



Over 60 years of age?

Problems walking?

Walking more slowly?

We need people to take part in a study

All participants take part in an exercise programme to improve walking and muscle strength.



Half of the participants are given protein drinks to help build their muscles.



We are trying to find out if having protein drinks make the exercise programme work better.

If you want to find out more then please read the rest of this information leaflet.



Insert local TRUST LOGO

Local Research Team: *Name; phone; email*

Local Investigator:

PARTICIPANT INFORMATION SHEET

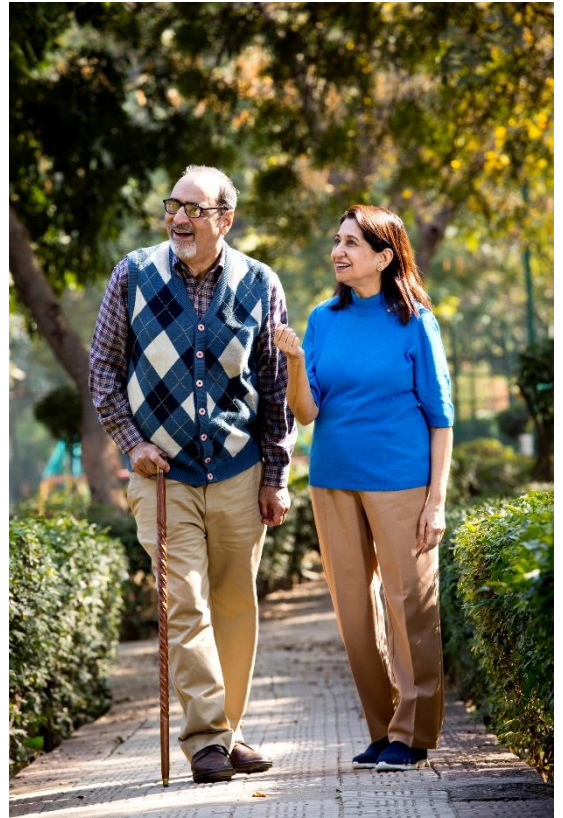
Maximising Mobility and Strength Training (MMoST) Feasibility Trial

You are invited to take part in our study. Before you decide, we want you to understand why the research is being done and what it involves. Please read this information. Feel free to discuss with others or contact us with any questions.

What is the purpose of the study?

Walking is the key to remaining independent and doing things we enjoy in later life. As we get older, our muscles get smaller and weaker, and we may find walking more difficult.

One way to improve walking is through exercises that build muscles. Having extra protein in your diet may also help. However, we do not know this for certain, so we want to undertake a study to find this out.



What is protein?

Protein is made up of chemicals called amino acids. Your body uses these amino acids to build and repair muscles. Protein is found in many foods including meat, fish, milk, yoghurt, cheese, nuts, seeds, lentils, beans, chickpeas, and tofu. Some older people may benefit from adding extra protein to their diet. Adding extra protein by having a protein drink may make exercises work better by building stronger muscles.

What are we hoping to learn?

We want to find out if older people who take extra protein by having a protein drink, as well as joining an exercise programme, experience better walking and have a better quality of life.

Large studies are expensive and challenging to run, so we are starting with this smaller study to make sure that it is possible to run a larger study. We want to check that we can find enough people who may benefit from extra protein and are willing to take part. We also want to ensure that participants are happy to take protein supplements and how easy it is for NHS physiotherapy departments and participants to conduct the exercise sessions.

What you would be asked to do?

There are three eligibility checks. Firstly, a research nurse will telephone you to make sure the study is right for you. Then, you will visit the study centre in [location xxxxxx xxxxxxxx xxxxxxxx xxxxxxx] for an assessment including a dietary assessment to work out how much protein you usually eat, to take a small blood sample and some physical measurements (travel costs paid). The final check is a second dietary assessment done via the computer or over the phone.

If you pass all three checks, you will be enrolled in a 24-week exercise programme designed especially for you by a physiotherapist to improve your walking. You will attend a weekly exercise class for 16 weeks at your local site and exercise at home once a week. When the classes finish, you will do 8 weeks of home exercises twice a week, with telephone support from the physiotherapist.

