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*Sarah Cockayne, Caroline Fairhurst, Rachel Cunningham-Burley, Jo Mann, Richard Stanford-Beale, Sarah Hampton, Sarah Wilkinson, Joy Adamson, Shelley Crossland, Avril Drummond, Catherine E Hewitt, Alison Pighills, Gareth Roberts, Sarah Ronaldson, Arabella Scantlebury and David J Torgerson on behalf of the FIREFLI team*

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Extended Research Article

# Effectiveness of Safe and Well Visits in reducing falls and improving quality of life among older people: The FIREFLI RCT

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## This article

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# Abstract

This report summarises the research, as commissioned and as undertaken, and lessons learnt in the 'Do Safe and Well Visits delivered by the Fire and Rescue Service reduce falls and improve quality of life among older people' randomised controlled trial. Due to challenges conducting the study, we were unable to recruit sufficient participants to the trial.

**Background:** Fire and rescue services in England routinely carry out Home Fire Safety Visits which aim to reduce risk of fire, support independent living and improve quality of life. The visits include a person-centred assessment and providing general advice on health-related topics such as preventing falls.

**Planned objective:** To assess the effectiveness and cost-effectiveness of Home Fire Safety Visits (also known as Safe and Well Visits) to reduce falls and improve quality of life in older adults living in the community.

**Design, setting and participants:** We designed a multicentre, randomised controlled trial with economic and qualitative evaluations, involving two fire and rescue services in England, to recruit 1156 community-dwelling adults aged 65 years and over.

**Interventions:** All participants could continue to access routine care from healthcare professionals and were provided with a falls prevention leaflet as part of the trial. The intervention group were additionally offered a Home Fire Safety Visit. The usual care group were offered a visit after they had completed the trial. Blinding was not possible. Participants were randomised 1 : 1 using a secure web-based system.

**Main outcomes measures:** The primary outcomes were (1) the number of falls per participant and (2) health-related quality of life (EuroQol-5 Dimensions, five-level version) over 12 months from randomisation. Secondary outcomes included fire risk-taking behaviours, loneliness, fear of falling and time to first fall. The planned economic evaluation comprised cost–utility and cost-effectiveness analyses. The qualitative study was designed to examine intervention fidelity and acceptability.

**Results:** It proved impossible to conduct the trial as planned in the current research landscape. We faced significant delays in setting up and starting recruitment, in large part due to this coinciding with the start of the COVID-19 pandemic. Obtaining regulatory approval took longer than anticipated. Additionally, we were unable to access general practitioner registration data to identify participants as planned and so we had to use Consumer Classification Platform data to identify potential households to send study invitations to. This resulted in a less targeted and non-personalised mail-out as this is not patient-level data so the householder names were unavailable. Ultimately, recruitment was much lower than expected. In total, 237 participants were assessed for eligibility and 63 randomised (intervention, $n$ = 32; usual care, $n$ = 31). The Home Fire Safety Visits were delivered as planned to both groups; however, the planned statistical and health economic analyses could not be conducted due to the limited data. Data from the qualitative evaluation indicated the intervention was largely acceptable to staff and service users.

**Conclusions:** Conducting trials in this setting is currently extremely challenging. To facilitate future research, we recommend an urgent review of research governance issues related to the types of personal data that can be accessed and used for research. This review should aim to provide support and avoid creating additional obstacles to research in this area.

**Future work:** The evidence for the effectiveness and cost-effectiveness of Home Fire Safety Visits remains inconclusive. Research governance in local authorities needs urgent review.

**Trial registration:** This trial is registered as Current Controlled Trials NCT 04717258.

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| **Report Supplementary Material 2** | Baseline questionnaire consultee v1.1 |
| **Report Supplementary Material 3** | Falls data collection sheet for participant (postal)_v2.0 |
| **Report Supplementary Material 4** | Main trial PIS for participants v4 09.03.2022 |
| **Report Supplementary Material 5** | EOI letter v1 29.07.2022 |

Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/DJHF6633).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

# List of abbreviations

| | |
|---|---|
| ACER | Academic Collaboration, Evaluation and Research Group |
| CAG | Confidentiality Advisory Group |
| CCP | Consumer Classification Platform |
| CONSORT | Consolidated Standards of Reporting Trials |
| DMEC | Data Monitoring and Ethics Committee |
| DSA | data-sharing agreement |
| DSPT | Data Security Protection Toolkit |
| EoI | Expression of Interest |
| FIREFLI | Do Safe and Well Visits delivered by the Fire and Rescue Service reduce falls and improve quality of life among older people |
| FRS | fire and rescue service |
| GP | general practitioner |
| GPRD | General Practice Research Database |
| HFSV | Home Fire Safety Visits |
| HRA | Health Research Authority |
| NIHR | National Institute for Health and Care Research |
| OT | occupational therapist |
| PCRM | Primary Care Registration Management |
| PHR | Public Health Research |
| PI | public involvement |
| RCT | randomised controlled trial |
| REC | Research Ethics Committee |
| SWAT | Study Within A Trial |
| SWV | Safe and Well Visit |
| TSC | Trial Steering Committee |
| YTU | York Trials Unit |

# Plain language summary

## Why did we do this trial?

Fire and rescue services in England offer Home Fire Safety Visits to people in the community. The visits include a fire risk assessment, recommendations to prevent fires and advice on topics such as preventing falls and stopping smoking. We wanted to find out if these visits reduced the number of falls older people had, improved their quality of life, what they thought about the visits and if they were good value for money.

## What did we do?

We tried to recruit 1156 people to the trial. However, we faced significant challenges in setting up and running the study. In the end, we only recruited 63 people. As planned, half were immediately offered a Home Fire Safety Visit and the other half were offered a visit 12 months later. We collected information about whether people fell each month and other health outcomes. We interviewed people who received a visit and members of the fire and rescue service who delivered them to find out what they thought about the visits.

## What did we find?

There were significant delays in getting approvals to run the study and getting addresses of people to mail invitation packs to. Recruitment was challenging and ultimately we had to stop the study early. This meant we did not collect enough information to be able to tell if the home visits reduced falls, improved quality of life or were good value for money. However, of note, in the interviews, people said they found the visits a positive experience, felt they were reassuring and found the advice useful.

## What does this mean?

Although we did not complete the study, the lessons learnt from running it should help other researchers to navigate future research studies in this area.

# **Chapter 1** Introduction

This report details the work undertaken in the 'Do Safe and Well Visits delivered by the Fire and Rescue Service reduce falls and improve quality of life among older people' (FIREFLI) randomised controlled trial (RCT) to establish the effectiveness and cost-effectiveness of Home Fire Safety Visits (HFSV) [also known as Safe and Well Visits (SWV)] to reduce the number of falls and improve quality of life in older adults living in the community. It arose from a call commissioned by the National Institute for Health and Care Research (NIHR) Public Health Research (PHR) programme. Trial set-up and recruitment were slower than anticipated and the trial was completed with a significantly lower sample size than its original target, which meant it could not meet its planned objectives or answer its research question. This report synthesises the commissioned research, what could and could not be achieved, and barriers to the successful completion of this study. A summary is provided in *Table 1*.

