintain my confidentiality.	
I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from University of Southampton study team, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	

I understand that my personal information collected about me such as my name or where I live will not be shared beyond the study team.	
I agree that anonymised data collected in this study may be used for future research by the study team.	
I would like my clinical care team to be notified that I am participating in this research.	

Name of participant (print name) .....

Signature of participant .....

Date .....

Name of researcher (print name) .....

Signature of researcher .....

Date .....

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[1 copy for the participant, 1 copy for the file]