

The FIREFLI study:

Do Safe and Well Visits delivered by the Fire and Rescue Service reduce falls and improve quality of life among older people? A randomised controlled trial (FIREFLI)

Can you help?

We invite you to take part in a study

- Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve.
- Please take time to read the following information carefully and decide whether you wish to take part.
- It's up to you to decide if you take part or not. Please ask us if there is anything that is not clear or if you would like more information. Talk to others about the study if you wish.
- If you have any questions, please contact us.

Contact details

If you require further information about this study, you can contact the study co-ordinators at York Trials Unit:

Rachel Cunningham-Burley
or Gareth Roberts

Freephone number: 0800 138 6555
email: ytu-firefli@york.ac.uk

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1 Why are we doing this study?

The Fire and Rescue Service nationally routinely carry out around 670,000 Safe and Well Visits each year in people's homes. During these free visits someone from the fire service gives fire safety advice within the home. They also check and fit free smoke alarms if needed. As part of the visit the fire service also take the opportunity to look at wider issues such as health, keeping warm in the winter, stopping smoking and how to prevent falls.

Falling is a common problem among older people, with most falls occurring in the home. While up to half of people over 80 may fall each year, falling is not a normal part of ageing and things can be done to help prevent falls.

In this study, we want to find out whether Safe and Well Visits undertaken by members of the Fire and Rescue Service reduce the number of falls people have and whether these visits improve the wellbeing of those visited.

2 Why am I being asked to take part?

The University of York is working together with Humberside Fire and Rescue Service to carry out this study. We are sending you this because you have contacted us requesting more information about the study. Thank you for your interest in the FIREFLI study!

3 Who can take part in the study?

We regret we are unable to include everybody in the study. We will check if you can take part when you return your completed screening form.

To be included in this study you need to be:

- aged 65 or over
- live in the area covered by Humberside Fire and Rescue Service
- eligible for a Safe and Well Visit from the Fire and Rescue Service

We will also need to check with the Fire and Rescue Service to see if you are eligible for a Safe and Well visit from them. This means we will need to let them know your address so they can check this before you can take part in the study.

4 What if I need help to take part?

If you need assistance to take part due to a condition that affects your memory, thinking or ability to make a decision, we may still be able to include you. If you think this may apply to you, please ask someone you live with to help you. We call this person a 'consultee'.

Your consultee will need to:

- provide their contact details on the enclosed contact sheet, so we can send them some more information explaining what they need to do
- agree to act as a 'consultee' and talk to the study team, advising them about your views and feelings about taking part in the study

5 What happens in this study?

People in the study will be contacted by a member of the Fire and Rescue Service to offer them a Safe and Well visit at an agreed date and time. Please note, your visit may take place at either the start or end of the study (after 12 months). However, because appointments are made on a random basis, you will not be able to choose when your visit will be. You will have an equal chance of receiving your visit at the beginning or end of the study. As part of the booking process the Fire and Rescue Service may ask you questions about yourself and your home on the phone, before your visit. You will also receive a falls prevention leaflet.

The visit will last approximately one hour during which a member of the Fire and Rescue Service will discuss and make you aware of any fire or falls risks in your home and what you can do to reduce or prevent these. They may also suggest ways to keep your home warm in winter.

During the visit the Safe and Well officer of firefighter will complete a checklist with you. While you do not have to accept or make any of the changes or modifications to your home that may be suggested during the visit, the Fire and Rescue Service will support any that you wish to make.

For the purposes of the study you will be asked to complete monthly 'falls calendars' recording any falls you may have each month, or, if you prefer, you can telephone us on a freephone number to let us know if you have fallen.

In the unfortunate event that you do fall or need a visit from the Fire and Rescue Service, or an occupational therapist, your participation in the study would not delay or prevent this and we will record what has occurred.