**TABLE 1** Summary of the planned work, achievements and barriers in the FIREFLI trial

| Planned work | Was the planned work delivered? | What was delivered | Barriers |
|---|---|---|---|
| Conduct a RCT to determine whether HFSV delivered by the fire and rescue service (FRS) will lead to a reduction in falls and an improvement in health-related quality of life among older people living in the community. | ✗ | The RCT gained the relevant regulatory approvals and was set up in two FRS.<br>Recruitment to the trial began. Five thousand and thirty-nine full recruitment packs were sent out and 7100 Expression of Interest packs were sent out. Two hundred and thirty-seven people were assessed for eligibility. Sixty-three out of 1156 participants were recruited, *n* = 32 intervention; *n* = 31 usual care.<br>Outcome data on falls were collected using prospective falls calendars over a 6-month period. | The start of recruitment was significantly delayed, and then recruitment was lower than expected.<br>The target sample size was not achieved.<br>Insufficient outcome data were collected to undertake the effectiveness and cost-effectiveness analyses. |
| Observations of the HFSV by a member of the research team to assess if key falls prevention components are included. | ✗ | A process was put in place to arrange the observations of HFSV and were in the process of being organised when the trial ended. Zero out of 25 observations were conducted. | The trial closed prior to any observations being undertaken. |
| FRS to complete an intervention delivery inventory for each HFSV to record the exact elements of the intervention delivered and provide these data to the trial team. | ✗ | Thirty out of 32 HFSV delivered to intervention participants.<br>York Trials Unit received data on the HFSV conducted by Humberside FRS up to the point of trial closure. Fifteen out of 32 inventory reports completed. | Resource-intensive task. Kent FRS did not have capacity to collate these data, so they were not provided. |
| Participant questionnaires will record adherence to recommendations and advice provided during the HFSV. | ✗ | Questionnaires were prepared and were ready to send out to participants at 4, 8 and 12 months post randomisation. No questionnaires were sent out. | Data collection stopped before the 4-month time point, so questionnaires were not sent out. |
| Qualitative interviews with trial participants and members of the FRS delivering the HFSV to explore acceptability and how suggested changes are incorporated into everyday life.<br>Fidelity assessments of the intervention. | ✓ | Interviews were undertaken with trial participants and members of the FRS.<br>Fifteen out of 32 trial participant interviews were conducted.<br>Seventeen out of 15–20 Firefighter/day duty safety advocates/Safe and Well Officer interviews were conducted.<br>Eleven out of 10 service lead interviews were conducted.<br>Intervention fidelity was not assessed. | Given the wider issues with trial delivery, fidelity assessments were no longer considered a priority and it was felt may inhibit trial participation even further, so were omitted. |
| Interviews with FRS service leads to explore current provision and how the trial findings could be incorporated into service development. | ✓ | Interviews were undertaken with service leads. Seven FRS service leads and 4 primary care service lead interviews out of 10 were conducted.<br>Seven additional interviews were undertaken with the study team and members of the Trial Steering Committee to elicit their views on issues with running the study. | — |
| Set up a public involvement (PI) group to provide the perspective of older people who fall. | ✓ | PI group was set up and meetings held.<br>PI members provided input into the study design and patient-facing documents. | — |
| Undertake recruitment Study Within A Trial (SWAT) to evaluate the effectiveness of a study invitation letter informed by self-determination theory, to increase recruitment. | ✗ | Four thousand and five hundred potential participants were included in the SWAT. Two thousand two hundred and fifty-two were sent the intervention letter and 2248 sent the control standard letter. | Due to poor recruitment, a shorter, Expression of Interest letter was sent to potential participants, so the SWAT was stopped early. |
| Undertake a retention SWAT to evaluate the effectiveness of including a pen with a postal questionnaire to increase response rates. | ✗ | | Data collection stopped before the follow-up questionnaires were due to be sent out. |

# Chapter 2 Background

Fire and rescue services (FRS) in England routinely carry out HFSV to people's homes which aim to reduce the risk of fire and advise on what actions should be taken in the event of a fire within the home. Over recent years, these visits have been expanded to include health-related topics, such as falls prevention; smoking cessation; social isolation; and winter warmth and have also been known as Safe and Well Visits. The aim of the HFSV is not only to reduce risk of fire but also to support independent living and help prevent avoidable hospital admissions and excess winter deaths. The FRS carry out about 670,000 home safety visits in England[1] each year.

There is some evidence to indicate that HFSV are effective. The Winter Pressures Pilot service evaluation,[2] commissioned by Public Health England and the Chief Fire Officers' Association, was conducted between October 2015 and March 2016. This evaluation found that the home visits were effective in addressing falls, cold homes and social isolation, but less effective at influencing the uptake of flu vaccinations. However, this was an observational study and not a RCT, which is the 'gold-standard' design for evaluating the effectiveness of an intervention. Additionally, potential improvements to quality of life were not considered, nor was a full economic evaluation undertaken.

A Cochrane systematic review[3] evaluating interventions for preventing falls in older people in the community identified six trials, involving 4208 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% confidence interval (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). While 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. Another Cochrane review[4] 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[5] 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. In addition to this, the SAFER2 trial[6] evaluated a complex intervention comprising of paramedic training and clinical protocols enabling paramedics to assess older people who had fallen and refer them to falls services. This cluster trial reported fewer intervention participants reporting further falls by 1 month: 413 out of 621 (66.5%) in the intervention group versus 409 out of 589 (69.4%) in the control group [odds ratio (OR) 0.72, 95% CI 0.54 to 0.96].

The FIREFLI study was funded in response to a commissioned call, to ascertain which of the FRSs' safety and health-related interventions were effective at improving health outcomes and reducing health inequalities. Due to the researchers' expertise in undertaking large, pragmatic RCTs evaluating falls prevention strategies, it was decided to primarily focus the research on the falls prevention aspect of the HFSV. However, to holistically evaluate the HFSV, it was decided to also include a second, health-related quality of life primary outcome along with several secondary outcomes evaluating other facets of the HFSV.

## Aims and objectives

The aim of the study as commissioned was to evaluate the effectiveness and cost-effectiveness of the HFSV to reduce falls (a fall was defined as an 'unexpected event in which the participant came to a rest on the ground, floor or lower level') and improve quality of life in older adults living in the community. The main objectives of the FIREFLI study were to:

1. Evaluate the effectiveness of HFSV to reduce falls and improve quality of life in older adults living in the community.
2. Evaluate the cost-effectiveness of HFSV aiming to reduce falls and improve quality of life in older adults living in the community.

3. Investigate adherence to recommendations made during the HFSV and to explore the acceptability of HFSV to older people and the FRS.
4. Undertake one recruitment Study Within A Trial (SWAT) evaluating the effectiveness of using an invitation letter informed by self-determination theory in the study invitation pack to increase recruitment to the study. Also conduct a retention SWAT evaluating whether including a pen with postal follow-up questionnaires improves response rates.

## Methods

The FIREFLI study was designed as a pragmatic, multicentre, two-arm, open RCT with embedded qualitative and economic evaluations. Full details of the planned study are published as a protocol,[7] but key details of the design are summarised in *Table 2* with an indication as to whether or not each element could be fully achieved or was changed. Due to a number of challenges, changes were made to the trial protocol before the trial ended. Details of the protocol changes and reasons the trial was unsuccessful are detailed in *New research evidence*, *Research infrastructure in fire and rescue service*, *Exploration of alternative sampling methods*, *Complex regulatory*

**TABLE 2** Summary of original trial protocol

| Methods | Details | Delivered as planned (no changes made)? |
|---|---|---|
| Recruitment | Participants would be identified for the trial via the General Practice Research Database from NHS England, replicating the normal practice used by the FRS in Humberside and Kent to identify potential households to be offered HFSV. | ✗<br>See *The recruitment process* |
| Eligibility | *Inclusion criteria*<br><br>All the following criteria needed to be met for inclusion in the FIREFLI trial:<br>• Aged 65 years and over in Humberside or aged 70 years and over in Kent[a]<br>• Live within the geographical areas covered by Humberside and Kent FRSs<br>• Willing to receive a HFSV from the FRS.<br><br>*Exclusion criteria*<br><br>Potential participants were excluded from the study if any of the following applied:<br>• Lived in a residential or nursing home<br>• Were bed bound<br>• Were unable to give informed consent and lived alone (as it was not possible to identify a consultee who lived with the participant and was willing and able to act on their behalf)[b]<br>• Had an OT visit within the past 12 months<br>• Had received a HFSV within the past 3 years<br>• Had been referred to the FRS or had already requested a HFSV within 12 months<br>• Were unable to read or speak English and had no friend or relative who was willing and able to translate/interpret for them. | No changes made to eligibility criteria |
| Randomisation | Eligible consenting participants who returned a completed baseline questionnaire (see *Report Supplementary Material 1* and *Report Supplementary Material 2*.) and at least 1 monthly falls calendar were randomised 1 : 1 using the York Trials Unit's (YTU's) secure, web-based randomisation system. The allocation sequence was generated by an independent statistician who was not involved in the recruitment of participants. Block randomisation stratified by FRS was used with blocks of 4, 6 and 8. | No changes made to randomisation process |
| Usual care and intervention groups | All participants were to receive usual care from their healthcare providers and an Age UK falls prevention booklet provided by YTU, which was not routinely given out by the FRS outside of the trial. The intervention group were offered a HFSV usually within 3 weeks of randomisation, while the usual care group were offered the visit 12 months after randomisation or when their part in the study had been completed. The HFSV were delivered by either a firefighter, day duty safety advocate or Safe and Well Officer and took around 45–60 minutes. Further details are provided in *Appendix 1*, *Table 8*. | Intervention delivered as planned |

