TRIAL PROTOCOL
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Full title: 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)

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1. **Contents**

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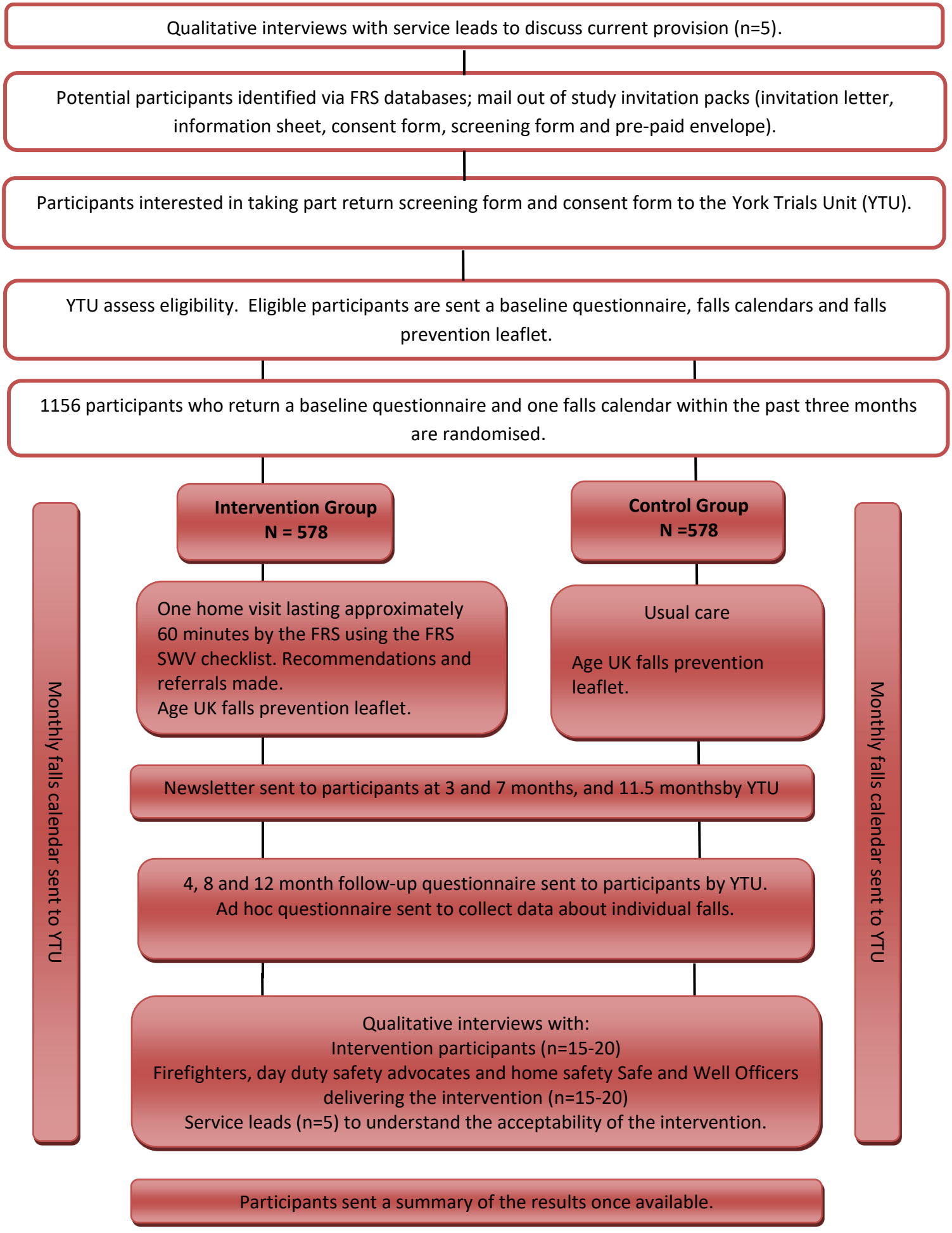
3. Trial summary

3.1 Trial summary table

Long title	Do Safe and Well Visits (SWV) delivered by the Fire and Rescue service (FRS) reduce falls and improve quality of life among older people? A randomised controlled trial.
Acronym	FIREFLI
Study design	A large pragmatic, individually randomised, controlled trial with embedded economic and qualitative evaluations.
Setting	Participants' homes.
Target population	1156 community dwelling men and women aged 70 years and over. Participants will be recruited from databases held by Humberside and Kent FRSs.
Control	Usual care from healthcare professionals; falls prevention leaflet; SWV by the FRS (either a firefighter, day duty safety advocate or Safe and Well Officer) offered 12 months post-randomisation.
Intervention	Usual care from healthcare professionals; falls prevention leaflet; SWV offered by the FRS (either a firefighter, day duty safety advocate or Safe and Well Officer) approximately three weeks post-randomisation.
Primary outcome	There are two primary outcomes: 1. The number of self-reported falls per participant over the 12 months from randomisation 2. Health-related quality of life measured by the EQ-5D-5L (EuroQol 5 Dimensions, 5 level version) over the 12 months from randomisation.
Secondary outcomes	• Time to first fall and between subsequent falls • Proportion of participants reporting at least one fall and multiple falls (two or more falls) • Fear of falling • Loneliness (UCLA 3-item) • Fall related injuries and costs • Fire risk taking behaviours • Uptake of flu jab • Smoking status of residents within the property; smoking inside the property; smoking in bed; referral to NHS stop smoking services • Participant-reported fire within the property that the FRS attended

	• Participant-reported fire within the property that the FRS did not attend • FRS-reported attendances to participants' homes for fire related incidents.
Estimated recruitment period	September 2021 to September 2022 dependent on COVID-19
Duration per patient	13 to 24 months approximately
Estimated total trial duration (subject to approval from PHR)	50 months February 2020 to March 2024 (Subject to delays due to COVID-19 pandemic)
Number of participants	1156
Number of trial sites	Two (Geographical areas covered by Humberside and Kent FRSs).
Inclusion criteria	• Men and women aged 70 years and over • Community dwelling • Willing to receive a SWV from the FRS
Exclusion criteria	• Living in a residential or nursing home • Bed bound • Unable to give informed consent to take part in the study **and** living alone • Had an occupational therapist (OT) home visit within the past 12 months • Received a SWV from the FRS in the past three years • Have been referred to the FRS as an urgent referral

3.2 Study flow chart of participants through the FIREFLI study



3.3 Participant assessment schedule

	Screening form	Baseline	Monthly data collection	Randomisation (Eligible patients + BLQ + 1FC*)	Approximately 2-4 weeks post-randomisation	Post-randomisation	3/7/11.5 months post-randomisation	4/8/12 months post-randomisation
Eligibility screening by researchers at YTU	√							
Postal informed consent	√							
Demographic data: DOB, gender	√							
Personal details: name, address, telephone number	√							
Contact details, GP details	√							
EQ-5D-5L		√						√
Falls data		√	√					
Economic evaluation data		√						√
Demographic questions: ethnic group, living arrangements		√						
Randomisation				√				
SWV **; intervention delivery checklist completed					√			
Observation of SWV					√			
Newsletter update							√	
Outcome data								√
Adverse events			√	√	√		√	√
Participant qualitative interviews						√		
Qualitative interviews with members of the FRS						√		
Qualitative interviews with service leads						√		

*BLQ – baseline questionnaire, FC – falls calendar; ** SWV - Intervention participants only, control group receive after trial completion

3.4 Plain English summary

The Fire and Rescue Services routinely carry out around 670,000 fire safety visits each year in people's homes. The aim of these 'Safe and Well Visits' is to reduce fire risks, support independent living, improve quality of life, and help prevent avoidable hospital admissions and excess winter deaths.

One part of the Safe and Well Visit (SWV) is looking at ways to prevent falls. The FRS will work with people to help them reduce their risk of falling. This may be helping people to identify trip and fall hazards within their home, or suggesting they attend a falls prevention clinic. For some people, falling can cause serious health issues and in some cases may be fatal. About a third of people over the age of 65, and half of those over 80, will fall each year. Most of these falls happen at home. Falling may cause people to lose confidence, feel as if they have lost their independence and become withdrawn. About a fifth of all of the falls people have need medical attention. There were around 210,000 people admitted to hospital, as an emergency, in England in 2016 due to having had a fall. It costs the NHS about £2.3 billion a year to treat patients who fall. The problem is likely to get worse as people are living longer. What we don't know is whether Safe and Well Visits undertaken by members of the Fire and Rescue Service reduce falls and if they are good value for money.

To find out if Safe and Well Visits reduce the number of falls people have, and improve their quality of life, we will conduct a trial. We will recruit 1156 people aged 70 years and over from lists of people held on Fire and Rescue Service databases. We will allocate half of the people to receive a Safe and Well Visit at the start of the study. The visit will last about an hour and will be tailored to the risks of the people living in the household. The other half of the people will receive the Safe and Well Visit after 12 months (when they have finished the study). Everyone will receive a falls prevention leaflet from Age UK and their usual care from their GP and other health care professionals. Participants will be asked to fill in monthly falls calendars and four questionnaires over 12 months to collect information about falls, their quality of life, how often they have used NHS services, and whether they are doing any activities that make them more likely to have a fire in their home. This information may be collected over the phone or we may send questionnaires in the post. Researchers will analyse the data to find out if the Safe and Well Visits reduce falls and if

they are good value for money. We also want to find out if the Safe and Well Visit is acceptable to and valued by older people and to the Fire and Rescue Service. We will explore this through a series of in-depth interviews.

Once we have completed the trial, we will make sure our results can be used by as many people as possible. We will send the people who took part in the study a summary of our findings, and the results will be presented at relevant conferences and published in scientific journals. We will share these findings with other Fire and Rescue Services.

4. Background

4.1 Safe and Well Visits

Fire and Rescue Services (FRSs) have traditionally delivered Home Safety Checks (HSC) in people's homes to reduce their risk of fire and advise what actions should be taken in the event of a fire. Many FRSs have expanded these HSCs to include health related themes. These include falls prevention; smoking cessation; social isolation; and winter warmth. Visits that include these health elements are usually known as Safe and Well Visits (SWV). The SWV target households known to have a higher risk of fire (likelihood and/or consequences) such as occupants aged 70 years and over, people with poor mobility, and people who have a history of alcohol or tobacco dependency.

The aim of the SWV is not only to reduce fire risk, but to support independent living, help prevent avoidable hospital admissions and excess winter deaths, and to contribute to improving quality of life particularly for people aged over 65. The FRS carry out approximately 670,000 Fire Safety Visits in people's homes each year in England (1). There is some evidence to indicate that these visits are effective. The Winter Pressures Pilot service evaluation, commissioned by Public Health England (PHE) and the Chief Fire Officers' Association (CFOA), was conducted between October 2015 and March 2016. It aimed to reduce the risk of winter-related ill health in vulnerable groups of people (2). The evaluation found that the home visits were more effective in addressing falls, cold homes and social isolation, but less effective at influencing the uptake of flu vaccinations. However, this was not a randomised controlled trial (RCT) and potential improvements to

quality of life were not considered, nor was a full economic evaluation undertaken [insert ref] .

4.2 Fire and falls

There are common risk factors for fire and falls. For example, older people and those with mobility problems are at increased risk of falling and at increased risk of injurious fires (3) as they may have difficulties getting out of their home, especially if they have fallen and cannot get up. There may also be common, modifiable risk factors for both fires and falls such as unsafe items in entrances/exits or hoarding.

