

How do I take part?

Please fill out the reply slip and send it to us in the FREEPOST envelope (no stamp is needed).

If you have any questions please contact the study team

Phone: 02380 591756 Email: stream@soton.ac.uk

Who is running the study?

This study is run by the Universities of Southampton, Oxford and Warwick and has ethical approval from the North West—Greater Manchester East Ethics Committee (Reference: 19/NW/0415).

The study is funded by the National Institute for Health Research, which funds most research in the NHS. The study is insured by the University of Southampton.

‘Eat well, feel well, stay well’ was written by a team of health professionals, patients and scientists from the University of Southampton.

Study contact

If you have any questions about this study, please contact:

Eat well, feel well, stay well study (STREAM trial) team

Local co-ordinator contact details: Natalie Thompson

Phone: 02380 591756 Email: stream@soton.ac.uk

What if I have a concern or complaint about the study?

Please contact:

Dr Alison Knight

Head of Contracts, Policy and Governance

Building 28, Room 2029

University Road

Southampton

SO17 1BJ

Phone: 023 8059 5058 Email: rgoinfo@soton.ac.uk

Eat well, feel well, stay well (The STREAM Trial)



You are invited to take part in a study

- ◆ Please phone us on 02380 591756 if you would like us to talk you through this leaflet.
- ◆ We are running a study to find out about the appetite and eating patterns of people aged 75 or over.
- ◆ Your doctor’s surgery is supporting this study.
- ◆ You are invited because you live at home and may also have one or more health conditions OR have recently been in hospital OR live alone. Any of these can affect your appetite and eating.
- ◆ This leaflet tells you what will happen if you choose to take part in the study.
- ◆ All our study activities and teams carefully follow Government advice about staying safe during the COVID-19 pandemic.

What is the study about?

We want to test a new tool that can help your doctor's surgery to support the health needs of people aged 75 and over. We are interested in how we can help people with their appetite, eating and drinking. Some surgeries will use this new type of support tool and other surgeries will continue with their usual care. Which type of support is decided by chance.

What would I do in the study?

We will send you a list of questions to answer. These will ask about yourself, your appetite and eating patterns, and will take about 30 minutes to answer. We will give you a FREEPOST envelope so that you can send them back to us.

Some people will then also be asked to:

- ◆ Keep a diary to note any coughs, colds or other infections
- ◆ Complete a questionnaire every 6 months (Max of 3).
- ◆ Speak with a nurse by phone or at the surgery a few times to see how you are finding your appetite and eating and check your weight and height. The nurse may offer booklets or supplement drinks if needed.
- ◆ Visit the surgery after 18 months for simple measures of height, weight, grip strength, standing and walking.

Don't worry, the team will let you know when it's time to do each step.

Is there anything else I can help with?

Optional extras: If you want to, we may ask you to:

- ◆ Provide 3 urine samples in one week, near the start of the study and again 18 months later
- ◆ Provide a blood spot sample, near the start of the study and again 18 months later.

The samples are to tell us if these simple tests can be used to assess people's nutrition accurately. Samples will be destroyed after analysis.

- ◆ Tell us what it has been like to be in the study (a small number of people will be asked to consider this)

You can still take part even if you don't want to do these optional things.

What are the risks and benefits of taking part?

We have tested the study tasks with 350 people, and our patient advisers, so we are confident that there is little burden and no risk in taking part.

- ◆ If your appetite is low, taking part may help reduce any worries you have about your eating patterns and support you to keep eating well, even when it's difficult.
- ◆ Any travel expenses will not be reimbursed.
- ◆ If you are sent the questions at 18 months, you will receive a £10 gift voucher.

Do I have to take part?

No, it is up to you if you take part in the study and you can change your mind at any time. You do not have to tell us why. Your medical care will not be affected if you stop taking part.

If you don't carry on with the study, we would still like to use any answers or information you have already given us, unless you tell us not to. If you tell us you don't want to carry on with the study, we will write to ask if there is anything you would still like to help with.

Will my details stay private?

The study team has to take care of any information about you. For more details please see the data protection privacy notice in your pack.

- ◆ Your personal details will be kept separate to any study information you give us (like your answers to lists of questions).
- ◆ During the study, information about you e.g. consent forms and contact details, will be kept securely at the University of Southampton, Oxford or Warwick. After the study, it will be transferred securely and stored in a sponsor approved secure facility for 10 years and then destroyed .
- ◆ All personal data stored on University computers will be deleted after study results have been analysed and published
- ◆ Only you, your healthcare team, the research team and study regulators will see information about you (Data Protection Act 2018).
- ◆ Your personal details will not appear in published results, and code names will be added to anything related to you, so you can't be identified.