**TABLE 2** Summary of original trial protocol (*continued*)

| Methods | Details | Delivered as planned (no changes made)? |
|---|---|---|
| Data collection | We planned to follow up participants with monthly postal falls calendars for 12 months post randomisation to collect data on the number of falls participants had sustained in the past month. Participants who reported a fall were sent a questionnaire/telephoned for details about their fall, including cause and if they went to hospital as a result.<br>Participants/consultees were due to be sent postal questionnaires at 4, 8 and 12 months post randomisation to collect data on falls (which would be used if no falls calendar data were provided), if any of the falls occurred in the home, fear of falling, fractures, quality of life EuroQol-5 Dimensions, five-level version scale (EQ-5D-5L), loneliness (UCLA 3-item), received a flu vaccination, fire risk-taking behaviours, participant-reported fire, and health service utilisation data. | Falls calendars collected data received<br>✗<br>Follow-up questionnaires not sent |
| Primary outcomes | We specified two primary outcomes to consider the overall impact on participants' health and quality of life:<br>• The number of self-reported falls per participant over the 12 months from randomisation<br>• Health-related quality of life measured by the EQ-5D-5L[8] over the 12 months from randomisation.<br>'Success' of the intervention was defined as showing an effect on either (as opposed to both) primary outcome with the *p*-value corrected for multiple testing ($p < 0.025$). | No changes made to intended primary outcomes; however, EQ-5D-5L outcome data not collected and limited data collected on falls |
| Secondary outcomes | • Proportion of participants reporting at least one fall in the 12 months from randomisation<br>• Proportion of participants reporting multiple (two or more) falls in the 12 months from randomisation<br>• Time to first fall from randomisation and time between subsequent falls<br>• Fear of falling<br>• Fall-related injuries and costs<br>• Participant self-reported fractures<br>• Loneliness (UCLA 3-item loneliness score)<br>• Flu jab uptake at 12 months<br>• Participant self-reported smoking or vaping status and behaviours of occupants within the household<br>• Participant-reported fires within the property over 12 months<br>• Fire risk-taking behaviours<br>• Number and reason for attendances to participant's homes by the FRS in the 12 months after randomisation.<br>Other data collected<br>Data on when the HFSV were delivered by the FRS and FRS-reported attendances to participants' home for fire-related incidents were collected from the FRS. Any adverse events related to being in the study or to the intervention were reported. | No changes made to intended secondary outcomes; however, no data provided for most as follow-up questionnaires not sent out |
| Sample size | Recruit 1156 participants, allowing for 10% attrition to provide 90% power (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%[5,9,10] in the usual care group to 25% in the intervention group, and an effect size of 0.23 in the EQ-5D-5L allowing for 20% attrition (StataCorp. 2013. Stata Statistical Software: Release 15. College Station, TX, USA: StataCorp LP). The primary falls outcome is actually a count variable (number of falls, while 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. After funding was awarded, some members of the research team completed the REducing Falls with ORthoses and a Multifaceted podiatry intervention (REFORM)[11] and Occupational Therapist Intervention Study (OTIS)[12] trials of falls prevention interventions in similar (older, community-dwelling) populations, using falls calendars to collect number of falls over 12 months. We used data from these trials to conduct a post hoc power calculation to estimate the minimum difference we expected to be able to detect in FIREFLI using negative binomial regression analysis. Assuming a falls rate in the usual care group of 1.7 and a dispersion parameter of 1.3, with 1156 participants we will have 90% power to detect a 25% decrease in falls (two-sided 2.5% significance). | No changes made to target sample size; however, this was not ultimately achieved |
| Recruitment SWAT | Study invitation letter informed by self-determination theory vs. standard YTU study invitation letter to increase recruitment to the study randomised in a 1 : 1 ratio.<br>The intervention letter aimed to make recipients feel they (1) had choice and were pursuing the research because it suited their values, (2) were competent to undertake the study and could do this well, and (3) were connected to other people taking part. | SWAT conducted |
| Retention SWAT | Retention SWAT to evaluate whether including a pen with postal follow-up questionnaires improves response rates. | ✗<br>SWAT not conducted as follow-up questionnaires not sent out |

a Reflecting the target populations for a HFSV in each FRS.
b People who suffered from dementia or other cognitive impairments were included in the trial if they lived with someone who agreed to act as their consultee and provide outcome data on their behalf where needed.

*approvals*, *COVID-19* and findings from the trial are provided in *Trial recruitment* and *Findings from the randomised controlled trial*.

### *Qualitative evaluation*

The qualitative evaluation was originally designed to assess the fidelity of the HFSV intervention and adherence to recommendations made during the HFSV and to explore the acceptability of HFSV to older people and the FRS. Due to the challenges in delivering the main trial, adaptations were made to the qualitative protocol to focus only on the experience and acceptability of the HFSV service from a range of stakeholders.

Qualitative interviews were conducted with individuals in receipt of HFSV, those providing the front-line service (i.e. firefighters/advocates/Safe and Well Officers) and service leaders from key stakeholder groups (e.g. fire service leaders, falls prevention services). Interviews were conducted online by video communication (via Zoom) or telephone. Topic guides were used to facilitate the interviews, which included a focus on the experiences and acceptability of delivering/receiving the service. Following transcription, the interviews were analysed thematically. In particular, barriers and facilitators to delivering/receiving the HFSV were identified alongside the integration of HFSV with other health and social care services.

As the trial ended before reaching the recruitment target, consultation with key members of the trial team [including members from the York Trials Unit (YTU) trial team, the FRS and the external steering committee ($n$ = 7)] took place to capture intelligence relating to attempting to deliver the FIREFLI trial and the barriers that were encountered. All key trial documents were also reviewed (e.g. minutes from trial management meetings, e-mails regarding setup and day-to-day management of the study). Data from the interviews and the documents provided the information on which the *New research evidence*, *Research infrastructure in fire and rescue service*, *Exploration of alternative sampling methods*, *Complex regulatory approvals*, *COVID-19* are based.

### *Regulatory approval*

National Health Service ethics approval was required for this study for two reasons. First, accessing confidential patient information without the patient's consent requires Confidentiality Advisory Group (CAG) approval. Any research application applying for CAG approval requires a favourable NHS ethical opinion. Second, as we planned to recruit participants who lacked capacity to consent, the ethics application had to be reviewed by an appropriate body. University committees are not deemed appropriate bodies, thereby requiring the study to be reviewed by an NHS committee. The ethics application included safeguarding procedures that were put in place for the trial which stated that both the FRS and University staff would follow their organisation's safeguarding policies if they became aware of any potential issues. Ethical approval for the study was obtained from Health Research Authority – West Midlands – Coventry and Warwickshire Research Ethics Committee (REC) (REC reference number 21/WM/0050) on 27 April 2021. CAG approval (CAG reference number 21/CAG/049) was given on 20 July 2021. The study was approved by the Health Research Authority (HRA) and Health Care Research Wales on 29 July 2021. Details of protocol amendments submitted to the REC are provided in *Appendix 2*, *Table 9*.

## Findings

### *Challenges in delivering the FIREFLI trial*

We faced significant and unanticipated challenges resulting in long delays in setting up FIREFLI and starting recruitment. *Table 3* provides details of the original anticipated study timeline against the actual timeline. *Figures 1–3* report summaries of the challenges we experienced. We plan to report further details of the challenges faced in an additional publication which we feel are important to highlight to funders and other researchers wishing to conduct research in this area.

**TABLE 3** Timelines of key planned and actual milestones on the FIREFLI study

| Year | Month | Planned milestone | Actual milestone |
|---|---|---|---|
| 2020 | February | Start of grant | Start of grant |
| | May–July | Submit application for regulatory approval | |
| | July | Start recruitment | |
| | October | | Integrated Research Application System application sent for Sponsor review |
| 2021 | February | | REC application submitted |
| | March | | CAG application submitted and study team respond to initial questions |
| | April | | Favourable ethical opinion for study received<br>CAG application reviewed |
| | May | | CAG issue provisional outcome letter and request change to data flow |
| | June | | Study team respond to CAG queries |
| | July | Recruitment ends | CAG approval issued on condition that there is a change in data flow<br>HRA approval issued for the study |
| | September | | Submission of protocol amendment to change data flow as per CAG's request |
| | October | | Discussion around use of sociodemographic data take place |
| | November | | REC and HRA approved protocol amendment to change data flow |
| | November–December | | Primary Care Registration Management (PCRM) data request submitted |
| 2022 | January | | Submission of protocol amendment to use sociodemographic data as the basis for the mail-out<br>Data Release Authorisation Board approve release of General Practice Research Database |
| | February | | REC approval to use sociodemographic data as the basis for the mail-out |
| | March | | HRA approval to use sociodemographic data as the basis for the mail-out |
| | April | | Recruitment packs sent out |
| | July | Follow-up ends | First participant randomised |
| | December | | Recruitment ends |
| 2023 | January | Analysis completed and final report submitted | Funder informed of study team's opinion that the study is no longer viable<br>End of grant |
| | October | | Final report submitted |