Falls in older people are highly prevalent and can have serious consequences. Approximately a third of people over the age of 65 years, and half of those over 80, will fall each year (3-5). Fall related fractures are a serious cause of morbidity and cost to society (6). A fifth of all falls are serious and require medical attention with 5% of falls leading to a fracture. This has a major impact on health care resource use, primarily due to fractures. Falling can cause people to lose confidence and independence, and become withdrawn. Repeated falls commonly precipitate admission to institutional care. They tend to be experienced by those over the age of 75 years, who are more frail and are more likely to sustain hip fractures due to slowed protective reflexes or have underlying medical conditions such as osteoporosis (3, 7). There were around 210,000 falls-related emergency hospital admissions in England in 2016/2017 (8) costing the NHS more than £2.3 billion per year to treat (5). If we can reduce the proportion of people who fall and the number of falls people have, there could be a large impact on admissions to hospital due to fall related injuries and consequent savings in primary and secondary care costs.

Approximately 85% of falls occur in the home. Environmental hazards are implicated as a major contributor to falls among older people and are frequently cited as causes of falls in the literature. One review described ‘accident/environment related’ factors as responsible for a mean of 31% (range 1-53%) of all falls (n=3,628) across 12 studies (7). The latest Cochrane review of interventions for preventing falls in older people living in the community (9) identified six trials, involving 4,208 participants, evaluating a home safety assessment and

modification. They concluded that home safety assessment and modification interventions were effective at reducing both the rate of falls (relative risk of rate of falling 0.81, 95% CI 0.68 to 0.97) and risk of falling (relative risk of falling 0.88, 95% CI 0.80 to 0.96). They also concluded that these interventions were more effective in people at higher risk of falling, and when delivered by an occupational therapist (OT). However, the conclusions of this review are not supported by the recent findings of the National Institute for Health Research – Health Technology Assessment funded OTIS trial [in press]. This trial found home hazard assessment and modification delivered by an OT did not reduce falls in community-dwelling older people deemed at higher risk of falling recruited to this trial. Whilst four of the trials included in the Cochrane review involved non-occupational therapists, none involved members of the FRS delivering a home assessment or modifications. Members of the FRS are not only concerned with the health consequences of falling, but also the need to get out of a property in the event of a fire. Whether this will motivate people to undertake the changes required to reduce risk of falls is unknown. In addition, the FRS are unlikely to change their practice around falls prevention based on the OTIS results, as this evaluated an OT falls prevention intervention and not one delivered by members of the FRS. Another Cochrane review (10) concluded that multifactorial interventions may reduce the rate of falls compared with usual care, although the quality of the evidence was rated as low. There is growing evidence to suggest that early identification, multifactorial assessment and early intervention can make a significant impact on an individual's risk of falls. As many falls are caused by simple hazards (7) such as trip hazards, it could be that if the FRS were able to identify and remove trip hazards or recommend relatively simple home modifications, coupled with onward referral to other services, then this could lead to a reduction in falls.

4.3 Smoking and risk of fire

In 2019, the proportion of current adult smokers in England was estimated at 14.1%. Men are more likely to smoke than women (15.9% compared to 12.5%) whilst those aged 65 years and above were less likely to smoke (7.8% compared to 13.9% in those aged 55 to 64, 15.9% in those aged 45 to 54, 15.5% in those aged 35 to 44, 19.0% in those aged 25 to 34, and 16.0% in those aged 18 to 24) (11). However, since 2012, the city of Kingston Upon Hull

has been in the ten local authorities with the highest proportion of current smokers at least seven times, with 22.2% of the population reporting they smoke (11).

Smoking within the home increases the fire risk within the home. In 2018/19 smokers' materials were reported as the source of ignition in 10% of accidental dwelling fire non-fatal casualties and 34% of fire-related fatalities. Fires caused by smoking materials result in more deaths than any other type of fire (12). Within the population as a whole, men were found to have a greater likelihood of dying in a fire than women. For men aged 65 to 79 the fatality rate was 9.6 per million compared to 6.2 per million for women. This increased to 20.6 and 14.5 per million respectively for those aged 80 years and over (13).

Over the last decade, there has been an increase in the number of people vaping and using personal vaporisers. There are an estimated three million adult vapers in Britain, almost all of whom are smokers and ex-smokers (11). Use of such devices is not risk free. There is both risk of fire and a risk of poisoning from ingestion of e-liquids. In March 2016, it was reported that there were 113 fires caused by e-cigarettes in three years, whilst Incident Recording System data from the FRS showed there were over 16,000 smoking related fires in the same period (12).

Smoking also has a well documented detrimental impact on the health of both the smoker and those exposed to second and third-hand smoke. Tobacco (both active smoking and environmental tobacco smoke) causes almost a fifth of all cancer cases in the UK (14). Regular exposure to second-hand smoke can cause non-smokers to develop the same range of diseases as smokers, including lung cancer and heart disease. Children are especially vulnerable to the effects of second and third-hand smoke (11).

Smoking is the leading cause of preventable deaths in the UK. In 2016 there was an estimated 77,900 deaths attributable to smoking, representing 16% of all deaths across the UK (11). It accounted for around 474,300 NHS hospital admissions in 2015 to 2016. It is one of the leading cause of socioeconomic inequalities in health in the UK. The difference in life expectancy between the poorest and richest can be as much as nine years (11), of which

approximately half can be attributed to smoking. According to the Government's Tobacco Control Plan for England, smoking costs the NHS £2.5 billion per year (15).

In addition to the reduced fire risk within the home and financial benefit to the individual, there are both immediate and long-term health benefits of smoking cessation. After three to nine months, lung function improves by 10%. After five years the risk of having a heart attack falls to about half that of a smoker. Stopping smoking also decreases the risk of many diseases related to second-hand smoke in children, such as asthma (16).

As part of the SWV, the FRS will use the Making Every Contact Count approach using the opportunities that arise during the SWV to help people make positive changes to their health. People will be given advice about smoking cessation, safer smoking practices, and signposted to stop smoking services. Whilst it is recognised that it is difficult to change smoking behaviour in one visit, SWVs can ensure people who continue to smoke do so in the safest way such as not smoking in bed, smoking outside and use of proper ashtrays.

4.4 **Social isolation and loneliness**

The term 'social isolation' refers to a lack of regular contact with family and friends or lack of involvement in social organisations. Whilst loneliness is a subjective state based on a person's emotional perception and it describes the sense of being alone or lacking affection or closeness with others. It is possible for someone to feel lonely but not be socially isolated. However, social isolation and loneliness are often weakly correlated (17, 18) .
Loneliness and social isolation are risk factors for all cause morbidity and mortality with, risks comparable to those such as smoking, lack of exercise, obesity and high blood pressure (19-21). They also impact on use of public services with socially isolated and lonely individuals more likely to visit a GP, visit A&E or go into residential care. Socially isolated individuals are also more likely to suffer from depression, and have an increased risk of developing diabetes or suffering a stroke or developing coronary heart disease (22). It has been suggested that tackling loneliness among older people may be a way of enhancing wellbeing and delaying or reducing demand for institutional care (23). Addressing social isolation and loneliness is

challenging. If the FRS identify this as an issue, they will signpost to other available services, such as befriending services.

4.5 Cold homes and winter warmth

Older people are particularly vulnerable during cold periods. There is some evidence to suggest that cold temperatures can cause increased blood pressure, which may lead to an increased risk of stroke (24) and can trigger respiratory conditions such as asthma and chronic obstructive pulmonary disease (25). These poor health outcomes contribute to inequalities in health. There is also evidence linking home temperatures and mental health, with increases in room temperature associated with reduced likelihood of experiencing anxiety and depression (26). In addition, cold temperatures can exacerbate existing medical conditions such as diabetes, ulcers and musculoskeletal pains and exacerbate symptoms of arthritis (27). Moreover, winter mortality rates in those aged 75 years and over increases by about 30% during winter and cold homes and influenza are likely to contribute to this figure (28, 29). Since it has been estimated that 21.5% of excess winter are attributable to the coldest 25% of homes (30) tackling cold homes may therefore be one way to improve health outcomes and reduce inequalities in health in England. As part of the SWV, depending on the time of year, advice about how to safely keep the home warm, and financial schemes to enable this will be discussed.

4.6 Aim of the research

This protocol has been designed in response to a commissioned call from the National Institute for Health Research (NIHR) Public Health Research (PHR) Programme, which asked the question "which fire and rescue safety and health-related interventions are effective at improving health outcomes and reducing health inequalities?". As the SWV cover a broad range of interventions, evaluating the SWV in its entirety would be challenging. With the agreement of the funder, we have specified that the main focus of this evaluation will be on: i) the falls prevention aspect of the visit, and ii) improving health-related quality of life. We recognise the importance of the other areas covered by the SWV and so we have also included a number of important secondary outcomes.

4.6.1 Primary aim

The primary aim of this study is to establish whether SWVs delivered by the FRS will lead to a reduction in the number of falls and an improvement in health-related quality of life among older people living in the community.

4.6.2 Secondary aims

Secondary aims include:

- To establish the cost-effectiveness of the SWV delivered by the FRS at reducing falls and improving health-related quality of life for older people living in their own homes.
- To investigate adherence to recommendations made during the SWV and to explore the acceptability of SWV to older people and the FRS.

5 Study design

5.1 Study design

FIREFLI is a pragmatic, two arm, randomised controlled trial, with embedded qualitative and economic evaluations.

5.2 Identification of sites

The trial will be undertaken in the geographical locations covered by Humberside and Kent FRSs. If additional sites are required, then members of the study team based in the FRS will identify and invite other potential FRSs to take part in the study.

5.3 Identification of participants to receive an invitation mail out

We will recruit 1156 men and women, aged 70 years and over, to the trial. Potential participants for the invitation mail out will be identified by searching databases held by the participating FRS. The Fire and Rescue Serivce routinely receive data from Experian on which they carry out risk profiling in order to identify households to offer a SWV that are most at risk from fire fatality . This is combined with Exeter data from the NHS to refine the age group to those over 70 - the priority group for SWVs. The search will identify households

with a high probability of to having an occupant aged 70 years and over within the Humberside and Kent areas. Nursing and residential homes identified during the search (for example, the address includes the words nursing or residential home) will be excluded from the mail out. An additional risk profile may be undertaken in order to prioritise those most at risk. For example, in Humberside, the risk profile is based on whether the householder lives alone, smokes, has mobility problems, or has impairment by alcohol or substances. Households that are deemed very high risk of fire, will be excluded from the mailout since they will require a SWV as soon as possible, and it would be unethical to ask those allocated to the control group to wait 12 months for their visit. Equally, those deemed at very low risk will not be prioritised, as they would not normally be seen by the FRS. If there are more households on the list to mail out to than needed, a random sample will be selected.

In order to undertake this database search, we will:

i) Apply for Health Research Authority (HRA) and Confidentiality Advisory Group (CAG) approval.

ii) Put data sharing agreements in place between the University of York and Kent FRS and Humberside FRS.

iii) Seek and follow the advice from NHS England and NHS Improvement about the use of Exeter data (patient data held on the National Health Application and Infrastructure Services system which the FRS routinely have access to for research purposes).