6 What happens if I want to take part?

Steps in the project

If you wish to take part in the study, please return the screening questionnaire and consent form by post to Department of Health Sciences, York Trials Unit, ARRC Building Lower Ground Floor, York, YO10 5DD



YTU staff will check your Screening Questionnaire to confirm if you are eligible to take part
AND
check with the Fire and Rescue if you are eligible for a Safe and Well Visit by sharing your address with them



If you can be included, we will send you some falls calendars and another questionnaire



You will receive a Safe and Well visit either at the start or the end of the study (in 12 months' time)



Complete and return the falls calendars every month



You will be sent follow-up questionnaires at four, eight and 12 months



You will receive a newsletter at three and seven months and just before the end of the study



We will send you a summary of the results (optional)



Study results published- we can send you copies of these too

- We would ask for your help for no more than 24 months. The information you provide will allow us to follow your health and see if it changes over time.
- If you have any questions, we would ask you to ring the researchers at the University of York. If you prefer, a family member or a friend can contact us on your behalf.
- If we need any further information from you during the time you are taking part in the trial members of the research team at York Trials Unit may contact you by post, telephone, or, if you agree, text or email.

Frequently asked questions

How long do the questionnaires take?

About 25 minutes in total.

Will I know the member of the Fire and Rescue Service is genuine?

YES. They will show their ID before they enter your home. You may also phone the Fire and Rescue Service to verify their identity.

How will I know when my Safe and Well Visit will take place?

A member of the Fire and Rescue Service will contact you to arrange the visit at an agreed date and time.

How do I return a falls calendar?

Please return these by post each month, alternatively please call us on our freephone number 0800 138 6555.

Will I need to travel?

NO. A member of Fire and Rescue service will come to your home and the questionnaires will be posted to you with a freepost envelope.

Will my GP be notified?

YES. We will inform your GP. We will also contact your GP if we have any concerns about your physical or mental health during your participation. If you do have a fall, we may contact your GP to find out some further information.

Can everyone over 65 be included?

No. Unfortunately we cannot include everyone in the study. We need to check the information you provide and see if you can take part.

What is a fall?

An event including a slip or trip, in which you come to rest on the ground floor or lower level.

7 What are the benefits and disadvantages of taking part?

- we cannot promise that taking part will help you personally. However, it may help us find out how to improve the well-being of older people.
- taking part in this study will involve some of your time to complete questionnaires.
- if you are offered a visit from a member of the Fire and Rescue Service, they will need to visit your home.

8 Do I have to take part?

NO. Taking part is entirely voluntary. If you decide not to participate, you may still be offered a Safe and Well Visit from your local Fire and Rescue Service. Alternatively, you may be able to request a visit by directly contacting the Fire and Rescue Service. If you change your mind at any point during the study, you will be able to withdraw your participation without having to provide a reason.

9 Will my taking part in the study be kept confidential?

YES. Any information you provide will be treated in confidence. At the beginning of the study authorised research team members at the University of York will record your name, address, telephone number and date of birth in order to contact you about the FIREFLI study. We will also keep a copy of your signed consent form. All paper records will be stored in secure storage facilities and all electronic records will be stored on an encrypted and password protected server within the York Trials Unit, or securely by companies operating within the UK or EU offering 'cloud' based services. If you decide you no longer wish to take part in the study, we will keep the information you have given us, up to the date you tell us you will be withdrawing from the study.

The University of York will send your address securely to the Fire and Rescue Service for them to check you are eligible for a Safe and Well visit before you can join the study and, if you do take part, they will send your contact details to enable the Fire and Rescue Service to contact you to arrange the Safe and Well Visit. They will follow the same rules about keeping your information safe. The Fire and Rescue Service will also let the researchers know if they have attended your home during the trial because of a fire.

What will happen to the data collected in the study?

The results of this study may be published or presented at meetings and in scientific journals. They may also inform Fire and Rescue Service policies and highlight where to focus their preventative/health protection work. The costs of treatment will also be explored to see if a Fire and Rescue service Safe and Well home visit is good value for money. Anonymised data that you provide may be used by authorised researchers studying other relevant research projects.

Your name will not be mentioned in any publications arising from the study and we will ensure that individuals cannot be identified from details in reports of the study results. If you agree to us contacting you about other studies, we will keep your personal data for a total of 10 years after the study has finished, to allow us to do this. Researchers working at the University of York, York Trials Unit may have access to your details.