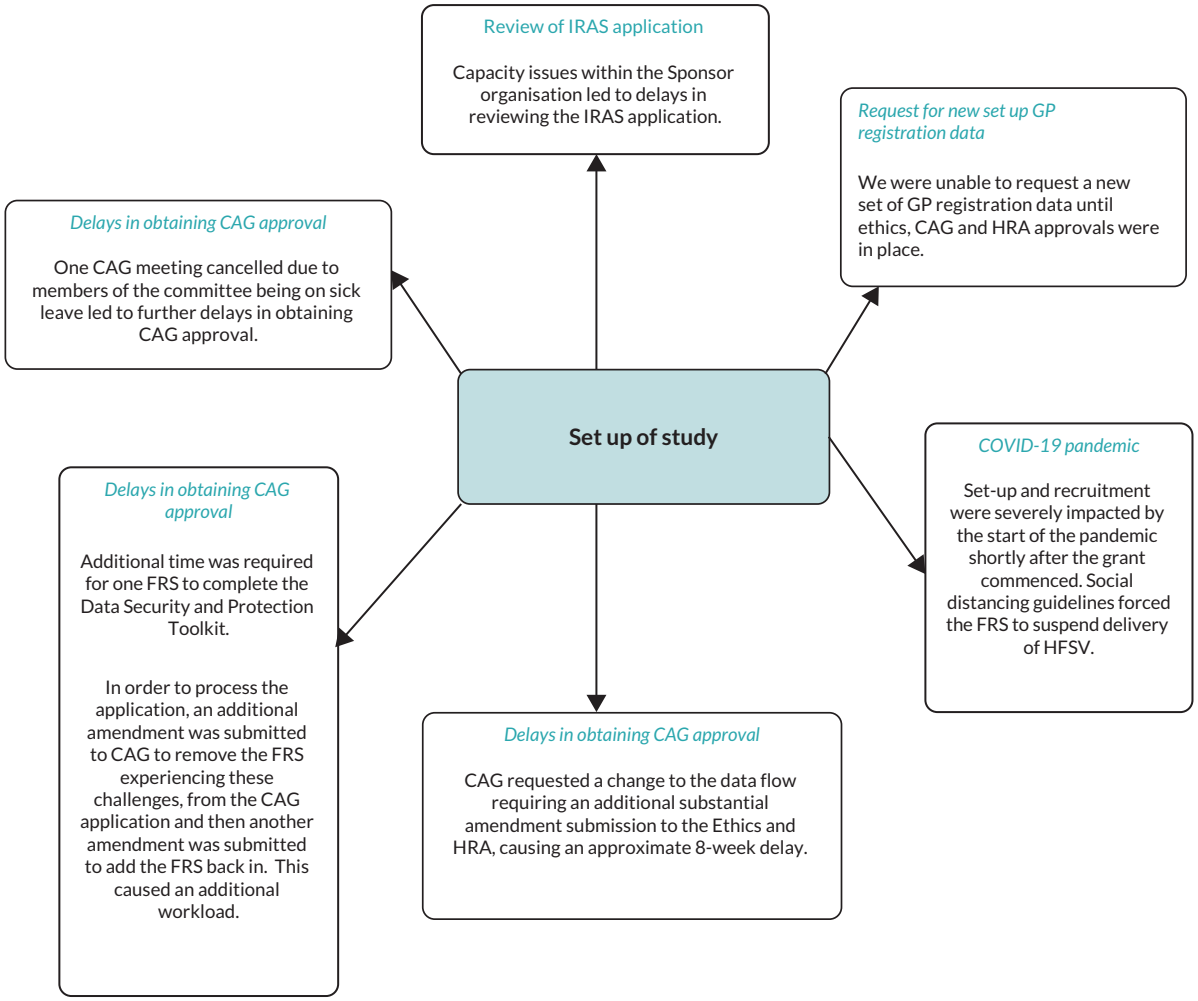


**FIGURE 1** Summary of set-up challenges in the FIREFLI study. IRAS, Integrated Research Application System. GP, general practitioner.

The main issue experienced in reaching the planned milestones for the following tasks were:

- Delay in obtaining regulatory approvals.
  - Review of the potential impact of the NIHR OTIS trial results on FIREFLI by the study team, Trial Steering Committee (TSC) and funder delayed submission for ethics approval. The application was not submitted until September 2020. Ethical approval for the study was not in place until April 2021.
  - CAG approval was delayed due to: the time taken to respond to CAG's provisional letter; a CAG meeting was cancelled due to illness; there was a delay in completing the Data Security and Protection Toolkit at one FRS; CAG requested a change to the data flow, which required submission of an amendment to REC.
  - HRA approval could not be put in place until CAG approval was in place.

- Challenges of delivering the trial.
  - Obtaining general practitioner (GP) registration data.
  - Unable to request GP registration data until REC, CAG and HRA approvals were in place.
  - GP registration data requested, and release authorised, but FRS never received the data.
  - Mail-out of recruitment packs could not take place until the FRS received GP registration data.
  - Both FRSs suspended delivery of HFSV due to the COVID-19 pandemic.

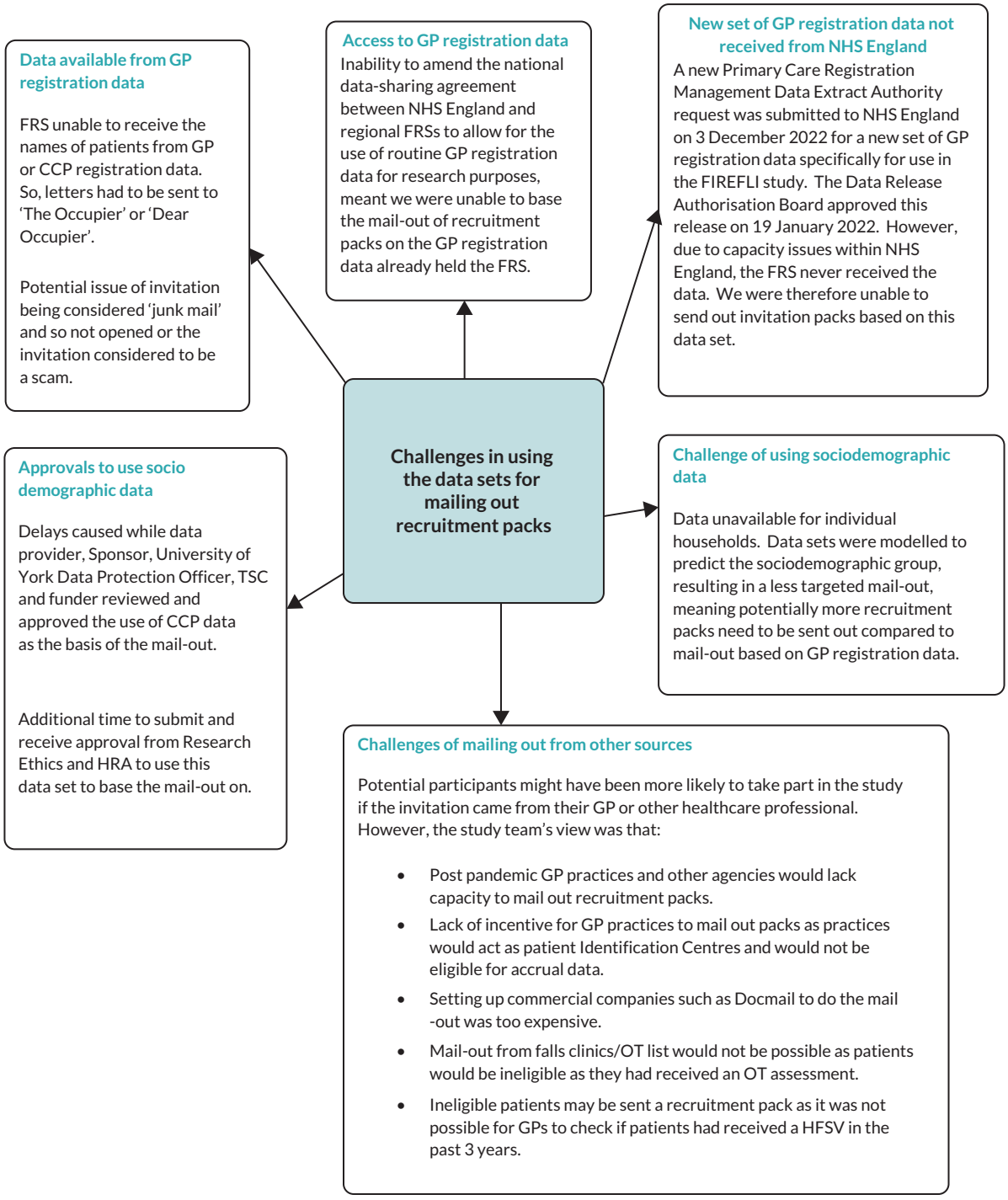


**FIGURE 2** Summary of challenges in using the data sets for mailing out recruitment packs for the FIREFLI study. CCP, consumer classification platform.

## New research evidence

Coinciding with the start of the study, new evidence from a large NIHR-funded trial on the effectiveness of home assessment visits on falls among individuals over 65 years emerged (the OTIS study[12]). As there were parallels between the intervention being tested in FIREFLI and that investigated in OTIS, assessed using the same outcome measures, the requirement for another trial was discussed with the internal team, the external independent steering committee and the funder. It was agreed that FIREFLI should be undertaken, and the funder confirmed the study could commence as planned in September 2020.