Following review by CAG, the committee has suggested an alternative data flow to the one outlined in the application. In their suggested method, the FRS will (1) search the routine data they hold, for households with anyone over the age of 70 years, (2) they will then remove any household which has had a SWV in the past 3 years or due a visit within the next 12 months (3) they will also remove any property with a nursing or residential home address. (4) The FRS will then send NHS England and NHS Improvement a list of Unique Property Reference Numbers (UPRNs) corresponding to these households. (5) NHS England and NHS Improvement will search this list and will remove any household which has opted out of being contacted about research (via the National Data Opt-out). They will then send

the FRS the list of addresses on this list. This list will be used by the FRS to undertake the mail out. The advantage of following this data flow is that it minimises the transfer of identifiable data, as UPRN is open data.

Due to the considerable delays and challenges of using the Exeter data to produce a list of households to mail out to, we would like to implement an alternative/ additional strategy to approach potential participants. As an alternative to using the Exeter data to produce a list for the recruitment mail out, as described above, the FRS will also use their Experian Mosaic data *on its own* to identify households for the invitation mailout. This process will be as follows, and similar to the process using the Exeter data:

i. The FRS will identify the Experian Mosaic groups to target, which will focus on older people. Mosaic data classifies people into socio demographic groups which can be used to identify people that are more likely to fall into the target group for this trial. For example, Group N known as 'Vintage Value' is described as "elderly people who mostly live alone, either in social or private housing, often built with the elderly in mind". Levels of independence vary, but with health needs growing and incomes declining, many require an increasing amount of support". Experian use data to identify the likelihood of someone falling into each group. If no data is available for an individual address then data for neighbouring addresses is used. Therefore although the model is very good at predicting the socio demographic group for an address it is on a probability basis. No personal data is included within the dataset.
ii. The FRS will produce a list of households that fall into that target group
iii. The FRS will then exclude households that have received a SWV in the last three years, or have one booked, and where possible, where other identifies these risks, the other groups outlined above who would not be eligble for the study (those households at very high risk of death due to fire, those at lowest risk, and those households that are nursing/ residential homes.
iv. The list thus produced will be used to post out a recruitment pack to those households in the list.

Due to the nature of the Experian Mosaic data, the list of households produced may also include residents under the age of 70. Therefore the study documentation for this mail out

will be amended to clarify the eligibility criteria for the trial. In addition, information about how ineligible people can access a SWV outside of the trial will also be included. The Experian Mosaic data may result in a less targeted mailout in terms of age, an issue which has been discussed with the study's Trial Steering Committee. However, the FRS use Experian data to risk profile the population to prioritise the SWV delivery in usual practice so the group defined by the mailout for the study will be similar to that approached for a SWV in routine service delivery. (All trial particpants have to fulfil eligibility screening before they enter the trial so the resultant trial population will only include those aged 70 or over). Given the prolonged issues the trial has had with using the Exeter data to undertake the mail out and the need to be able to move the trial forward and start recruitment, the Trial Steering Commitee were supportive of this strategy.

Households identified as eligible for a mail out will be posted an invitation pack. The pack will contain an invitation letter, addressed to the occupier, as opposed to a named person in the household, from the FRS asking if a member of the household, aged 70 years and over, would like to participate in the study. It will also include a participant information sheet, consent form, screening questionnaire and two pre-paid envelopes. The letter will explain that only one participant per household will be permitted to take part in terms of completing data collection (though all household members may benefit from the SWV). If more than two people in the household over the age of 70 express an interest in taking part, then we will include the oldest person, as they are likely to have the greater risk of falling. Participants who are unable to speak or read English will be able to participate in the study, if they have a family member or friend who is willing to translate/interpret for them.

5.3.1 Opting out of the mail out

We are aware that we will be approaching households via a mail out without their consent at this first phase of the study. We want to enable people to opt out of receiving an invitation recruitment pack if they do not wish to be included. This will require a period of pre-notification where we will provide information in advance, that the mail out will be

occurring. Information about how to contact the FRS to express their dissent at receiving a pack will be included.

We will notify members of the public about the mail out of recruitment packs in a variety of locations- using the same platforms we propose for advertsing for participants (as detailed in section 5.3.2). At the request of CAG, we will also explain that the FRS already receive data from the NHS in order to offer Safe and Well visits, in case people wonder how the FRS access their data.

5.3.2 Advertising for participants

We may also advertise for participants to take part in the trial. This may include: radio, newspaper, on websites e.g. the recruiting FRS and University of York, 'My Community Alert e.g. https://www.mycommunityalert.co.uk/', ' next door' https://go.nextdoor.com/ukpublicservices, social media platforms such as Instagram, Facebook, Twitter, television and other media advertisements; flyers or posters within the recruiting area e.g. libraries; Primary Care Centres, GP practices or through organisations such as the University of the Third Age, Age UK, Women's Institute, Townswomen's Guilds, the Rotary Club, Over Sixties clubs, faith organisations, Parish councils, ward newsletters, Police and Crime commissioners engagement network, Fire Authority passing information on to their constituents, and Neighbourhood networks. Opportunistic screening of family members or friends of people who receive a study information pack may also be undertaken.

5.4 Declining participation in the study

Participation in the FIREFLI study is voluntary. People who do not wish to take part in the study will not have to return any forms to the YTU. They will not have to give a reason why they do not wish to take part but if a reason is provided it will be recorded. People who do not respond to the invitation mail out will not receive any further correspondence from the YTU about the study.

5.5 People who wish to take part in the study

People wishing to take part in the study will be asked to return their completed consent form with a contact form to the YTU and their screening questionnaire, separately by post to the YTU.

5.5.1 Assessment of eligibility

Researchers at the YTU will assess the returned screening form for participant eligibility according to the criteria in section 6. If a person is found to be ineligible for the study, for example if they have had a SWV within the past three years, they will be informed in writing. No further correspondence will be sent from the YTU.

5.5.2 Informed consent and completion of the consent form

If respondents require any further information about the study prior to giving their consent to take part they will be able to contact members of the research team based at the YTU, who will have undertaken Good Clinical Practice (GCP) Training. If the respondent prefers, a family member, friend, carer or other nominated person may contact the YTU on their behalf. Respondents will have at least 24 hours to consider participation in the study. People who wish to take part in the study will be asked to write their name on, sign and date the consent form. They will also initial each of the consent statements to indicate they agree with them. If, however, a participant places a tick or a cross against the consent statements rather than their initials, these shall be taken as an indication of consent. Nevertheless, all due care will be taken to ensure that the participant has provided consent to take part in the study. As the consenting process is postal, we have to work on good faith that the person signing the consent form is who they say they are. If we have a completed screening form and valid consent form, we will make the assumption that the person has capacity and that the screening form has been completed by the person signing the consent form. If the study team at the YTU has any doubts about whether a person wishes to take part in the study they will telephone them to confirm. Patients may nominate a family

member or friend to talk to the trial team on their behalf. This will be documented on the consent form.

Throughout the course of the study, we will assume continuing capacity unless we have proof otherwise or at the start of the study consultee approval was required. During the study, we will have contact with participants and consultees when we telephone to collect data for example about falls, or review responses from follow-up questionnaires and falls calendars. If a concern about mental capacity is raised during the course of a conversation with a participant (or family member/friend/carer if they have consented to this in the main trial consent form), or from something written on a questionnaire or falls calendar received by the research team, the researcher will telephone the participant (or family member/friend/carer if indicated on the consent form) to further reassess the mental capacity of the individual.

5.5.3 Informed consent and completion of the consent form in participants lacking capacity

In line with the first principle of the Mental Capacity Act 2005 (MCA), our starting point will be that a person has capacity to make a decision (in this case, wishing to take part in the FIREFLI trial) unless proved otherwise. Therefore, any potential participant who returns a completed consent form and screening questionnaire will be deemed to have capacity. However, given the age of the population it is expected that some potential participants will have cognitive problems such as dementia, which may affect their ability to process information, make informed decisions about their involvement in the trial and provide outcome data. This population are, however, at a higher risk of falling due to problems with balance and mobility, medication side effects and depression (31). In addition, the FRS would routinely undertake SWV in homes where an occupant has cognitive problems. We therefore consider that those with impaired capacity have as much to gain from inclusion in the study as those with full capacity. They will be included in the study if they live with

someone who agrees to act as their personal consultee and provide outcome data where needed.

Participants who lack capacity will be identified in one of the following ways:

(i) The screening questionnaire will include the following question. "Do you have a condition or impairment that affects your memory, thinking or ability to make decisions?" Those who respond 'Yes' to this question will be asked to read a further statement, which informs them of the need for the study team to talk to a family member or friend. If the potential participant is happy for the study team to do this, the participant will be instructed to ask their family member to read the information sheet they were sent and then write their name and contact details at the end of the contact sheet. The research team will then contact the potential consultee by phone.

(ii) The main participant information sheet includes information about being a consultee and who to contact for further information and discuss trial participation.

The process of seeking consent to be in the study for participants lacking capacity will be approved by the Research Ethics Committee and in accordance with the MCA 2005 . The MCA establishes a framework for the protection of the rights of people who lack the capacity to make a decision themselves. It is designed to ensure that the interests and rights of people who lack capacity are protected and that their current and previously expressed wishes are respected.

A personal consultee will be someone who knows the person lacking capacity and is able to advise about the person's wishes and feelings in relation to the study. Due to the requirement to report falls outcome data, the consultee will have to be a person living in the same household, but should not be someone who is acting in a professional or paid capacity.

The consultee will initially be informed about the trial by reading the information provided in the invitation pack. Once identified, the research team at the YTU will send a consultee Information Leaflet which includes information about the role of the consultee. They will be asked to advise on what the participant's wishes and feelings would be about taking part and whether they would be agreeable to taking part in such research or if they would have objections. A member of the research team from the YTU (who was formerly a General Practitioner or a nurse, who has received training and is experienced in assessing patient's capacity) will contact the consultee by telephone or using an on-line platform such as Zoom or Skype according to the consultee's preference, to discuss the study, answer any questions the consultee has and if necessary, undertake a capacity assessment. Should a suggested consultee feel unable to take on this role, then the potential participant will be deemed ineligible for the study and the consultee and potential participant will be thanked for their time.

The capacity assessment will be based on the HRA e-learning module on research involving participants lacking mental capacity and the BMA Mental Capacity Act Toolkit. As far as practically possible, we will include both the participant and the consultee in the discussion about taking part in the study. During the discussion, the following will be discussed in order to make an assessment of the mental capacity of the individual:

- Consideration of the participant's medical history to determine if there is a cause for impairment of brain or mind. If no, the participant will be able to give informed consent and will be asked to complete the participant consent form and study documentation; if yes, we will consider if this impairment affects the person's ability to make a decision.
- Determine if they are able to understand information about the study.
- Determine if the participant can retain the information for long enough to make the decision, weigh up the information to make the decision about taking part and let us know about their decision.
- We will ask the consultee to help and support the process but will take into account the person's views, wishes and beliefs and make an objective assessment of whether taking part in the research is in their best interest.

During the discussion, we will be careful to make sure we use appropriate language and not use technical wording. We will avoid questions which would be answered with 'yes' or 'no' replies.

We will keep a record of the process of assessing mental capacity; for those that do not agree to take part in the study, we will confidentially destroy this information after the letter of ineligibility has been sent.

If the personal consultee decides that the patient would have no objection to participating in the research then a Personal Consultee Declaration Form will be completed.