Half the participants will take daily protein drinks. These will be delivered to your home (free of charge). The drinks are not suitable for people with milk or soya allergies or who are intolerant to lactose. A physiotherapist or dietitian will review you regularly throughout the study.

Eight months after starting the study, you will go to the study centre for a final assessment and blood samples (travel costs paid).

Reasons you may not be able to take part

We need to ensure it is safe for people to take part in the study. Therefore, you will not be able to take part if, you are unable to walk 3 metres without physical assistance; live in a residential care or nursing home; have been diagnosed with dementia (or would be unable to safely follow verbal instructions); have Parkinson's disease, dysphagia (or require a modified diet due to swallowing problems), or severe kidney disease; if you are already taking protein supplements or taking insulin to control diabetes or if you are allergic to milk or soya or you are lactose intolerant.

Things you need to know before deciding to take part:

Who is taking part and why have I been invited?

We want to recruit 50 people aged 60 and over who have problems with their walking and may benefit from extra protein in their diet. You have been invited to take part because you have indicated to a health professional, or in answers to a questionnaire, that you have some difficulties with your walking.

What are the benefits of taking part in the study?

We have already tested this exercise programme in another study, and it improved participants' walking. We hope you will have similar benefits. We do not know whether taking the protein supplements will improve your strength and walking, as this is the reason we want to conduct a study.



Could I be harmed from taking part in the study?

You are unlikely to be harmed by doing the exercises. A physiotherapist will assess you to make sure that the exercises are at the right level for you. You may experience muscle soreness after completing some of the exercises. This is normal and the physiotherapist will give you advice on how to manage this.

Protein supplements may cause mild gastrointestinal complaints including diarrhoea, constipation and bloating. These types of complaints are usually short lived as your body adjusts to the supplements. The supplements may cause some loss of appetite

and weight loss so we will monitor your weight regularly and adjust the dose, if needed.

We will ask you for a blood sample, which will be taken using a finger prick test, so we can check your kidney function. We will collect about 0.5ml of blood which is around 8 to 10 drops of blood. There is a possibility of bruising to your finger and/or fainting, but care will be taken to avoid this happening. We will perform the blood test once prior to you joining the study and then once more, at the very end of the study. There is a small chance that the blood sample cannot be analysed which would result in us needing to take a second sample.

Do I have to take part?

No, you do not have to take part in the study. You can also change your mind and withdraw from the study at any time. This will not affect your medical care.

Expenses and payments

The University of Oxford will pay for your travel expenses to attend the two research assessments. The University of Oxford are not able to pay you for taking part or to pay travel expenses to attend the exercise classes.

<Insert for certain sites PIS only, as applicable: - However, at your study site there are local arrangements to support your attendance at the classes which you may be eligible for. Your local research clinician will discuss this with you.>

If you are still interested in taking part, then here is more detailed information about the study processes.

Eligibility assessment – is this the right study for you?

If you are interested in taking part, you will be asked to provide your contact details and your permission to be contacted by a researcher. Then a researcher will take you through the following steps:

STEP 1. A researcher will telephone you to discuss the study (10-15 minutes). They will ask you questions about your health, diet and mobility to check your eligibility. We are looking for people who may benefit from extra protein in their diet. To do this, with your consent, the researcher will ask questions about your current diet. We will also ask your permission to access recent blood test results from your health records, which can help us check this study if right for you (explained in Step 2). If you appear to be eligible and you are willing to continue, the researcher will arrange an appointment to see you in person.



They will post you a simple food diary to record what you have to eat and drink for a 24-hour period before the appointment so we can do a fully dietary assessment to check how much protein you currently eat each day.

STEP 2. You will attend an appointment at

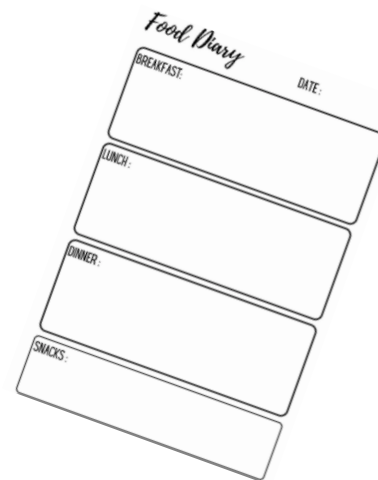
[LOCATION xxxxx xxxxxx xxxxxxxx xxxxxxxxx xxxxxxxxx]

(90 minutes). A researcher will ask further questions to check that you are suitable for the study (and you want



to take part), you will be asked to sign and date a consent form and provide your full contact details.