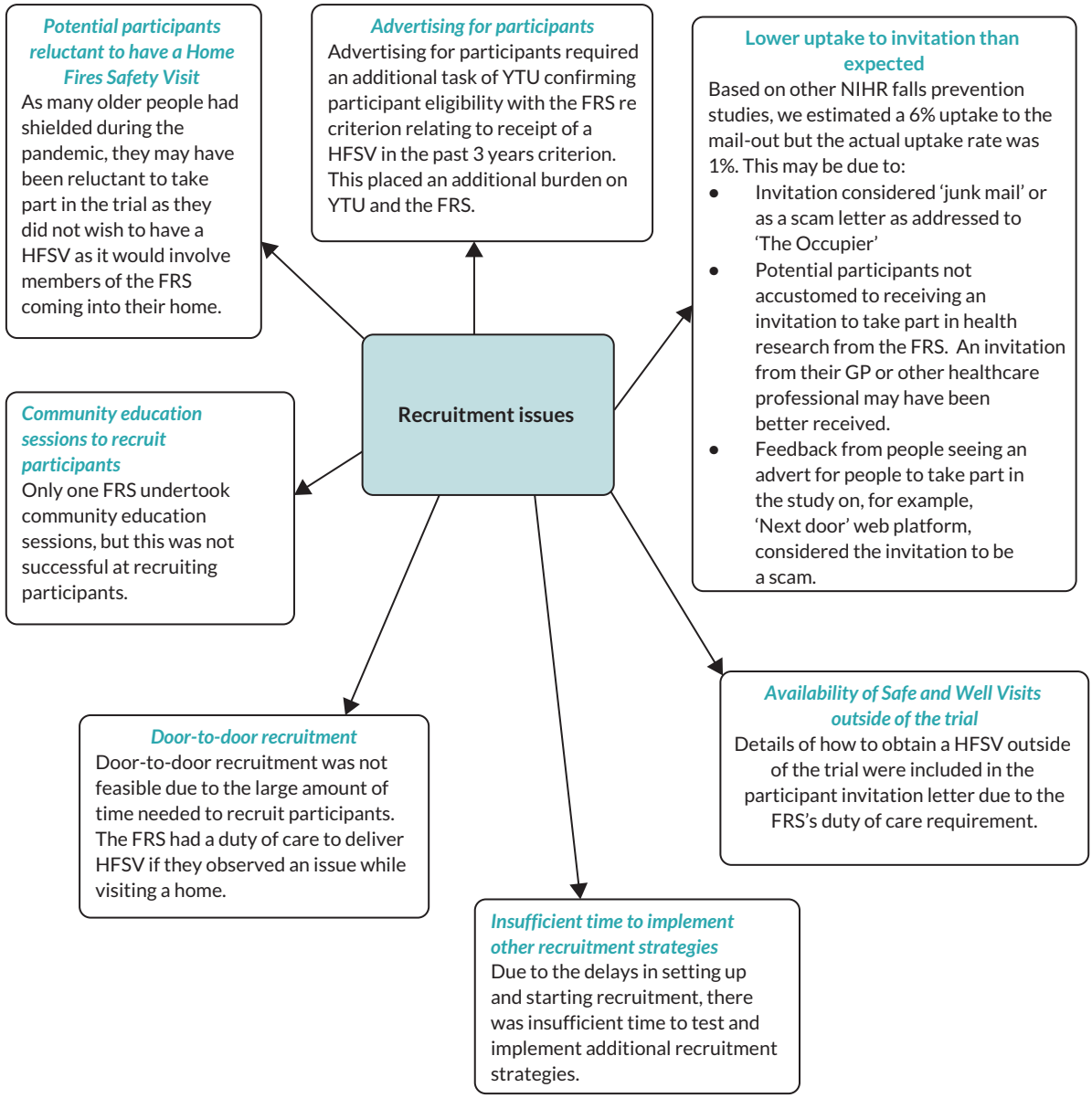


**FIGURE 3** Summary of recruitment issues experienced during the FIREFLI study.

## Research infrastructure in fire and rescue service

To our knowledge, this was the first large NIHR-funded evaluation of a fire service intervention; therefore, it is a relatively new context in which research is taking place. The associated lack of research infrastructure, and lack of familiarity with researching this context, caused unanticipated delays.

We originally planned to identify potential participants from the General Practice Research Database (GPRD), as this was the data set routinely used by the FRS to offer households HFSV. FIREFLI was designed as a pragmatic trial and as such was designed to reflect normal practice as much as possible. The FRS obtain GPRD data on address, sex and year of birth of people living within the areas they cover from NHS England and our research planning had assumed it would be possible to recruit using these data. However, the data-sharing agreement (DSA) between the FRS and NHS England did not allow these data to be used for research purposes and NHS England were unwilling to change the DSA as this is a national-level agreement with all FRSs in England. This resulted in an unforeseen request for GPRD data having to be completed by the FRS via a Primary Care Registration Management (PCRM) Data Extract Authority request. This is a

lengthy and complex process which requires ethics, CAG and HRA approvals to be in place. Neither the research team nor the fire service collaborators were aware in advance that the data sharing for research purposes would be such a major issue. Therefore, future research should consider this in advance and allow extra time to seek the permissions required. The PCRM Data Extract Authority request form was submitted on 3 December 2021. The Data Release Authorisation Board approved the release of data on 19 January 2022. However, due to capacity issues within NHS England, the FRS did not receive the requested data before the end of the trial. Capacity issues within NHS England are unpredictable and outside of the control of the research team. However, these issues should be considered a risk to research delivery by NIHR.

Further significant delays were encountered with the CAG application with regard to the submission of the Data Security Protection Toolkit (DSPT) application. Any organisation processing confidential patient information under a CAG application needs to have their DSPT self-assessment submission reviewed by NHS England, to provide assurances that the organisation had achieved the appropriate standards, a process which can take up to 60 days. The FRS are not routinely required to submit a DSPT application, and for one of the FRS participating in the study, service demands and staffing issues meant this was difficult to deliver. For example, in order to meet DSPT requirements, a very high proportion of all staff in the service are required to have research governance training every year. This frequency of training is not a normal requirement of FRS staff and therefore accreditation needed to wait until training had been refreshed for the entire organisation, even though only a small number of staff were involved in the trial or would have access to the NHS data. This unanticipated requirement was burdensome to the study collaborators and caused delays. Current governance systems mean that research teams working with service providers outside of the NHS need to factor in more time to ensure these, often unfamiliar, standards are met.

## Exploration of alternative sampling methods

As well as the GPRD, several alternative data source options were discussed, (but not necessarily implemented) within the study team and the external trial oversight committee [joint TSC/Data Monitoring and Ethics Committee (DMEC)] in an attempt to mitigate the delays experienced and are summarised in *Table 4*.

**TABLE 4** Alternative data sources for sampling

| Option | Barriers | Was the strategy implemented? |
|---|---|---|
| Mail-out via GP practice lists | • Lack of capacity given post-pandemic workload<br>• Challenging GP database search strategy to identify appropriate patients<br>• Inefficient mail-out as high numbers of patients may be ineligible due to having received a HFSV within the past 3 years<br>• Patient Identification Centres are not eligible for accrual data so GPs may be reluctant to help without getting this recognition | ✗ |
| Mail-out via OT databases | • Lack of capacity given post-pandemic workload<br>• Challenging database search strategy to identify appropriate patients<br>• Inefficient mail-out as high number of participants may be ineligible due to having received falls prevention service or HFSV within the past 3 years<br>• Patient Identification Centres not eligible for accrual data so OTs may be reluctant to help without getting this recognition | ✗ |
| Mail-out via FRS's Consumer Classification Platform database | • Data not available at individual household level; therefore, a less targeted mail-shot requiring a greater number of ineligible participants would be contacted<br>• Letters can only be addressed to 'The Occupier' | ✓ |

In their usual practice, due to capacity constraints, both FRSs use risk profiling to prioritise the households most requiring a visit due to potential risk of fire. The FRS use Consumer Classification Platform (CCP) data as part of this risk profiling. Demographic data, social factors, population and consumer behaviour are used to group together, and describe households likely to share similar traits. Despite the disadvantages associated with using these data as a means of identifying possible study participants, this was considered the most viable option for the trial in the research climate at that time. However, further permissions and adjustments to the regulatory approvals had to be made, including agreement from the data supplier for use for research purposes, agreement from the Sponsor, the University of York Data Protection Officer, the TSC/DMEC and funder; following agreement, a protocol amendment to use CCP data was submitted and approved by ethics and HRA.

### Complex regulatory approvals

While NIHR are committed to increasing research capacity outside of the NHS, as noted in *Research infrastructure in fire and rescue service*, working with service collaborators who do not have an existing research infrastructure can impose unanticipated challenges. The lack of infrastructure alongside complex regulatory requirements imposed severe limits on the ability to deliver research in this space. As outlined above, the GPRD application to NHS England was contingent on ethics, HRA and CAG approval. CAG itself was contingent on the DSPT submission from the FRS. The CAG process was delayed due to the cancellation of meetings by them due to staffing issues and, coupled with this, CAG requested a change to the proposed data flow, which required an ethical amendment to the approved protocol, causing further delays. This circular, fragmented series of regulatory requirements seriously inhibited the ability to deliver the trial.

### COVID-19

All of the above took place against the backdrop of the COVID-19 pandemic, which severely impacted the study. The grant commenced just 1 month prior to the first UK COVID-19 lockdown (March 2020) which meant we were attempting study set up in a period of unprecedented demand on research sponsors and approvals committees, whose remit was amended to prioritise studies relating to COVID-19,[13] causing delays in obtaining the necessary approvals.