Copies of the consent forms and Consultee Declaration Forms will be stored at the YTU in a locked cabinet in a locked room and in accordance with the YTU Standard Operating Procedures (SOPs). Identifiable data will be stored separately to pseudononymised data (i.e. where a unique trial identification number is used to identify the participant). A copy of the completed consent form/consultee declaration will be sent back to the participant/consultee.

5.5.4 Completion of the baseline questionnaire

All eligible, consenting participants will be sent a baseline questionnaire and a batch of monthly falls calendars by post. Participants who return a valid baseline questionnaire and at least one falls calendar within the three months prior to the point of randomisation will be randomised into the trial.

Our preference would be for participants to complete study documentation via the post; however, in order to mitigate the potential impact COVID-19 may have on the running of the study, data may be collected over the phone instead.

6. Eligibility criteria for the FIREFLI trial

6.1 Assessment of eligibility

6.1.1 Inclusion criteria

Potential participants will be eligible for the trial if they fulfil the following criteria:

- Men and women aged 70 years and over
- Live in the community within geographical areas covered by the participating FRS

6.1.2 Exclusion criteria

Potential participants will be excluded if they fulfil any of the following criteria:

- Live in residential or nursing home
- Unable to give informed consent **and** live alone
- Are bed bound
- Have had an occupational therapist visit within the past 12 months
- Have had a SWV within the past three years
- Have been referred to the FRS or have already requested a SWV within 12 months
- Are unable to read or speak English and have no friend or relative who is willing and able to translate/interpret for them

N.B. People who suffer from dementia, or who have other cognitive impairments may be included in the trial if they live with someone who agrees to act as their consultee and provide outcome data on their behalf where needed.

6.2 Primary outcome

There are two primary outcomes:

i) The number of self-reported falls per participant over the 12 months from randomisation (a fall is defined as an 'unexpected event in which the participant comes to a rest on the ground, floor or lower level' (32)

ii) Health-related quality of life as measured by the 5-level version of the EuroQoL 5 Dimensions (EQ-5D-5L) over the 12 months from randomisation.

6.3 Data collection for the primary outcome for the trial

6.3.1 Falls data

Participants will be asked to record on monthly falls calendars if, in the past month, they had any falls including a slip or trip in which they lost their balance and landed on the floor, ground or lower level. An explanation of what the researchers consider to be a fall will be included in the participant information sheet, on the falls calendars and in the newsletters. If a participant is uncertain as to whether an event is classified as a fall, then they will be encouraged to ring the research team at the YTU to discuss. Data will be collected via participant self-reported monthly falls calendars in the 12 months following randomisation. Falls calendars will be sent to participants in the post along with their baseline questionnaire. If they had a fall that month, participants will be asked to mark on the calendar the number of falls they had on each day and return their monthly falls calendar to the YTU via FREEPOST. Participants who do not return their falls calendar within 10 days of the due date will either be telephoned, or sent a reminder letter in the post by the YTU, to collect this information. We will also collect falls data at four, eight and 12 months after randomisation using a participant postal questionnaire. The falls data from these questionnaires will be used for those participants who do not return their monthly falls calendar and cannot be contacted by phone.

Participants will also be given the YTU free phone number to ring during office hours to report any fall they have as soon as it is safe and convenient for them to do so.

YTU personnel will follow up every reported fall to collect information on the cause/reason for fall, consequence of fall e.g., superficial wound (bruising, sprain, cut, abrasions), fractures (including type of fracture) and hospital admissions. This information will be collected either by postal questionnaire or via a phone call to the participant.

6.3.2 Health-related quality of life (EQ-5D-5L) data

Health-related quality of life will be measured using the 5-level EuroQoL 5 Dimensions (EQ-5D-5L)(33) over 12 months. This generic, validated, patient-reported outcome measure (34)(www.euroqol.org) has five health domains (mobility; self-care; usual activities;

pain/discomfort; and anxiety/depression) with five response options for each domain (no problems, slight problems, moderate problems, severe problems, and extreme problems). In addition, it has a health status visual analogue scale (VAS) that measures self-rated health anchored at 0 ('the worst health you can imagine') and 100 ('the best health you can imagine') . The measure is easily completed. The EQ-5D-5L will be collected at baseline, and at four, eight and 12 months post-randomisation by questionnaires sent in the post by the YTU.

6.4 Secondary outcomes and other important data

Secondary outcomes in this study are:

- Fall related secondary outcomes: As recommended in the Cochrane review of interventions for preventing falls in older people living in the community (9), the following outcomes will be measured: time to first fall from date of randomisation and time between subsequent falls; proportion of participants reporting at least one fall in the 12 months from randomisation; and the proportion of participants reporting multiple (two or more) falls in the 12 months from randomisation.
- Fear of falling: Participants will be asked at baseline and at four, eight and 12 months post-randomisation to score how often they have worried about having a fall in the past 4 weeks. Six response categories will be used (all of the time, most of the time, a good bit of the time, some of the time, a little of the time, and none of the time). These will be scored from 1 to 6, with higher scores indicating less concern about falling.
- Fall related injuries and costs: See economic evaluation sections 6.3.2 and 8.8 for further details.
- Patient self-reported fractures.
- Loneliness: Participants will be asked at baseline and at four, eight, and 12 months post-randomisation to complete the UCLA 3-item loneliness scale that comprises of three questions that measure three dimensions of loneliness (35, 36). These are relational connectedness, social connectedness, and self-perceived isolation. Each

question is rated on a 3-point scale (hardly ever, some of the time, often) with higher scores indicating greater degrees of loneliness.

- Flu jab uptake: Participant self-reported uptake of a flu jab in the 12 months from randomisation.
- Smoking status: Participant self-reported smoking or vaping status of occupants within the household, smoking inside the property, smoking in bed, referral to NHS stop smoking services collected at baseline, four, eight and 12 months.
- Participant-reported fire within the property that the FRS attended and fire within the property that the FRS did not attend over 12 months.
- Fire risk taking behaviours: Participants will be asked at baseline, and at four, eight and 12 months post-randomisation, to indicate whether they undertake any of the following behaviours: use of candles, chip pans, and portable heaters, use of paraffin based skin creams; cooking left unattended; history of cooking related fire; maintenance of electrical wiring as determined by the presence of scorch marks on plugs or electric sockets; testing smoke alarms; and smoking habits such as falling asleep whilst smoking; shutting internal doors at night; escape plan; ability to escape in event of a fire; fire safety knowledge. A summary score of the number of behaviours identified will be calculated.
- Number and reason for attendances to participant's homes by the FRS 12 months pre-randomisation and in the 12 months from randomisation.

6.5 Data collection for secondary outcomes

Secondary outcome data will be collected by monthly falls calendars and postal questionnaires sent at four, eight and 12 months post-randomisation. The postal questionnaires will collect data on: fear of falling, fractures, health resource use data, uptake of flu jab within the past 12 months, loneliness (UCLA 3-item), smoking status, smoking inside the property, smoking in bed, and referral to stop smoking services, EuroQoL 5 Dimensions (5L) utility score (EQ-5D-5L) and fire risk taking behaviours.

The following data will be collected from the FRS: date the SWV(s) was/were conducted; referrals made (for example, to falls clinics, occupational therapists, etc); advice given; cost

of equipment provided by the FRS to participants; and number of attendances and reason for attendance to participants' homes by the FRS.

6.6 Participant withdrawal

Participants can withdraw from the trial at any point during the course of the study by directly contacting the trial coordinator at the YTU or informing a member of the FRS delivering the intervention. However, data collected up to the point of withdrawal will be retained for inclusion in the analysis up to the point that the participant informed the study team they wish to withdraw. If a participant indicates that they wish to withdraw from the study, they will be asked whether they wish to withdraw from the intervention only (i.e., opt not to receive the SWV) or withdraw fully from the study. Where withdrawal is only from the SWV, then follow-up data will continue to be collected. The reason for the participant wishing to withdraw from the study will not have to be stated; however, if the participant indicates the reason this will be recorded.

6.7 Randomisation

The FRS will notify YTU when they have capacity to deliver SWVs and the number of visits they are able to undertake at that time. Participants who fulfil the eligibility criteria and who have provided written consent to take part in the study and returned at least one falls calendar within the past three months will be randomised by a member of the research team based in the YTU. Participants will be randomly allocated using the YTU secure web-based randomisation system designed and maintained by an independent data systems manager at the YTU, who is not involved in the recruitment of participants. Participants will be randomised in a 1:1 ratio to either the intervention or usual care group, using block randomisation, stratified by centre.

The YTU will write to the intervention participants informing them of their group allocation and that the FRS will be in contact with them to arrange a SWV if allocated to the intervention group. The YTU will notify the FRS that participants have been randomised and send them the name and contact details of participants' requiring a SWV via the University of York's secure DropOff file-transfer system (https://dropoff.york.ac.uk/) or other secure

method. The FRS will then contact participants to arrange the SWV. It is expected that the SWV will be delivered approximately three weeks after randomisation.

The YTU will write to the participants' GPs informing them about their participation in the study.

6.8 Blinding

Blinding of participants to group allocation in the main FIREFLI trial will not be feasible, nor is blinding of the members of the study team who are actively involved in the administration of the study, the statistician or health economist.

6.9 Usual supportive care group

All participants will receive usual care from their GP and other health care professional(s). To describe this care, we will collect health service use data (such as GP attendance; nurse, occupational therapist and physiotherapist visits; attendance at falls clinic/services; and hospital admissions) via postal questionnaires sent to participants at baseline, and at four, eight and 12 months post-randomisation. All participants will be sent a falls prevention leaflet, produced by Age UK, with the baseline questionnaire. Participants will be sent a newsletter at three, seven and 11.5 months to inform them about study progress and encourage retention in the trial. We have found, in an embedded RCT, that using such a newsletter increased response rates to postal questionnaires in a similar population (17). To further increase response rates to the postal questionnaires, all participants will receive an unconditional £5 with their 12 month questionnaire as this has been demonstrated to be an effective strategy (18). (In order not to coerce participants, no mention of the £5 will be made in the participant information sheet.) Participants randomly allocated to the control group will be offered a SWV when their participation in the study has ended. If, however, during the course of the study the FRS evaluate a household as being high risk, and in need of a SWV earlier than in accordance with the trial protocol this will be permitted.

6.10 Intervention group

Participants allocated to the intervention group will receive usual care from their GP and other healthcare professionals. Health service use data will be collected in the same way as

detailed in the control group section above. They will also receive the same falls prevention leaflet, newsletters and unconditional £5 with their 12-month questionnaire. In addition, they will be offered a SWV at their home within approximately three weeks after being randomised.

The aim of the SWV is to reduce fire risks, support independent living, help prevent avoidable hospital admissions and excess winter deaths, and contribute to improving quality of life for older people living in England.

A firefighter, day duty safety advocate or Safe and Well Officer will deliver the SWV at a day and time convenient to the participant. The FRS will endeavour to deliver the SWV within the home. However, this may not be possible in all cases, for example due to the need to comply with either national or local public health guidance (with respect to the potential impact of COVID-19 or as a result of a local outbreak). In such cases, part or all of the SWV may be delivered over the telephone. A risk based approach to working in the home setting will be undertaken in accordance with local FRS procedures, with attempts to minimise the amount of time spent within the home. For example, participants may be asked about travel abroad. In cases, where there is high COVID-19 vulnerability, then a triage process may be used, through telephone calls and doorstep questioning (with PPE and social distancing). Such steps are required to ensure the potential benefit of the SWV are balanced against the risk to staff and the public of transmission of the COVID-19 virus.