If you would like to read more information about how we will use your personal data and what your rights are under the Data Protection Act 2018 and General Data Protection Regulation (GDPR), please see the information on this website:

<https://www.york.ac.uk/healthsciences/research/trials/trials-gdpr/>

If you prefer, we can send you a copy of this information in the post; please contact the research team on Freephone 0800 138 6555

Further information about Data Protection and GDPR (the small print)

The University of York is the sponsor and data controller for this study based in the United Kingdom. We will be using information from you and records from the Fire and Rescue Service about you, to undertake this study.

How will we use information about you?

We will need to use information from you, and the Fire and Rescue Service for this research project.

This information will include your name, contact details, information you send us in questionnaires and falls calendars about:

- any falls you have
- your quality of life
- your health conditions
- any health services you have used
- general information about you
- details about the Safe and Well Visit if you had one
- if the Fire and Rescue Service came to your home because you had a fire, during the trial period

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 write our reports in such 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 up until the point you asked us to withdraw you from the research.

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/
- at www.hra.nhs.uk/patientdataandresearch
- at <https://www.york.ac.uk/healthsciences/research/trials/trials-gdpr/>
- at <https://www.york.ac.uk/healthsciences/research/trials/trials-gdpr/research-participants/>
- by asking one of the research team
- by sending an email to ytu-firefli@york.ac.uk , or
- by ringing us on phone number Freephone 0800 138 6555

10 Who is running the study?

This study is being organised by researchers from the University of York in collaboration with researchers from the University of Nottingham, James Cook University Australia, Leicester Partnership NHS Trust and Kent Fire and Rescue Service and Humberside Fire and Rescue Service.

Before any research goes ahead it is looked at by an independent group of people called a Research Ethics Committee, who look out for your safety, rights, wellbeing and dignity. This study has been reviewed and approved by the West Midlands - Coventry & Warwickshire Research Ethics Committee, Reference Number 21/WM/0050. The University of York's Department of Health Sciences Research Governance Committee has also reviewed the study.

11 What if there is a problem?

If you have concerns about any aspect of this study first please contact one of the FIREFLI study co-ordinators Rachel Cunningham-Burley or Gareth Roberts on Freephone 0800 138 6555, who will do their best to answer your questions.

If you wish to raise a complaint on how we have handled your personal data, you can contact the University of York's Data Protection Officer, who will investigate the matter (dataprotection@york.ac.uk). If you are not satisfied with our response or believe we are processing your personal data in a way that is not right or lawful, you can complain to the Information Commissioner's Office (ICO) whose details can be found here: (www.ico.org.uk).

While we anticipate no harm or distress to anyone as a result of this study it is important to state that there are no special compensation arrangements. If you are harmed due to someone's negligence, then you have ground for legal action, but you may have to pay for it.

12 What do I do now?

Having read the information, you have the following options:

[Yes, I want to take part](#)

If you want to take part in the study, please complete the consent form and contact details sheet and return these in the **smaller** of the pre-paid envelopes provided (no stamp needed) and return the completed screening questionnaire in the **larger** envelope.

If you need any help to complete the forms, please phone us and we will be happy to help.

We will then write to you in a few weeks to ask you to fill in a short questionnaire. We will write to you to confirm you are involved in the study and tell your GP.

[No, I do not want to take part](#)

There is no need to do anything if you do not want to take part.

[I am unsure and want more information](#)

If you have any queries about this participant information sheet or concerns about how your data is being processed, please contact Rachel Cunningham-Burley or Gareth Roberts on Freephone 0800 138 6555 in the first instance. If there is no answer, please leave a message.

[If you want to act as a consultee on someone else's behalf](#)

If you want to act as a consultee on behalf of someone who has a condition which affects their memory, thinking or ability to make a decision, then please contact a member of the study team using the details above to discuss.

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<https://www.fundingawards.nihr.ac.uk/award/NIHR128341>

*Thank you for reading
this information sheet!*