The researcher will then go through your completed food diary with you and check whether you might benefit from extra protein in your diet. The information about your food intake will be entered into an online diet questionnaire which will add up how much protein you have eaten that day. You will then be asked to do some simple physical tasks including a walking and balance test and complete a paper questionnaire about your health and wellbeing.



People with reduced kidney function should not have protein supplements. We will check your kidney function using a blood test unless you have already told us that you have had a kidney function blood test in the past three months and we are able to access the results of this (with your permission). The blood sample will be collected using a finger prick and will collect approximately 8-10 drops of blood. If your kidney function is too low, you will not be able to take part in the study. We will contact you and your GP to make sure you are aware of this and that you receive the appropriate care.



STEP 3. After this appointment, you will be asked to complete the second food diary at home as we need to assess your diet on more than one day. The information about your food intake will be entered into the online questionnaire again; you can either do this yourself or the researcher will do this for you. If you choose to do this yourself, the researcher will give you instructions on how to do

this. If you choose to complete the questionnaire yourself online, we can email you a link to the questionnaire or write it out for you (if you don't have an email address). Alternatively, the researcher will phone you and you will be asked to provide the information from your food diary to allow the researcher to complete this. We will use the information from your two food diaries to find out whether this study will be suitable for you. Once we have this information and the result of your blood test we will contact you to let you know whether you are eligible to join the study.

What happens if I am eligible?

If you are eligible, you will be allocated to one of two treatments.

| | | |
|---|-----------|---|
| Treatment A: Exercise classes | OR | Treatment B: Exercise classes plus protein supplements |
|---|-----------|---|

A computer randomly selects which treatment you will receive. You or the researcher cannot choose the treatment you receive. This is important because it ensures that the treatments are tested fairly, and no one can influence which treatment group the computer puts you in.

What will the treatment involve?

Individual physiotherapy assessment (60-90 minutes)

All study participants will be invited to attend an individual appointment with an NHS physiotherapist at [locationxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx] prior to attending the exercise classes. The physiotherapist will run through the exercise programme with you and ask you some questions so they can set the exercises to the right level for you and teach you the exercises. These are the exercises you will do at the exercise class and at home. You will be told at this appointment whether

you will receive the protein supplement, or not, and given instructions on taking them.

Exercise classes - Mobility and Strength Training

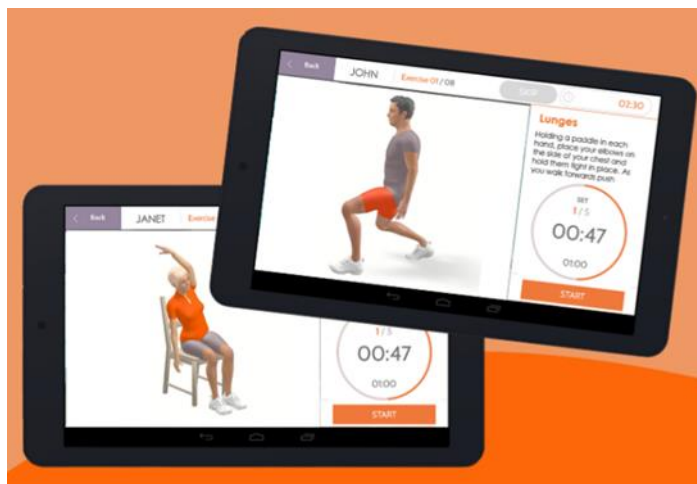
You will be invited to attend a weekly group exercise class for 16 weeks with other people taking part in the study at [locationxxx]. Each class lasts for 1 hour and is led by an NHS physiotherapist. During the class you will carry out the exercises and walking programme tailored to your own individual ability. There will be group discussions about how to develop good exercise habits at home and for the long term. A researcher from the Study Team at the University of Oxford may attend some of your exercise classes to check that the classes are being run as planned.