The telephone call will aim to mirror the actual SWV as far as possible. It is anticipated that the phone call may take around 20 minutes to complete, and this will be made clear to the participant at the start of the call. The FRS will ask the same questions over the telephone as they would in person. The normal SWV form will be used to record the telephone call and the customer records management system will be updated with the information. The FRS will follow local and/or national guidance on how such telephone calls should be conducted.

Where a home visit is possible, the visit will last for approximately one hour. If applicable, participants will be informed in the participant information sheet (and at the start of the

visit if applicable) that the visit may be carried out by a firefighter who is operational, so they may be called away at a moment's notice. If this happens then the participant will be contacted to arrange another date and time to complete their visit if needed.

In addition to the assessment of fire risk, there are four additional key elements to the SWV: falls prevention; smoking cessation; social isolation (this element is covered by Humberside FRS but not Kent FRS); and cold homes. Delivery of the SWV between the two FRS varies slightly, however, the SWV will be delivered in each area, as per usual practice. For each appropriate element, a risk assessment is conducted and, if appropriate, an intermediate intervention is undertaken with referral to specialist help in line with their routine practice. Individual FRS have produced their own SWV checklists, and these will be used to deliver the SWV and to record what elements of the SWV were delivered to each individual participant.

6.10.1 Fire safety issues

The firefighter, day duty safety advocate or Safe and Well Officer will undertake a person-centred fire risk assessment by talking to the participant and taking into account the person factors (age, health, mobility, cognitive ability, hearing, etc.), home factors (building construction, fire detection, shared spaces, escape routes etc.) and behaviour factors (smoking, testing of alarms, closing doors at night, etc.). Advice and interventions will be provided on the following: smoke alarms (type, number, location and testing), kitchen and cooking safety, safe use of candles, electrical fire safety, fires and heaters safety, clutter and hoarding, smoking safety, escape planning (including mobility) and safeguarding.

6.10.2 Falls prevention

Delivery of the falls prevention element of the SWV varies slightly between the two FRS. Each FRS will deliver this element according to their usual practice. This may include: a record of health conditions; dementia; mental health; information about number of medications; history of falls; balance issues; conditions limiting mobility; fear of falling; ability to get out of a chair; ability to undertake exercises; removal of trip hazards; use of mobility aids is reinforced and footwear advice; a falls prevention booklet and falls service leaflet may be given out; reminder to have flu jab; onward referral to falls service or occupational therapists or postural stability services.

6.10.3 Smoking cessation

An assessment of smoking practices; Use of the Making Every Contact Count (behaviour change approach); referral on to stop smoking services; provision of fire retardant bedding and other equipment, if required, will be undertaken.

6.10.4 Social isolation

Living arrangements, assistance from carers and assessment of social isolation will be undertaken in the FRS that routinely deliver this. (Currently this is assessed in Humberside FRS.)

6.10.5 Cold homes and housing conditions

Depending on the time of year of the SWV, room temperature will be discussed; advice about financial schemes and how to keep the home warm and safe use of heating appliances will be conducted; a thermometer may be provided where necessary and a winter wellness advice booklet will be given out.

Any concerns about housing conditions including heating, damp, vermin infestations, and unsafe electrical systems will be identified and advice given. Where appropriate, referrals to other agencies including local authorities will be made.

6.11 Training for clinicians delivering the trial treatment

Training in how to deliver the SWV will not be required as the FRS will be delivering the SWV in accordance with their usual practice. Relevant training in day-to-day trial management activities will be provided to appropriate members of the FRS by the trial team at YTU.

7. Data collection

7.1 Quantitative data collection

Participants will be asked to return monthly falls calendars to document whether or not they have had a fall in the past month. Any participant reporting a fall will either be telephoned or sent a follow-up questionnaire in the post to collect information about the

cause/reason for fall, consequence of fall e.g. superficial wound (bruising, sprain, cut, abrasions), fractures (including type of fracture), and hospital admissions.

Participants will be asked to complete follow-up questionnaires sent in the post at four, eight and 12 months post-randomisation. Participants who do not return their follow-up questionnaire within two weeks will be sent up to two reminder letters plus a copy of the questionnaire by post followed by a telephone call two weeks later.

All participants will be sent three newsletters about the trial progress at three and seven months post-randomisation, and two weeks before their final 12 month questionnaire is due to be sent out. They will be sent an unconditional £5 with the 12 month questionnaire in recognition of their commitment to the study and to cover any expenses incurred in completing the questionnaires. Members of the research team may also contact participants or their delegated contact as documented on the consent form, by telephone, post, email or text regarding any queries they may have in relation to the follow-up questionnaires or falls calendars.

The YTU will manage the questionnaire and case report form (CRF) data in accordance with the YTU's Standard Operating Procedures. Paper CRF/participant questionnaires will be scanned and processed by data management staff. This will include cross checking data against the hard copy of the CRF. Quality control will be applied at each stage of data handling to ensure that all data are reliable and have been processed correctly. The trial coordinator/manager and statistician will write a Validation Plan for the CRFs in consultation with the YTU Data Manager. The plan will include detailed coding for the CRFs and data query resolution rules/procedures.

7.2 Mixed methods process evaluation

7.2.1 Implementation, fidelity and acceptability of interventions:

To address important issues of fidelity and acceptability of the SWV, the following qualitative and quantitative data will be collected:

(i) Observations of those delivering the service using a checklist developed specifically to record aspects of intervention delivery. The checklist will include all aspects identified as key components to falls prevention as part of the wider SWV. Up to 25 firefighters and day duty safety advocates, selected at random, from the Humberside FRS and all of the Safe and Well Officers from Kent FRS will be observed delivering the intervention on at least one occasion during the trial period (by author Shelley Crossland). We will aim to observe the delivery of the intervention to participants from a range of age, gender and deprivation backgrounds.

(ii) An intervention delivery inventory will be completed for all trial participants detailing exact elements of the intervention as delivered.

(iii) Outcome questionnaires (at four, eight and 12 months) will include information on adherence with the intervention and/or recommendations made by SWV relating to key elements of falls prevention.

(iv) Interviews with trial participants from the intervention arm (approximately n =32 (37)) will be conducted. We will ascertain the acceptability of the intervention and how the participants incorporated the suggested changes into their everyday lives and whether the SWV had any effect on the wider household. Interviews will be conducted face-to-face, over the telephone or via online video calls according to the preferences of each interviewee. We have set out the proposed sampling frame in the table below to ensure maximum variation according to gender, age and social deprivation. The sampling frame for each site (Humberside and Kent FRS) would be:

	Women		Men	
	Younger	Older	Younger	Older
Deprivation* low	2	2	2	2
Deprivation high	2	2	2	2

*deprivation score to be based on home post code http://imd-by-postcode.opendatacommunities.org/), educational level and the Mosaic geodemographic classification of households (collected and used by the FRS). These would be selected at random from trial participants in the intervention group who have agreed to be contacted. Whilst we have suggested two participants per cell in the sampling frame, it is

important to note that early data analysis will run concurrently with further data collection to allow for an element of flexibility according to a pragmatic definition of data saturation.

(v) Interviews with firefighters/day duty safety advocates/Safe and Well Officers (approximately n=15-20) (37) will be conducted. Participants will be purposively sampled to ensure maximum variation on the basis of staff type, years of experience and those who have undertaken many or only a few trial appointments. Information will be collected on their experience of delivering the service, views on whether it is fit for purpose, how they interface with other service providers and to highlight challenges/facilitators associated with service delivery.

(vi) Interviews with service leaders (n=10) from key stakeholder groups (e.g. fire service, social care services, primary care services, falls prevention services) who are involved in the design and implementation of the service will be conducted at two time points: during project set up to discuss current provision and at the end of the trial period to discuss incorporating trial findings into service development.

We will use the FRS contacts within the NHS trusts of the areas they cover and other organisations to identify potential service leads to interview. Kent FRS have identified the following organisations, that may be approached: Medway Community Healthcare, Kent Community Health Trust, Medway CCG, Kent Public Health Observatory, SECamb, Medway Public Health, Kent County Council Public Health, Kent County Council, and Age UK.

Humberside FRS have close working relationships with the Integrated Care Centre at the Jean Bishop Centre in Hull. Other trusts covered in their area include: Humber Teaching NHS Foundation Trust, City Health Care Partnership – Hull. We may seek local R&D departments assistance to identify individuals who could be interviewed. The study has been adopted by the CRN, and so we could also ask for their help in identifying potential interviewees.

This mixed methods process evaluation will be examined according to a revised version of the Carroll et al. conceptual framework for implementation fidelity (38) as outlined in the table below:

Fidelity component	Data utilised
Context Current delivery of SWV. Reasons for the introduction of SWV to the fire service. Integration of SWV with existing health and social care provision.	Initial interviews with service leaders
Coverage/Recruitment What proportion of the target group participated in the intervention? What recruitment procedures are used, and potential barriers to participation/maintaining involvement?	Broad socio-demographic quantitative data on non-responders and decliners. Interviews with service delivery staff. Initial interviews with service leaders.
Evaluation of adherence Was each intervention component implemented as planned, correct frequency/duration, appropriate quality?	Observations. Intervention delivery inventory. Interviews with firefighters/day duty advocates.
Participant responsiveness How engaged were participants with SWV? Relevance of, and satisfaction, with SWV. Perception of outcomes associated with SWV. Response to the recommendations made.	Interviews with participants. Outcome questionnaires. Interviews with firefighters/day duty advocates.
Intervention complexity/comprehensiveness How complex is the intervention? How specific is the description of the intervention?	Initial interviews with service leaders. Assessment by study steering group.
Strategies to facilitate implementation How was the intervention supported? Perceptions of challenges to implementation.	Initial interviews with service leaders. Interviews with firefighters/day duty advocates.

To inform how the trial findings may be incorporated into developments in service delivery of SWV we will draw on data from the second stage interviews with service leaders. Main trial findings on the effectiveness and cost-effectiveness of the SWV on falls prevention and health-related quality of life will be discussed and how these findings, combined with those on implementation fidelity, can be incorporated into future service planning.

7.2.2 Qualitative analysis

Qualitative interviews will be audio-recorded and transcribed verbatim. We will use NVivo software to assist our organisation of the qualitative analysis. To achieve a systematic

approach to data analysis we will conduct Framework analysis (39) (using the broad categories as described in the implementation fidelity model) engaging in: detailed familiarisation; identification and indexing of key themes; contextualising these themes in relation to the broader dataset; and interpreting them with a focus on addressing the specific questions in each phase of the research.

7.3 Study within a Trial (SWAT)

RCTs are the key stone of evidence-based healthcare. However, trial teams often experience difficulties in recruiting and maintaining follow-up and questionnaire response rates from participants, which can introduce bias, reduce the sample size and statistical power, and affect the validity, reliability and generalisability of findings.

There is therefore a need to develop and test interventions to improve recruitment and retention of participants. One method is to 'embed' trials of recruitment and retention interventions in ongoing RCTs. Testing interventions in ongoing trials ensures causality of intervention effectiveness is assessed and avoids limitations associated with testing in a quasi-randomised controlled trial, or non-randomised setting such as the feasibility of intervention implementation. These embedded trials are often referred to as a Study Within a Trial (SWAT).

The FIREFLI trial will act as a host trial for a SWAT that aims to study an intervention to improve recruitment and a further SWAT to improve retention. The protocol for these SWATs can be found in Appendix 1.