The FRS were forced to suspend usual delivery of HFSV multiple times between 11 March 2020 and 21 June 2021 due to local and national social distancing restrictions. Therefore, we had to amend our research protocol to account for a range of potential changes to service delivery that would still allow the evaluation to go ahead. We were required to make reactive decisions to our research plans in response to an uncertain service landscape and had to make continual changes to our regulatory approval applications accordingly. For example, the potential range of service delivery formats required a range of different versions of study documentation (e.g. to allow for a telephone HFSV service delivery), which in the end turned out not to be required as home visits were resumed by the time the approvals were in place.

## *Trial recruitment*

### The recruitment process

Recruitment took place within our two FRS collaborators (Humberside and Kent). Participants were recruited by the FRS mailing out postal recruitment packs based on CCP data. Recruitment packs contained an invitation letter addressed to 'The Occupier', study information (see *Report Supplementary Material 4* and *Report Supplementary Material 5*), consent form, screening questionnaire and pre-paid return envelopes. See *Box 1* for criteria used by FRS to inform the mail-outs. Information about how to opt out of the mail-out was provided on the FRS's website. Those interested in taking part were asked to return study documentation to the YTU, University of York, and consenting participants were assessed for eligibility. Eligible participants were then sent a baseline questionnaire and a pack of falls calendars. Participants had to return the baseline questionnaire and at least one falls calendar before they were randomised to demonstrate engagement with this method of data collection, as this was used to collect co-primary outcome data of falls post randomisation. Mail-outs began in April 2022.

**BOX 1** Sociodemographic profiling data used by FRS to determine mailing list

**Humberside FRS risk profiling criteria were:**

- Age.
- Living alone.
- Smoking prevalence.
- Above-average use of drugs/alcohol.
- Mobility issues.
- Use social groups which have above-average likelihood of single occupancy.

These risk criteria were highlighted from analysis of the national fire fatality data. Households were classified as category A (high risk) to F (low risk). Those deemed as category A were excluded from the mail-out as they needed a HFSV as soon as possible and it would have been unethical to make those assigned to the control group wait 12 months.

**Kent FRS risk profiling process:**

- Addresses from CCP data selected that were most likely to match the study criteria and were identified as higher than average risk.
  - Higher than average risk was identified by correlating output areas with accidental dwelling fires.
- Addresses previously identified as very high risk or had recently been offered a HFSW or had already been referred to the FRS for a HFSV were excluded.

We also advertised for participants on the FRS' websites, Twitter (Twitter, Inc., San Francisco, CA, USA), neighbourhood social media (Nextdoor for Public Services, Nextdoor Holdings, Inc., San Fransisco, CA, USA) and the University of the Third Age – u3a (a collection of groups for people who are no longer in full-time employment or raising a family, who run local and online member-led learning across the UK[14]). Anyone responding to the adverts were advised to contact YTU to be sent a recruitment pack.

In an attempt to increase response rate (through simplification of the study documentation) and reduce the cost of mailing out recruitment packs, a shorter two-page Expression of Interest (EoI) letter, containing summary details of the study, was sent to potential participants from October 2022. Anyone interested in finding out more about the study was asked to return a contact details form to the study team, who would then send them the full invitation pack.

## Recruitment rates

Recruitment took place between April 2022 and December 2022 and the flow of participants is reported in the Consolidated Standards of Reporting Trials (CONSORT) diagram in *Figure 4*. Reasons for ineligibility are reported in *Table 5*.

A total of 63 participants were randomised between 20 July 2022 and 9 December 2022, 32 to the intervention group (50.8%) and 31 (49.2%) to usual care. Nearly two-thirds ($n$ = 40, 63.5%) were from Humberside and 23 (36.5%) from Kent. The overall randomisation rate, from the total number of full recruitment packs sent out ($n$ = 5118), was 1.2%, significantly lower than the expected 6%. The EoI did not result in any recruits since recruitment was closed not long after these were sent out.

We originally estimated that between the two FRS there were 258,000 households that could be approached to take part in the study. As our ultimate recruitment strategy utilising CCP data meant that we had a less targeted approach to contacting households and the response rate being so low, the number of households we would need to contact in order to meet our original target sample size was unfeasible and costly. The research team made the recommendation to the funder that the trial should be closed in December 2022. The last participant was randomised in December 2022 and data collection was stopped on 31 January 2023.

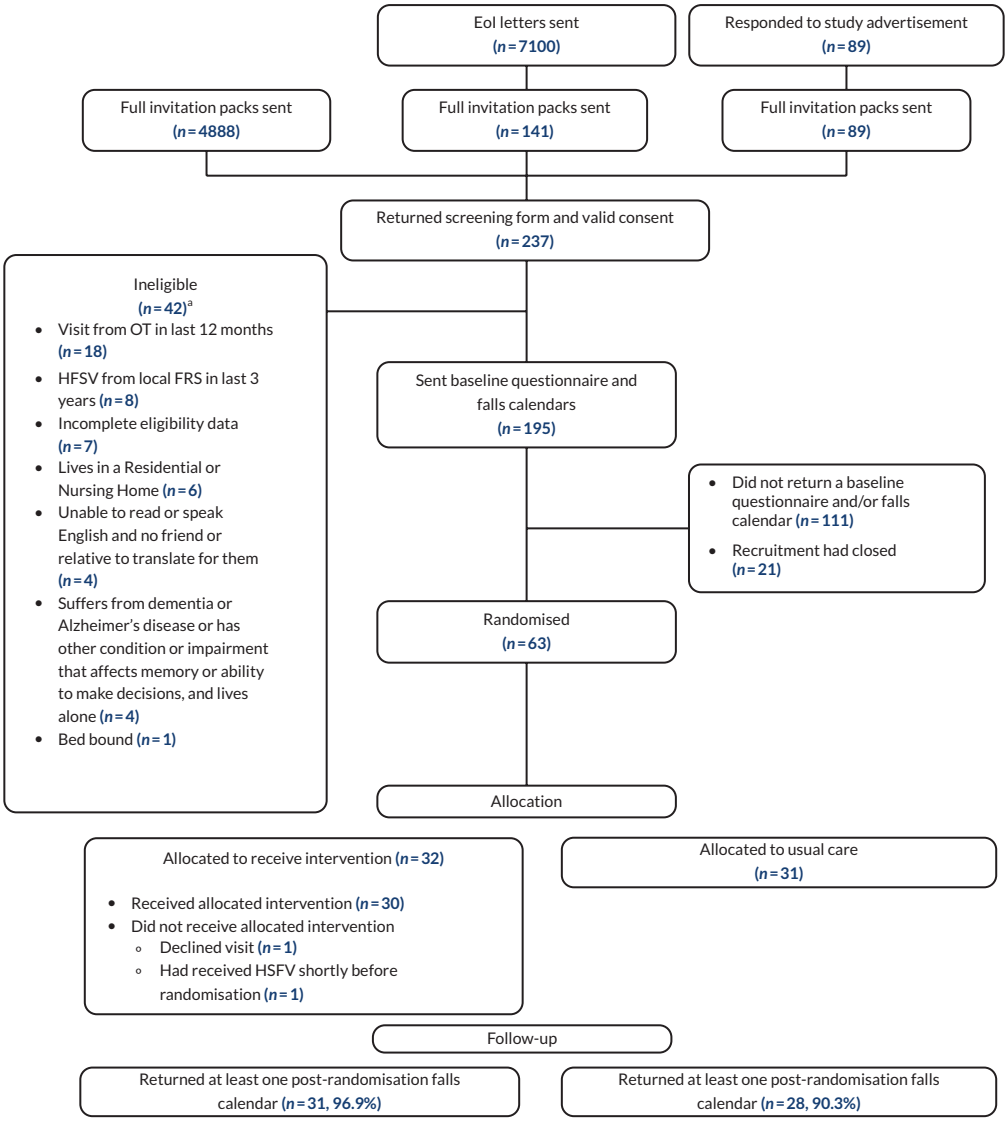


**FIGURE 4** Consolidated Standards of Reporting Trials flow diagram of FIREFLI participants through the trial. a, More than one reason can apply.

## Reasons for low recruitment

Response to the mail-out was much lower than anticipated. Several reasons may have contributed to this.

1. Lack of contact name for the invitation letter
   Consumer Classification Platform data do not provide the name of resident(s), only the address. This meant the envelope and invitation letter had to be addressed to 'The Occupier' or 'Dear Occupier'. Members of the trial team became aware that in one location the recruitment packs were deemed to be 'junk' or 'scam mail' and not opened. The public involvement (PI) group and study team discussed the steps that could be taken to alert potential participants to the fact that the invitation pack was from a safe source. As the invitation packs were sent out by the FRS, all envelopes were franked with information about the individual FRS. The invitation letter contained both the FRS and study logos, along with the address of the FRS. Other documentation in the pack included the University of York's logo and 'Funded by NIHR National Institute for Health and Care Research' logo. Links to information about the study were put on both FRS's and the University of York's websites and the NIHR study funding page. The PI group approved all these plans and, moreover, could not suggest any other strategies.