We hope that classes will be run face-to-face. However, if COVID-19 restrictions mean that this is not possible, a physiotherapist may visit you at home (if you give your permission for this) to deliver the exercises or you may be given the option of an online class. Local COVID-19 rules will be followed at all times.

Exercise at home

While attending the weekly class, you will be asked to do your exercises at home on one other day each week. After the classes have finished, you will be asked to do your exercises at home, twice a week, for a further 8 weeks. During this period the physiotherapist will telephone you up to 3 times to check how you are getting on. You will be given an exercise diary to record the exercises you complete. We will collect this from you during the group exercise session and then at the end of the study we will ask you to complete the exercise diary and return it to the study team (a stamped, addressed envelope will be provided).

To support your home exercises, you will also be given the option of using an app that is designed to help people to exercise at home, called GoodBoost. Using the GoodBoost app is entirely optional. If you would like to use the app then you would need to download it onto your smart phone or tablet and create an account. We will give you instructions. We are interested to know how many people decide to use this app and how many times they use it.



With your permission, a researcher from the Study Team at the University of Oxford may visit you at home to see how you are getting on with the home exercises. If so, they will call you beforehand to arrange a convenient date and time.

Protein supplement

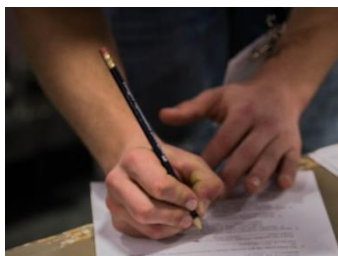
Half of the people taking part in the study will receive protein drinks.

The protein drink has been made for people needing to increase their muscle size and strength. It is supplied by Nutricia (part of Danone). It comes in a powder, and you will need to make up a drink by adding it to water in a special shaker, which we will give you. It is strawberry or vanilla flavoured and has a similar consistency to milk. You will have the chance to choose which flavour you prefer. The supplements will be delivered to your home, free of charge. It is not suitable for those with a milk or soya allergy or who are intolerant to lactose so if you have any of these allergies you will not be able to take part in the



study. The supplement drink is halal. It is not suitable for vegans or those who follow a kosher diet.

The physiotherapist (with input from a qualified dietitian), will advise you on the amount to take and how to take it. The number of protein drinks per day will be based on the information you gave us about your diet when you first joined the study. You will be asked to take the protein drinks daily for 24 weeks and start taking them on the day of your first exercise class. We will give you a diary to record the drinks you have taken each day. You can also receive text message reminders if you want to do so.



If you are already taking vitamin D and/or calcium tablets, you may need to stop taking them because the protein drink contains vitamin D and calcium. If applicable, the physiotherapist will discuss this with you and may ask you to talk to your GP.

What happens after I have received the treatment?

Eight months after joining the study, you will be invited to [location xxxxxxxxxxxx xxxxxxxxxxxx xxxxxxxx] for a follow-up appointment with the researcher. We will ask you to complete a questionnaire about your health and wellbeing and do some simple physical tasks including a walking and balance test. We will contact you before you attend the appointment to also ask you to complete the food diary (either online or on paper). You will be asked to then complete the food diary one final time after the appointment. We will re-check your kidney function using a blood test, to see if this has changed since you started the study. If you have had a blood test in the past month, we



will ask your permission to check this result. Otherwise, we will take a blood sample from your finger as before.

Will my General Practitioner (GP) be informed of my participation?

With your permission, we will write to your GP to tell them you are taking part. We will contact your GP if there are any findings at any stage of the study that they need to know about. This includes, the results of some of the screening tests which indicate you should seek medical advice, if we identify that you have substantial problems with your memory, the study dietitian has concerns about your general health due to very low weight or very poor dietary intake, or if blood test results show you may have reduced kidney function. We may also request your GP review your Vitamin D and/or calcium prescription.

During this study, we will collect information or data about you. You need to know what happens to your data. The rest of this information leaflet explains how we keep your data safe, who can see it and the processes in place to make sure the study is run correctly.

United Kingdom data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the sponsor for this study, based in the United Kingdom, and is the data controller and is responsible for looking after your information and using it properly.

The University of Oxford will use information from you (including the contact details you provide) and your medical records in order to undertake this study and will use the minimum personally-identifiable information possible. We will keep identifiable

information about you for one year after the study has finished. This excludes any research documents with personal information, such as consent forms, which will be held securely at the University of Oxford for 3 years after the end of the study.