8 Statistical considerations

8.1 Sample size

In order to more holistically evaluate the SWV, we have specified two primary outcomes (number of falls and EQ-5D-5L) to consider the overall impact on participants' health and quality of life. The primary research question is formulated so that the 'success' of the intervention is defined as showing an effect on either (as opposed to both) primary

outcome; hence, the p-value has been corrected for multiple testing and the two outcomes will be tested at the 0.025 significance level.

Approximately a third of people over the age of 65 years and half of those over 80 will fall each year (5-7). We will recruit and randomise 1156 participants in a 1:1 ratio (i.e., 578 to control and 578 to intervention). This number allows for 10% attrition and provides 90% power (using two-sided significance at the 2.5% level) to show a difference in the percentage of participants who experience at least one fall in the 12 months following randomisation from 35% in the control group to 25% in the intervention group (StataCorp. 2013. Stata Statistical Software: Release 15. College Station, TX: StataCorp LP). The primary falls outcome is actually a count variable (number of falls, whilst proportion of participants experiencing at least one fall over the 12 months is the key secondary outcome); however, powering a trial for count data is complex and requires greater assumptions and so a binary approach to the sample size calculation was taken for the funding application.

Since funding was awarded, some members of the research team have completed the REFORM and OTIS trials of falls prevention interventions in similar (older, community-dwelling) populations, using falls calendars to collect number of falls over 12 months, analysed using a negative binomial regression model. We can therefore use data from these trials to estimate the minimum difference we may be able to detect in this trial. In REFORM, we observed a mean predicted falls rate per person, over 12 months, of 1.66 in the usual care group and 1.45 in the intervention group (incidence rate ratio of 0.88). The dispersion parameter from the negative binomial regression model was estimated at 1.34. In OTIS, we observed a mean predicted falls rate, over 12 months, of 1.76 in the usual care group and 2.05 in the intervention group (incidence rate ratio of 1.17). The dispersion parameter was estimated at 1.29. We estimate that, assuming a falls rate in the usual care group of 1.7 and a dispersion parameter of 1.3, with 1156 participants (1:1 allocation) we will have 90% power to detect a 25% decrease in falls (two-sided 2.5% significance).

This sample size will also provide ample power for the analysis of the EQ-5D-5L. Assuming a more generous attrition rate of 20%, recruiting 1156 participants would give us 90% power to detect an effect size of 0.23, using two-sided significance at the 2.5% level. In the

REFORM trial, the baseline standard deviation (SD) for the EQ-5D-3L index value was 0.24 and in the OTIS trial, where the 5-level version was used, it was 0.20. Assuming this range of SD, a standardised effect size of 0.23 equates to a difference in EQ-5D index value of 0.046 to 0.055. Walters and Brazier (22) in a review paper of the EQ-5D-3L found a difference of 0.074 (mean) or 0.081 (median) to be a minimum clinically important difference (MCID) among a variety of patients, whilst McClure and colleagues found a difference of 0.063 (mean) or 0.064 (median) for the EQ-5D-5L using simulated data (23). These estimates of the MCID are greater than the likely difference we are powered to detect and so the sample size will be conservative for the EQ-5D-5L analysis.

8.2 Statistical analysis for the main FIREFLI trial

There will be one single analysis at the end of the trial. All analyses will be conducted in Stata v15 or later (StataCorp, 4905 Lakeway Drive, College Station, Texas 77845 USA). Analyses will be described in detail in a Statistical Analysis Plan drafted by the study statisticians and reviewed by the Trial Steering and Monitoring Committee. It will be signed off by the Chief Investigator and the study statisticians prior to the analysis being undertaken. The main planned analyses are summarised below.

All analyses will be conducted following the principles of intention-to-treat with participant's outcomes analysed according to their original, randomised group, where data are available, irrespective of deviations based on non-compliance. Two sided tests at the 2.5% significance level will be used for the primary outcomes, and at the 5% level for the secondary outcomes.

The trial will be reported according to the CONSORT guidelines for clinical trials (Consolidated Standards Of Reporting Trials statement, http://www.consort-statement.org/). Baseline data (sex, age, diagnosis distributions, etc.) will be summarised descriptively by trial arm and presented in tabular form. Continuous measures will be reported as means and standard deviations whilst the categorical data will be reported as counts and percentages. No formal statistical comparisons will be undertaken on baseline data.

8.3 Primary outcome for the main FIREFLI trial

The number of falls per person will be analysed using a negative binomial regression model adjusted for gender, age, history of falling, and site (Kent or Humberside), to estimate the difference in falls rate between the groups. The model will include an exposure variable for the number of months that the participant returns a monthly falls calendar. The point estimate for the treatment effect in the form of an incidence rate ratio (IRR) and its associated 95% confidence interval (CI) and p-value will be provided.

EQ-5D-5L index value will be analysed using a covariance pattern model incorporating all post-randomisation time points and adjusting for baseline score, gender, age, history of falling, site, treatment group, time and a treatment group-by-time interaction. The correlation of observations within participants over time will be modelled, using participant as a random effect. The Akaike information criterion will be used to compare models specifying different correlation structures (smaller values preferred). The adjusted mean difference and its associated 95% CI and p-value will be extracted for each individual time point and overall. The estimate over the whole 12 months will serve as the primary endpoint while the differences at four, eight and 12 months will serve as secondary endpoints.

8.4 Subgroup analyses

We will include a subgroup analysis for the primary outcome based on socioeconomic status (e.g. deprivation index (IMD) assessed via home post code http://imd-by-postcode.opendatacommunities.org/), educational level and the Mosaic geodemographic classification of households (collected and used by the FRS). In order to find out participant's education level, we will ask them a single question. They will select one option from the following categories: no formal qualification; qualification relating to clerical work or a trade; formal school qualification at 16 years (O level/CSE/School Certificate); formal school qualification at 18 years (A level/Higher school certificate) or above. We have included the option of school certificate as this is a qualification relevant to this population. These data will be used to produce a deprivation index score that will also be used in the qualitative sampling strategy.

8.5 Sensitivity analyses

Sensitivity analyses for the primary outcomes will be conducted to consider the effect of clustering by firefighter day duty safety advocate or home safety Safe and Well Officer.

8.6 Missing data

We anticipate that missing data for the statistical analysis will be relatively small. The amount of missing data will be reported for each randomised arm, and we will also compare the baseline characteristics of participants who are included in the primary analysis to ensure that any attrition has not produced any imbalance in the groups in important covariates. To account for any possible selection bias, a logistic regression will be run to predict non-response (no falls data received post-randomisation) including all variables collected prior to randomisation. The primary analysis will then be repeated including as covariates all variables found to be significantly predictive of non-response to determine if this affects the parameter estimates.

8.7 Intervention adherence

Complier Average Causal Effect (CACE) analyses to assess the impact of compliance on treatment estimates will be undertaken for the primary outcomes. CACE analysis allows a treatment estimate of, in this case, a SWV by a firefighter, day duty safety advocate or Safe and Well Officer in the presence of non-compliance. It is less prone to biased estimates than the more commonly used approaches of per protocol or 'on treatment' analysis as it preserves the original randomisation and uses the randomisation status as an instrumental variable to account for the non-compliance.

8.8 Secondary outcomes for the main FIREFLI trial

8.8.1 Proportion of participants falling, experiencing a fracture or fear of falling

The following secondary outcomes will be analysed by logistic regression adjusting for gender, age, history of falls, and site as in the primary analysis:

- Proportion of participants who fall at least once over the 12 months from the date of randomisation

- Proportion of multiple fallers (two or more falls) in the 12 months from randomisation
- Proportion of participants having at least one fracture over the 12 month follow-up
- Proportion of participants obtaining multiple fractures (from different events, if this occurs a sufficient number of times) over the 12 month follow-up
- Proportion of participants who report that they are worried about falling at least some of the time at 12 months post-randomisation

Odds ratios and their associated 95% CI and p-value will be provided.

8.8.2 Time to fall

The time to the first fall will be derived as the number of days from randomisation until the patient reports having a fall as detailed on the participant's falls calendar, falls data collection sheet or self-reported questionnaire. Time between any subsequent falls will also be calculated. Participants who do not have a fall will be treated as censored at their date of trial exit, date of last available assessment or 365 days/trial cessation, as appropriate. The proportion of patients yet to experience a fall will be summarised by a Kaplan Meier survival curve for each group. Time to fall will be analysed using the Andersen and Gill method for analysing time to event data when the event can be repeated. The analysis treats each time to event or censoring as a separate observation. The data will be analysed by Cox Proportional Hazards regression using robust standard errors to account for dependent observations by participant, and adjusting for gender, age, site and history of falling. The hazard ratio, 95% CI and p-value will be provided. The proportional hazards assumption will be evaluated using Schoenfeld residuals.

8.8.3 Fear of falling, loneliness and fire risk score

Fear of falling (in its continuous form), the loneliness scale and fire risk score will all be analysed using a covariance pattern model as described for the EQ-5D-5L index values.

8.8.4 Flu jab, smoking outcomes

Uptake of the flu jab and smoking outcomes (e.g. whether any resident of the household smokes, and whether smoking is permitted inside the property) will be analysed using

logistic regression adjusting for gender, age, history of falls, and site as in the primary analysis.

8.8 Economic analysis

The cost-effectiveness of the SWV versus usual care will be assessed via a within-trial economic evaluation, which will comprise a cost-utility analysis and cost-effectiveness analysis. The analyses will be conducted on an intention-to-treat basis using patient-level trial data and data sourced from the FRS. Health-related quality of life, based on the EQ-5D-5L(34), will be used as the outcome measure for the cost-utility analysis. A cost-effectiveness analysis will also be undertaken to explore findings in terms of falls prevention, with a cost per fall averted being generated.

Health benefits and cost data will be collected over a follow-up period of 12-months, with costs presented in UK £ for the appropriate year. Discounting of costs and outcomes will not be required due to the time horizon not exceeding 12 months. The base case analysis will be undertaken from the societal perspective, with a secondary analysis capturing the perspective of the NHS and personal social services. The analysis will be undertaken in Stata release v15 (StataCorp, 4905 Lakeway Drive, College Station, Texas 77845 USA) or later and the analysis methods will follow, wherever possible, the recommendations of the National Institute for Health and Care Excellence (NICE) reference case (40).

Falls-related costs will be collected via participant self-reported questionnaires (at baseline, four, eight and 12 months), by asking participants to record their health care resource use within primary care and the community (i.e. visits to the GP, nurse, occupational therapist and physiotherapist) and secondary care (i.e. inpatient nights spent in hospital, day case attendances, outpatient attendances, and accident and emergency admissions). In order to capture the broader impact we will collect further information in addition to health care costs, such as information regarding participants' time and expenses (i.e. travel costs for appointments, additional equipment), and informal care provided by family/friends, including productivity losses.

The cost of the SWV intervention will be estimated using information collected from the FRS, such as the time spent at the visit (including for the falls prevention component) and the cost of equipment provided by the FRS to participants. Unit costs will be obtained from established costing sources wherever possible, such as NHS Reference Costs (41) and PSSRU Unit Costs of Health and Social Care (42), and applied to the resources used to provide an estimate of the total cost per participant. The opportunity cost of the time spent by FRS personnel on the SWV will also be explored and described, by estimating the costs of alternative uses of the FRS. Such opportunity cost data will be obtained from surveys of FRS personnel.