**TABLE 5** Reasons for ineligibility according to inclusion and exclusion criteria (*n* = 42/239 screened, participants may have had more than one reason for ineligibility)

| Reason for ineligibility | *N* = 42, *n* (%) |
|---|---|
| Visit from OT in last 12 months | 18 (42.9) |
| HFSV from local FRS in last 3 years | 8 (19.0) |
| Incomplete eligibility data | 7 (16.7) |
| Lives in a residential or nursing home | 6 (14.3) |
| Unable to read or speak English and no friend or relative to translate for them | 4 (9.5) |
| Suffers from dementia or Alzheimer's disease or has other condition or impairment that affects memory or ability to make decisions, and lives alone | 4 (9.5) |
| Need a HFSV from local FRS in next 12 months or referred to FRS as urgent case | 4 (9.5) |
| Bed bound | 1 (2.4) |

The study team did consider whether it would be possible to link the names and addresses of residents from the electoral open register to the CCP, which would have allowed for a more personalised approach. The open register of electors is available for general sale and can be used for any purpose. It contains the names and addresses of electors who have not opted out of being included in the open register and thus a limitation to using these data is that not every household would be included. The FRSs contacted their local council requesting access to these data; however, they were unsuccessful in obtaining it. The study team considered purchasing the data on behalf of the study, but this was not considered appropriate as the cost and the inefficiencies associated with this were not deemed worth the projected limited impact this would make on the response rate at that stage in the study.

2. Invitation received from the FRS
   Households were not used to receiving letters about health interventions from the FRS and the invitation may have been better placed coming from their GP or another healthcare professional. However, our PI group were asked specifically about this at the grant application stage, and they anticipated no concerns about members of the FRS approaching them about health topics in addition to fire safety issues and would have actually welcomed their help. It is also possible that potential participants were disconcerted by the fact that the letter was sent to them by the FRS, but they were being asked to return documentation to the University of York.

3. Ability to obtain HFSV outside of the trial
   The FRS's duty of care meant that the invitation letter had to contain information about how to access a HFSV for those not wishing to be in the study. However, neither FRS reported a significant increase in the number of requests for HFSV outside of the trial following the mail-out of recruitment packs, and so it may not have been the case that potential participants did not take part because they knew they could access a HFSV without taking part in the study.

4. Provision of information
   Study information was only provided in written form and in English and will have excluded some potential respondents. Consideration was given to the development of an online consent and screening form. However, as 40% of those aged 75 years and older and 12% of those aged 65–74 do not use the internet,[15] it was felt this would not have a significant impact on recruitment.

### *Findings from the randomised controlled trial*

While a comprehensive analysis to investigate the effectiveness and cost-effectiveness of the FIREFLI intervention was planned, due to the trial's closure prior to attaining the required recruitment target, the limited data are only summarised descriptively [Stata v18 (StataCorp LP, College Station, TX, USA)]. No formal hypothesis testing was undertaken.

## Baseline data

Baseline data for the 63 randomised participants are presented in *Table 6*, and in *Appendix 3*, *Tables 10–14*. Two were completed by consultees rather than the participant. The mean age of participants was 78.5 years [standard deviation (SD) 5.6, range 69–94] and half were male (*n* = 32, 50.8%). Concern about falling was relatively low with only 16 participants (25.4%) reporting that in the last 4 weeks they had worried about falling at least some of the time. Twenty-three (36.5%) participants [13 (40.6%) in the intervention group and 10 (32.3%) in usual care] reported having had at least one fall in the 12 months before they completed the baseline questionnaire (average of 2.3 falls, SD 2.2).

**TABLE 6** Baseline demographics of randomised participants (*n* = 63)

| Characteristic | Intervention (*n* = 32) | Usual care (*n* = 31) | Overall (*n* = 63) |
|---|---|---|---|
| ***Age, years*** | | | |
| Mean (SD) | 80.6 (6.1) | 76.3 (4.0) | 78.5 (5.6) |
| Median (IQR) | 79.7 (76.4–84.2) | 76.0 (72.3–78.2) | 77.3 (74.3–82.6) |
| Minimum–maximum | 69.2–94.0 | 70.7–85.4 | 69.2–94.0 |
| ***Sex, n (%)*** | | | |
| Male | 12 (37.5) | 20 (64.5) | 32 (50.8) |
| Female | 20 (62.5) | 11 (35.5) | 31 (49.2) |
| ***BMI (kg/m2)*** | | | |
| Mean (SD) | 27.8 (6.4) | 26.2 (4.5) | 27.0 (5.5) |
| ***Living arrangements, n (%)*** | | | |
| Alone | 24 (75.0) | 19 (61.3) | 43 (68.3) |
| With a friend or relative | 1 (3.1) | 1 (3.2) | 2 (3.2) |
| With a partner or spouse | 6 (18.8) | 11 (35.5) | 17 (27.0) |
| In sheltered accommodation | 2 (6.2) | 1 (3.2) | 3 (4.8) |
| ***Education, n (%)*** | | | |
| No formal qualifications | 16 (50.0) | 14 (45.2) | 30 (47.6) |
| Qualification related to clerical work or trade | 9 (28.1) | 10 (32.3) | 19 (30.2) |
| O level/GCSE/CSE | 6 (18.8) | 8 (25.8) | 14 (22.2) |
| A level/higher school certificate | 2 (6.2) | 3 (9.7) | 5 (7.9) |
| Degree | 2 (6.2) | 2 (6.5) | 4 (6.3) |
| Taking > 4 medications a day prescribed by a doctor, *n* (%) | 18 (56.2) | 20 (64.5) | 38 (60.3) |
| Had medication review in past 12 months, *n* (%) | 17 (53.1) | 19 (61.3) | 36 (57.1) |
| Flu jab in the past 12 months, *n* (%) | 30 (93.8) | 26 (83.9) | 56 (88.9) |
| Need to use arms to push self out of a chair, *n* (%) | 25 (78.1) | 20 (64.5) | 45 (71.4) |
| ***Judgement of balance, n (%)*** | | | |
| Good and want to keep it that way | 14 (43.8) | 15 (48.4) | 29 (46.0) |
| Quite good but would like to improve it | 10 (31.2) | 7 (22.6) | 17 (27.0) |
| Some problems with balance that want to overcome | 7 (21.9) | 9 (29.0) | 16 (25.4) |
| Missing | 1 (3.1) | 0 (0.0) | 1 (1.6) |

**TABLE 6** Baseline demographics of randomised participants (*n* = 63) (*continued*)

| Characteristic | Intervention (*n* = 32) | Usual care (*n* = 31) | Overall (*n* = 63) |
|---|---|---|---|
| ***Difficulties with balance while walking or dressing, n (%)*** | | | |
| Yes, often or always | 5 (15.6) | 8 (25.8) | 13 (20.6) |
| No, or just occasionally | 25 (78.1) | 23 (74.2) | 48 (76.2) |
| Missing | 2 (6.2) | 0 (0.0) | 2 (3.2) |
| ***Risk of falling, n (%)*** | | | |
| High[a] | 15 (46.9) | 16 (51.6) | 31 (49.2) |
| Low | 16 (50.0) | 15 (48.4) | 31 (49.2) |
| Missing | 1 (3.1) | 0 (0.0) | 1 (1.6) |

BMI, body mass index; CSE, Certificate of Secondary Education; GCSE, General Certificate of Secondary Education.
a Balance problems while walking or dressing, or at least moderate problems doing usual activities, or one or more falls in previous 12 months.

## Follow-up

No participant had been sent their 4-month follow-up questionnaire when the decision was made to cease recruitment, and there was insufficient time left on the grant to make starting this data collection worthwhile. Therefore, no participants were sent their 4-month questionnaire. Participants had been randomised into the trial for up to 6 months when follow-up of falls calendars ceased; any falls calendars received up to the end of January 2023 were accepted and included in the analysis. Data about the fall, for example cause, location and injuries sustained, were collected using a data collection sheet (see *Report Supplementary Material 3*).

There were no formal withdrawals from the intervention or follow-up.

## Intervention delivery

All intervention group participants except two (one from each FRS) received a HFSV during the trial. The visits occurred a median of 20.5 days after randomisation (mean 30.5, SD 22.4, range 5–89). One intervention participant declined a visit, and the other did not receive a HFSV during the trial because it was discovered after randomisation that they had actually received a visit shortly before they were randomised and so were not offered another one. A HFSV was not delivered to any of the control participants within the trial intervention period (although the control group were offered a HFSV after the study closed).

The response rates for the monthly falls calendars, where month 0 is the month of randomisation, are presented in *Appendix 3*, *Table 15*. Overall, the response rate per month was consistently > 70% and was reasonably comparable across the intervention and usual care groups.

## Primary outcome

In total, 59 randomised participants (93.7%) returned at least one falls calendar post randomisation: 31 in the intervention group and 28 in usual care (see *Appendix 3*, *Table 15*).

Among the 59 patients who returned at least one falls calendar post randomisation, 7 participants in each group reported at least one fall (7/31, 22.6% in the intervention group, and 7/28, 25.0% in the usual care group). The average number of falls reported was 0.66 (SD 1.87, median 0, range 0–10) over an average of 4.2 months (SD 1.8, median 4.3, range 0.8–7.4):

- Intervention group – average number of falls reported was 0.65 (SD 1.78, median 0, range 0–8) over an average of 4.1 months (SD 2.0, median 4.3, range 0.8–7.4).