The [local NHS Trustxxxxxxxxxxxxxxxx] will use your name, home address, phone number and email address (where applicable), to contact you about the research study, and to oversee the quality of the study. They will keep identifiable information about you from this study, including those with personal information, such as consent forms, securely at [Name of NHS Trust xxxxxxxx xxxxx xxxx xxxx] for 3 years after the study has finished.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at <https://compliance.web.ox.ac.uk/individual-rights>

You can find out more about how we use your information by contacting the MMoST Study Team on mmost@ndorms.ox.ac.uk

Will my taking part in the study be kept confidential?

All information collected will be kept strictly confidential by the research team. Apart from your consent form and your contact details, all study information will be identified by a study number only. All information will be stored securely and only accessible by study staff and authorised personnel.

The only people in the University of Oxford who will have access to the information that identifies you will be people who need to contact you about your involvement in the study, to provide you with the follow-up questionnaire, to send you a copy of the study results or to audit the data collection process.

If you are allocated to receive the protein supplement, with your permission we will pass your contact details and your date of birth to the delivery company (Nutricia Homeward) via a secure nhs.net email. They need this information to deliver the supplements and to confirm your identity. They will hold this information until the end of the study.

We are using an online dietary assessment tool (Myfood24.org) but we do not enter any information that will identify you. If you chose to complete the diet questionnaire yourself online, a unique link will be created for you and sent to you using your email address.

If you want to use the Good Boost app then you will be required to create an account and agree to the terms and conditions of use. Good Boost will give the Oxford Study Team information about how many participants used the app and how many times. They will not share any of your personal data entered into the app with us. We will not share any of your study data with Good Boost.

If we take a blood sample from you, your year of birth and gender will be shared with Medicecks.com Ltd via a secure online portal. This information is needed by the laboratory for the measurement of kidney function, but no other personal identifiable data will be shared.

Responsible members of the University of Oxford [and the relevant NHS Trust(s)] may access your data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

What will happen to the samples I give?

The blood samples taken for this study will be transferred to an accredited laboratory which is planned to be Eurofins County Pathology Ltd, (although an alternative approved and accredited laboratory may be used if required) using Tracked Royal Mail delivery for processing and once the kidney function result (eGFR) is known, the sample will be destroyed.

What will happen if I don't want to carry on with the study?

You can leave the study at any time, without giving a reason. This will not affect any care that you receive from the NHS or any other healthcare provider. Data collected up to the point of withdrawal would still be used.

What will happen to the results of this study?

The results of this study may help us decide if it is possible to do a large trial. We plan to share the results in medical journals, at conferences and online. You will not be identified in any report or publication. At the end of the study, you will be posted a summary of the study findings which will also be made available on the study website

What if we find something unexpected?

If during the clinical assessments, exercise sessions, blood tests or from your responses to the questionnaires, concerns about your health are raised then we will notify your GP who may contact you.

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment which is provided.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact the Chief Investigator, Dr Esther Williamson, (Email: mmost@ndorms.ox.ac.uk; Tel: 0800 085 3922)

You may also contact the University of Oxford Research Governance Ethics and Assurance office on 01865 616480, or the director of RGEA via email: rgea.complaints@admin.ox.ac.uk

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study. If you wish to contact the PALS team please contact [insert relevant NHS site phone number and email from the PALS website <http://www.ouh.nhs.uk/patient-guide/pals.aspx>].

How have patients and the public been involved in this trial?

Other patients like yourself have been involved throughout the design of this study and will continue to be involved in the running of the study. These patient advisers have helped guide us on how best to conduct dietary assessments. They were also involved in reviewing this Patient Information Sheet, and all participant information/documents used in the study.

Who is organising and funding the trial?

This trial is sponsored by the University of Oxford and funded by the National Institute for Health Research.

Who has reviewed the trial?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by London - Surrey Research Ethics Committee.

For further information contact the MMoST Study Team:

Email: mmost@ndorms.ox.ac.uk

Telephone: 0800 085 3922

Post: Botnar Research Centre, University of Oxford, Windmill Road, Headington, Oxford, OX3 7LD

Thank you for considering taking part.