The EQ-5D-5L will be used to derive utilities for the estimation of quality-adjusted life years (QALYs). The current NICE guidance available at the time of analysis will be followed regarding the value set to use for the EQ-5D-5L. QALYs will be generated using the area under the curve approach (43). Regression methods will be used to calculate mean within-trial estimates of costs and health benefits, allowing for the correlation between costs and benefits, and adjusting for covariates. Missing data will be dealt with using multiple imputation methods (44) in the base case, with a complete case analysis explored through sensitivity analysis.

Mean costs and effects will be estimated for both groups (i.e. the intervention and usual care) and findings will be presented in terms of incremental cost-effectiveness ratios; specifically, the incremental cost per QALY gained and the incremental cost per fall averted. Net health benefit will also be used to represent the findings (45). Sensitivity analyses will investigate the impact of underlying assumptions of the analysis and key cost drivers in terms of the cost-effectiveness results. The uncertainty around the decision to adopt the SWV for falls prevention and improve well-being will be represented by cost-effectiveness acceptability curves (46), which will depict the probability of the SWV being cost-effective for different willingness-to-pay (per QALY) thresholds. Analyses will be detailed in a pre-specified health economics analysis plan written by the trial's Health Economist, reviewed by the TSC/DMEC and signed off by the Chief Investigator.

8.9 Definition of the end of the trial

The end of the study is defined as the date when the last randomised participant is due to return their 12 month follow-up questionnaire. The trial will be stopped prematurely if:

- Funding for the trial ceases;
- Mandated by the Research Ethics Committee; or
- Following recommendation from the Trial Steering/Data Monitoring and Ethics Committee.

The Research Ethics Committee will be notified in writing if the trial has been concluded or terminated early.

9. Adverse Event Reporting

9.1 Adverse Events

In the context of this study, we will record and report only details of any serious adverse events (SAEs) that are required to be reported to the Health Research Authority (HRA) i.e., events which are related to an aspect of taking part in the study and are of an unexpected occurrence. Non-serious adverse events will only be recorded and reported for this study if the event is related to being in the study or is related to the intervention.

Details of any SAEs reported to the YTU either directly by the participant or by a member of the FRS will be recorded using a trial adverse event form. Events reported by the FRS should be reported to the YTU within 48 hours of them becoming aware of the event. Once received, causality and expectedness will be confirmed by the Chief Investigator. A follow-up report will be completed if additional information becomes available.

The most common Adverse Event (AE) likely to occur within the study relates to falls, which are being recorded (in patient self-reported falls calendars and follow-up questionnaires) as part of the trial. If a participant has a fall, an AE form will only be completed if the consequence is serious and unexpected.

9.2 Definition of Serious Adverse Events

For this trial, a Serious Adverse Event (SAE) is defined as any untoward occurrence that:

(a) Results in death

(b) Is life threatening

(c) Requires hospitalisation or prolongation of existing hospitalisation

(d) Results in persistent or significant disability or incapacity

(e) Consists of a congenital anomaly or birth defect

(f) Is otherwise considered medically significant by the investigator.

9.3 Expected Adverse Events and expected side effects

Incidents of hospitalisations, disabling / incapacitating / life-threatening conditions, aging-associated diseases (such as cancer, cardiovascular disease, diabetes, arthritis, osteoporosis, dementia), other common illnesses such as depression, falls and deaths are expected in the study population due to the age of the cohort. Similarly, any hospitalisation that was planned prior to entry into the study or cannot be attributed to taking part in the study or prolongation of an existing hospitalisation due to social reasons will not be recorded as a SAE. A pre-existing condition (i.e., a disorder present at the start of the study) will not to be reported as an AE. An 'unexpected event' is defined as a type of event not listed in the protocol as an expected occurrence.

9.4 Definition of a related adverse event

An event is defined as 'related' if the event was due to the administration of any research procedure as detailed in the current regulatory approved protocol. The relatedness of an event will be reviewed by the Chief Investigator and another member of the Trial Management Group and the Trial Steering/Data Monitoring and Ethics Committee.

9.5 Reporting period

The AE reporting period for this trial begins as soon as the participant consents to be in the study and ends 12 months after they are randomised. For those participants who are not randomised, the reporting period will end once the participant is informed that their participation in the study has ended.

10. Trial monitoring

10.1 Site monitoring

Site monitoring visits for this study will not be undertaken on behalf of the sponsors with the following justification:

(a) The eligibility for the study is undertaken by review of potential participant's self-reported data by researchers based at the YTU
(b) Consent is taken via the post
(c) The majority of source data for this study is patient self-reported via questionnaires or falls calendars
(d) Data on adverse events will mainly be collected via participant self-report data sent to the YTU. However, if a member of the FRS becomes aware that an adverse event has occurred, then they will report this to the YTU using an Adverse Event Form.

Participating sites may be asked to assist in trial related monitoring when required, for example audits, ethics committee review and regulatory inspections.

10.2 Standard Operating Procedures

The study will be run in accordance with the York Trials Unit's (Health Sciences, University of York) Standard Operating Procedures and with the FRS's data protection policies.

11. Public Involvement and Engagement (PIE)

Public involvement and engagement input has played a part in shaping this study at the grant application stage, and will continue to be at the heart of the trial going forward.

We will establish a Public Involvement and Engagement (PIE) group. It is anticipated that the group will consist of five men and women over the age of 70 years who have fallen and will meet approximately four times during the course of the study, at a date and time convenient to the group and at key points of the study. We anticipate that during the course of the study some members of the group will leave. If this is the case we will recruit

additional members. Members of the PIE will be sought from the OTIS trial, Humberside and Kent older people user groups, people in the research website (https://www.peopleinresearch.org/) or from the local Age UK or other local groups attended by older people. We may also advertise for members.

The group will provide input into, and feedback on, study documents including the protocol, patient information sheets and consent forms, questionnaires, contents of the newsletters and plain English summaries of the findings. We anticipate that they will also assist with disseminating the study findings to the public. In addition, we will invite at least one member of the PIE group to join the joint Trial Steering Committee/Data Monitoring and Ethics committee.

12. Ethical issues

We are aware that some older people may represent a vulnerable group. We will conduct a risk assessment, which will include an assessment of potential safeguarding issues, which could potentially arise within the day-to-day running of the study. The FRS, person undertaking the fidelity observations and members of the research team based in the YTU will work to their local safeguarding procedures. Participation in the study is voluntary. Participants will be able to withdraw from the study at any point without prejudice by contacting the trial coordinator.

Confidentiality Advisory Group (CAG) approval will be required to gain access to the data held by the FRS. Therefore, an application for Health Research Authority (HRA) and Research Ethics approval will be sought.

12.1 Protocol amendments

Any amendments to the protocol during the course of the trial will be submitted for approval by the REC/HRA as necessary.

12.2 Legal bases of processing data

Notwithstanding the above, personal data and special category personal data will be processed in connection with this study under the legal bases of Article 6(1) (e) and Article 9(2) (j) of the General Data Protection Regulation (GDPR), respectively for processing for the performance of a task carried out in the public interest, and as necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, with Article 9(2) (j) operating in conjunction with the safeguard requirements set out in Article 89(1) of the GDPR.

12.3 Anticipated risks and benefits

This study does not involve any invasive/potentially harmful procedures and is therefore considered low risk for participants. The trial intervention is the same as the SWV currently being delivered by the FRS within the recruitment area so we do not anticipate any additional risks or potential harms above that experienced in routine practice

12.4 Informing participants of anticipated risks and benefits

The participant information sheet will provide information about the possible benefits and anticipated risks of taking part in the study. Participants will be given the opportunity to discuss participation with the study team at the YTU prior to consenting to participate. In the unlikely event that new information arises during the trial that may affect participants' willingness to take part, this will be reviewed by the TSC/DMEC for addition to the patient information leaflet. A revised consent form will also be completed if necessary.

12.5 Retention of study documentation

All data will be stored for a minimum of ten years after the end of the main analysis of the trial in accordance with the current YTU's Standard Operating Procedures. All paper records will be stored in secure storage facilities. Personal identifiable paper records will be stored separately from anonymised paper records. All electronic records will be stored on a password protected server within the YTU or on the University of York approved cloud.

Electronic data stored at the YTU will be held in a secure environment, with permissions for access limited to the study team. The Department of Health Sciences, in which YTU is based

at the University of York, has a backup procedure approved by auditors for disaster recovery. Full data backups are performed nightly using rotational tapes, to provide five years' worth of recoverable data. The tape backup sessions are encrypted and password protected, with tapes stored in a locked fire-proof safe in a separate secured and alarmed location. Additionally , data will be stored securely on the University of York approved cloud, by companies operating within the UK or EU offering 'cloud' based services. The University of York has signed up to the EU model clauses to ensure compliance with GDPR (https://cloud.google.com/security/compliance/eu-mcc). All study files will be stored in accordance with Good Clinical Practice guidelines.

The separate archival of electronic data will performed at the end of the trial, to safeguard the data for the period(s) established by relevant regulatory requirements. All work will be conducted following the University of York's data protection policy, which is publically available (www.york.ac.uk/recordsmanagement/dp/policy.

Essential trial paper documentation, for example participant questionnaires and consent forms, will first be archived in the YTU's archive, and may be moved to an off-site location in accordance with YTU's Standard Operating Procedures.

12.6 Access to data

A statement of permission to access source data by study staff and for regulatory and audit purposes will be included within the patient consent form with explicit explanation as part of the consent process and Participant Information Sheet. Once the YTU has completed the analysis and published all intended papers in scientific journals, the data may be made available for other researchers. Requests for access to data will follow YTU SOPS.

12.7 Confidentiality

All data collected during the course of the trial will be pseudo-anonymised using a unique identifier code, which can be linked back to the participant. The FRS data manager will ensure all routinely collected FRS data is pseudo-anonymised using a unique identifier code before being transferred the YTU. If required, data sharing agreements will be set up between the members of the research team. Participants will be asked to give their consent

to allow the FRS to share data required for the trial, with the YTU. Any release of data to other research groups will be truly anonymised with the unique identifier stripped away.

All information provided for the purposes of this study will be kept strictly confidential. However, if the participant discloses information which would raise concerns about their health, (for example during a qualitative interview or a follow-up telephone call), or if in line with standard FRS procedure, there is a Safeguarding issue or if there is an interest of public safety or prevention of criminal activity, then the researchers will be required to break that confidence and inform the participant's GP or other relevant person/agency.

12.8 Consent

12.8.1 Consent to the main trial

Participation in the study will be entirely voluntary. Potential participants will receive an information pack about the trial in the post including a consent form. Potential participants will be given the trial coordinator's or trial support officer's telephone number to phone if they have any queries about taking part in the study.

12.8.2 Consent to the qualitative study

The qualitative researcher will obtain informed consent from the participant for the qualitative part of the study.

12.8.3 Consent to the SWAT

Due to the nature of the intervention of the SWAT, it will not be possible to ask participants to give their informed consent to enter either of the SWATs. We will therefore ask the ethics committee to waiver consent for this part of the study only. We do not consider this to be a major ethical issue.

12.8.4 Consent for the observation

Consent for an occupational therapist (OT) to observe the SWV will be sought from the member of the FRS conducting the SWV. They will be given a Participant Information Sheet

explaining why the visit is being observed and will be given the opportunity to ask questions. They will be asked to sign a consent form to document their agreement to being observed.

Consent will also be sought from the trial participant for the observation. Verbal consent will be obtained during the initial phone call to arrange a home visit. At this point the purpose of the attendance and the fact that the focus will be on the person from the FRS delivering the SWV and not the participant will be reiterated. Written consent will then be obtained at the beginning of the home visit. Participants will be able to decline the OT attending the visit at any point during the process, and will still be able to have a home visit.

13. Oversight

13.1 Sponsorship

The University of York will act as the sponsor for the study.

13.2 Indemnity

The University of York will provide insurance for the design of the research as embodied in this protocol that shall extend to participating NHS organisations and collaborators where conducting procedures in accordance with the protocol. Non negligent harm will not be covered. The FRS have insurance which covers all legitimate practices within the remit.

13.3 Funding acknowledgement

Research funding has been secured from the National Institute of Health Research – Public Health Research reference 128341.

13.4 Independent Trial Steering and Data Monitoring and Ethics Committee

Due to the low risk nature of this study, approval from the funders has been given to set up one Independent Steering and Monitoring Committee to undertake the roles traditionally undertaken by the Trial Steering Committee (TSC) and the Data Monitoring and Ethics Committee (DMEC). The independent members will include the Chair who will be a clinician with expertise in falls prevention, a statistician, a health economist, an occupational therapist, a member of the patient public group and a member of Age UK. Dependent

members will include the Chief Investigator, trial statistician, trial coordinator and a trial methodologist based in the YTU. Other study collaborators may also attend the meeting. The committee will adhere to the NIHR terms of reference for TSC and DMEC committees. Their role will include the review of all serious adverse events which are thought to be treatment related and unexpected. The committee will meet at least annually or more frequently if the committee requests.

13.5 Trial Management Group (TMG)

A TMG will be set up. It will consist of the Chief Investigator, the study's grant co-applicants, data managers based in the YTU and delegated person at sites delivering the intervention. Regular meetings will be held according to the needs of the trial. The role of the TMG is to monitor all aspects of the conduct and progress of the trial, ensure that the protocol is adhered to and take appropriate action to safeguard participants and the quality of the trial itself. The frequency of the meetings will depend on the needs of the trial.

Trial progress will also be reviewed at the YTU's Trial Coordinator meetings. These meetings are held by the Director of the York Trials Unit approximately every two months.

13.6 Disclaimer

The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

14. Publication policy

The study will provide evidence on the effectiveness and cost-effectiveness of including a falls prevention element in the SWV delivered by the FRS to older people and whether the SWV improves their health-related quality of life. We will seek advice from our PIE Group and TSC/DMEC to develop a dissemination strategy. Age UK has agreed to endorse our research study and will assist with knowledge transfer and dissemination of study results, if the results of the trial show a benefit. However, it is intended that the study will be presented and results disseminated in the following ways:

- A short summary of the results, written in lay language will be produced and sent to trial participants.
- Oral presentations or posters at local, national and international conferences such as the PHE Conference, Humberside Safe and Well Conference, the Prevention, protection and health conference,the Australian and New Zealand Falls Prevention Conference, the Society for Research and Rehabilitation conference, and at regional prevention group meetings.
- Publication in peer-reviewed scientific journals (including the trial protocol), such as the Journal of the American Geriatric Society, Age and Ageing, or Occupational Therapy journals such as the British Journal of Occupational Therapy, OT News and OT magazine.
- The Cochrane falls review group will be sent a copy of the results, which will be incorporated into their next update for falls prevention in the community.
- The funders, the NIHR PHR, currently publish all monographs on their website https://www.journalslibrary.nihr.ac.uk/PHR/#/ and it is anticipated that the full trial report will be available approximately one year after the final report is submitted.
- A briefing document about the study and its results will be shared with: the National Fire Chief Council (NFCC) committees including the NFCC prevention committee, which collaborates with the NFCC health committee on the SWV standard evaluation framework; Public Health England; and Chief Fire Officers for all the FRSs, through the NHCC across the UK.
- The results of the study will be disseminated through PPI representatives, for example talks at the University of the Third Age (U3A) and other clubs for older people and briefing documents to put in Age UK's website.
- Press Offices and Media Relations at the Universities of York, Nottingham and James Cook (Australia), and Kent and Humberside FRS will promote the study on their webpages and issuing press releases and social media.
- The content of the Kent and Humberside SWVs will be informed by the results of the study and the results will be used in the ongoing development of the SWVs nationally

15. Plan of investigation and timetable

The FIREFLI study was proposed to run from the 1st February 2020 to the 31st January 2023. However, due to the COVID-19 pandemic, recruitment to the trial has been delayed. The summarised project plan is provided below.

	Month 0-6	Month 7-18	Month 19-30	Month 31-36
Set-up				
Recruitment				
12 month follow-up				
Analysis and write up				

16. Declaration of interests

Sarah Cockayne declares no conflicts of interest.

Prof Avril Drummond declares that she is a member and Deputy Chair of the HEE/NIHR Integrated Clinical Academic Programme Review Panel

Prof Catherine Hewitt declared that she is a member of the NIHR HTA commissioning board

Prof Joy Adamson declares that she is a member of the NIHR HTA commissioning board

Caroline Fairhurst declares no conflicts of interest.

Rachel Cunningham-Burley declares no conflicts of interest.

Arabella Scantlebury declares no conflicts of interest.

Alison Pighills declares no conflicts of interest.

Sarah Ronaldson declares no conflicts of interest.

Shelley Crossland declares no conflicts of interest.

Prof David Torgerson declares no conflicts of interest.

Sarah Wilkinson declares no conflicts of interest.

Jo Mann declares no conflicts of interest.

Richard Stanford-Beale declares no conflicts of interest.

Steve Duffield declares no conflicts of interest.

17. List of abbreviations

Abbreviation	Explanation
AE	Adverse event
CONSORT	Consolidated Standards of Reporting Trials
EQ-5D-5L	EuroQol 5 Dimension (5-Level) scale
FRS	Fire and Rescue Service
GP	General Practitioner
MCA	Mental Capacity Act
NICE	National Institute for Health and Care Excellence
NIHR	National Institute of Health Research
PHR	Public Health Research
PIS	Participant/ Patient Information Leaflet
PHE	Public Health England
PIE	Public Involvement and Engagement
QALY	Quality-adjusted life year
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
SOP	Standard Operating Procedure
SWAT	Study within a Trial
SWV	Safe and Well Visit
TMG	Trial Management Group
TSC/DMEC	Trial Steering Committee/Data Monitoring and Ethics Committee
YTU	York Trials Unit

18. Table of protocol changes

Version number	Date of protocol	Summary of changes

1.1	02.09.2020	Additional fire taking behaviour items added: shutting internatl doors at night; escape plan; confidence in escaping safely in the event of a fire; how safe the participant feels in their home; fire safey knowledge.
2.0	31 March 2021	Clarification added at the request of REC regarding: the identification of those who are unable to give consent; capacity assessment process; clarification that for those who have withdrawn from the study, their data will be used up to the point that they ask to withdraw. Additional text added to Sections 5.5.2. and 5.5.3 and 6.6. Additional sites where service leads may be interview have been added to section 7.2.1.
3.0	04.05.2021	REC reference number added. Duration of recruitment and study updated, however, these dates are to be agreed with the PHR. In order to mitigate the effects of COVID-19, Safe and Well Visits may partly be delivered over the phone in addition to being delivered in the participant's home. Name change from Home Safety Officer to Safe and Well Officer. Clarification to the consenting process for those without capacity. Additional locations to advertise for volunteers and for prenotification of recruitment invitations being sent out. Change in data flow in the FRS obtaining data from NHS Addition that data will be stored on the cloud.
4.0	27.10.2021	Adding about using Experian data for the mailout

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20. Appendix 1

We will undertake two Studies Within A Trial (SWAT) to evaluate the effectiveness of an invitation letter based on the principles of Self-Determination Theory (47) on recruitment of participants to the FIREFLI study and a pen to increase response rates to postal questionnaires.

20.1 Recruitment SWAT

Self-Determination Theory is a theory of human motivation, and what moves people to act. The theory outlines three core needs which facilitate self-determined (autonomous) motivation, these include autonomy (having choice), competence (feeling effectant), and relatedness (feeling connected to others). The invitation letter has been designed, with an aim to make people feel (i) they have choice and are pursuing the research because it suits one's values, (ii) they are competent to undertake the study and they could do this well, and (iii) that they feel connected to other people taking part.

Participants allocated to the intervention group will be sent an invitation letter informed by Self-Determination Theory with their trial invitation pack whilst control participants will receive the 'standard' invitation letter used within the YTU to recruit participants via the post. Participants will be randomised using block randomisation with randomly varying

block sizes in a 1:1 ratio . The allocation schedule will be generated by a York Trials Unit statistician otherwise not involved in the recruitment of participants.

Inclusion criteria
Any patient identified in the FRS mail out as eligible to receive a FIREFLI trial invitation pack will be entered into the invitation letter recruitment SWAT.

Outcome measure
The primary outcome will be the proportion of participants who go on to be randomised to the FIREFLI trial.

Secondary outcomes include:

a. Proportion of participants who return a screening form
b. Proportion of participant who are eligible for randomisation
c. Proportion of participants who remain in the trial at three months post-randomisation (defined as returning at least the first three months' worth of falls calendars from the date of randomisation)

Sample size
As is usual with an embedded trial within a trial, no formal power calculation will be undertaken for the study, as the sample size will be constrained by the number of participants available to mail out to.

Statistical analysis
Binary data will be compared using logistic regression.

20.2 Retention SWAT

There is some evidence to suggest that including a pen with a postal follow-up questionnaire has a positive impact on response rates and number of reminders required. In theory including a pen not only facilitates its completion, but also acts as an

acknowledgement of the participant's help with the study, making the recipient more likely to complete it. Participants in the FIREFLI trial will be posted a follow-up questionnaire four months post-randomisation. Participants who do not return their follow-up questionnaire within two weeks will be sent up to two reminder letters plus a copy of the questionnaire by post followed by a telephone call two weeks later.

We will undertake an embedded randomised controlled trial in order to evaluate the effectiveness of including a pen with the first reminder letter for participants who do not return their four month questionnaire within two weeks of it being sent.

Block randomisation, stratified by main trial allocation, with randomly varying block sizes will be used to randomise participants to receive a pen or not with their reminder questionnaire. The allocation schedule will be generated by a York Trials Unit statistician otherwise not involved in the recruitment or follow-up of participants.

Inclusion criteria

For logistical reasons, all participants due to be sent a four month questionnaire will be randomised into the SWAT. However, only those sent a four month questionnaire reminder letter will be included in the analysis.

Exclusion criteria

Participants who withdraw from follow-up before their four month questionnaire is due and those for whom it is not necessary to send a reminder letter will be excluded from the SWAT.

Outcome measures

The primary outcome will be the proportion of participants in each SWAT group who return the questionnaire. Secondary outcomes will include time to response (length of time taken to return the questionnaire), and completeness of response (the number of questions completed).

Sample size

As is usual with an embedded trial within a trial, no formal power calculation will be undertaken for the study, as the sample size will be constrained by the number of participants in the FIREFLI trial who are required to be sent a reminder letter due to non-response to the four month questionnaire.

Statistical analysis

Binary data will be compared using logistic regression, time to response by a Cox proportional hazards model, and completeness of response by a linear regression model. All models will adjust for main trial allocation.