- Usual care group – average number of falls reported was 0.68 (SD 2.00, median 0, range 0–10) over an average of 4.2 months (SD 1.6, median 4.3, range 1.3–7.4).

Data about the fall were available for 11 out of the 39 falls that participants reported during follow-up (*Table 7*).

**TABLE 7** Details collected on post-randomisation falls, for 11 of the 39 reported falls

| Details of fall | Intervention (*n* = 5) | Usual care (*n* = 6) | Overall (*n* = 11) |
|---|---|---|---|
| ***Location of fall, n (%)*** | | | |
| Inside own home | 5 (100.0) | 2 (33.3) | 7 (63.6) |
| Inside, but not in own home | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Outside but within grounds of own home | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Outside, beyond own home | 0 (0.0) | 4 (66.7) | 4 (36.4) |
| ***Activity when fell, n (%)*** | | | |
| Getting in/out of bed, chair, bath, toilet, shower | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Turning | 1 (20.0) | 1 (16.7) | 2 (18.2) |
| Going up/down steps or stairs | 1 (20.0) | 2 (33.3) | 3 (27.3) |
| Walking | 1 (20.0) | 2 (33.3) | 3 (27.3) |
| Reaching/bending | 2 (40.0) | 1 (16.7) | 3 (27.3) |
| Rushing | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Unknown/can't recall | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Other | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| ***Cause of fall, n (%)*** | | | |
| Trip, didn't pick feet up, fell over something | 1 (20.0) | 4 (66.7) | 5 (45.5) |
| Slip, skid | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Uneven surface | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Steps/gradient | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Legs gave way, just went over/down | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Dizzy, woozy, groggy, lightheaded, passed out | 2 (40.0) | 0 (0.0) | 2 (18.2) |
| Lost balance | 1 (20.0) | 2 (33.3) | 3 (27.3) |
| Knocked, pulled, or blown over | 1 (20.0) | 0 (0.0) | 1 (9.1) |
| Footwear issue | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Poor visibility/lighting | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Do not know/can't recall | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Other | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| ***Outcome of fall, n (%)*** | | | |
| No injury | 5 (100.0) | 2 (33.3) | 7 (63.6) |
| Superficial wounds, for example bruising, sprain, cut, abrasion | 0 (0.0) | 4 (66.7) | 4 (36.4) |

**TABLE 7** Details collected on post-randomisation falls, for 11 of the 39 reported falls (*continued*)

| Details of fall | Intervention (*n* = 5) | Usual care (*n* = 6) | Overall (*n* = 11) |
|---|---|---|---|
| ***Visit accident and emergency because of fall, n (%)*** | | | |
| No | 5 (100.0) | 6 (100.0) | 11 (100.0) |
| ***Stay in hospital overnight because of the fall, n (%)*** | | | |
| No | 5 (100.0) | 6 (100.0) | 11 (100.0) |
| ***Stay in hospital for the day only, because of the fall, n (%)*** | | | |
| No | 5 (100.0) | 6 (100.0) | 11 (100.0) |

**Note**
There were no recorded serious or non-serious adverse events.

## Recruitment Study Within A Trial

The first mail-out batch from each FRS was not included in the SWAT as this allowed the FRS to familiarise themselves with the mail-out process with no additional complexities. A total of 4500 recruitment packs were randomised into the SWAT (3000 from Humberside and 1500 from Kent) to either receive an invitation letter informed by Self-Determination Theory with their trial invitation pack (*n* = 2252) or the 'standard' invitation letter used within the YTU to recruit participants via the post (*n* = 2248). The primary outcome for the SWAT was the proportion of participants who went on to be randomised into the FIREFLI trial (*n* = 37, 1.6% in the intervention letter arm, *n* = 25, 1.1% in the standard letter arm; OR 1.49, 95% CI 0.89 to 2.48; *p* = 0.13).

Secondary outcomes were:

- proportion of participants who returned a screening form (*n* = 71, 3.2% in the intervention letter arm, *n* = 67, 3.0% in the standard letter arm; OR 1.06, 95% CI 0.75 to 1.49; *p* = 0.74)
- proportion of participants who were eligible (*n* = 61, 2.7% in the intervention letter arm, *n* = 50, 2.2% in the standard letter arm; OR 1.22, 95% CI 0.84 to 1.79; *p* = 0.30)
- proportion of participants who remain in the trial at 3 months post randomisation, defined as returning at least the first 3 months' worth of falls calendars from the date of randomisation (*n* = 29, 1.3% in the intervention letter arm, *n* = 19, 0.9% in the standard letter arm; OR 1.53, 95% CI 0.86 to 2.74; *p* = 0.15).

Results favoured the intervention letter arm of the SWAT for all outcomes, though differences were not statistically significant. However, as is usual with an embedded trial within a trial, no formal power calculation was undertaken for the SWAT, as the sample size was constrained by the number of participants available to mail-out to.

### *Qualitative findings*

Seventeen service providers (6 firefighters, 11 advocates) and 11 service leaders were interviewed. Advocates are also known by various other names such as prevention advisors or safe and well officers. They are a non-operational role within the FRS focusing on fire prevention and community work. Service leaders included members of the FRS (*n* = 7) and primary care services (*n* = 4). Service providers had an average of 13 years of experience within the FRS (range 3 months to 25 years). Four themes were identified from the qualitative interview data relating to the experiences and acceptability of the HFSV from across the stakeholder perspectives: (1) culture change within the FRS; (2) relationships with other services; (3) reaching and supporting vulnerable people; and (4) efficacy and impact of the HFSV service. These findings are being submitted for publication to the *Journal of Public Health* in December 2023. Once accepted, it will be a linked publication.

In addition, 15 trial participants were interviewed (10 women and 5 men, mean age 82 years, range 74–92 years). Findings from the descriptive thematic analysis are presented below.

### Experience and acceptability of Home Fire Safety Visits from perspective of trial participants

Participants had broadly positive views of their visit. There was a sense of gratitude that the service targets older people and those living alone. They reported feeling cared for and that it was good to know that older people are not forgotten. Some participants who lived alone reported feeling lonely and valued the company that the visit provided.

> *[I]t's a good idea to check on older people, you know, it gives you reassurance and, you know, to know that there is somebody looking out for you, especially when you live on your own*

### Organisational aspects

Participants generally found the visit pleasant and commented that the FRS member they saw was friendly, polite and professional. Some participants expressed that prior to the visit they experienced apprehensions, fearing that the offer of a visit may be a scam. Participants' family members tended to assure participants of the study's legitimacy, and this appeared to allay participants' fears.

> *To be honest I was a little bit anxious because I'm on my own but he was a nice chap and he showed his ID as he came to the door and after he came in I was comfortable. Everything went really well.*

Participants sometimes expressed a preference for being called in advance of the visit in order to inform them of the date and time of the visit. Some participants who were not notified in advance of the date and time of their visit reported that the visit therefore happened at an inconvenient time, and that this meant they were less able to engage in the visit.

> *[T]hey are an emergency service in their own right and so perhaps they can't always predict exactly when they're going to turn up. But certainly if I were expecting them, I would have been better prepared instead of me being in the middle of cooking my tea.*

### Content of the visit

For many participants, the main beneficial aspect of the visit appeared to be that it provided them with reassurance. They found it comforting to have a professional check their home and reassure them that they are safe.

> *I mean it just gives you a bit more confidence in yourself about the fact that there's no lurking dangers and any issues like that were highlighted and we were able to sort of rectify or correct to minimise the risk.*

Participants also reported receiving practical benefits of the visit such as having smoke alarms tested or fitted, and some felt they gained pieces of knowledge they were not previously aware of. This tended to be knowledge of fire safety such as advice on escape routes in case of fire, advice on electrical equipment and the advice to shut doors at night. Participants who received advice reported following the advice post visit, and this was largely small changes such as closing the kitchen door at night.

Prior to the visit, participants reported having expected the visit to focus on risk assessment in terms of home safety and generally felt that the visit matched those expectations. However, some participants expected the visit to focus on risks related to falls (this expectation appeared to be due to the Firefli study's focus on falls) and reported being surprised when falls were not mentioned by the FRS member they saw.

Several participants felt that the visit was brief. While some acknowledged that this was appropriate due to not needing much support, others were disappointed that the visit was not more comprehensive. In particular, a minority of participants were disappointed that the FRS member did not look around their home as much as they would have liked.

> *[S]he had a quick look and said, oh I see you've just got cables or an electric blanket, have you got any adaptors anywhere, you know, with more than one thing in it, which I hadn't. I was just a bit surprised that I had to suggest that she look in the bedrooms and the bathroom.*

### Relevance of the Home Fire Safety Visits to the participant

Participants generally felt that HFSV are relevant to older people living alone. It is important to note that while those deemed as in greatest need by the fire service demographic profiling were excluded from the trial (see *Box 1*), only those who would be normally included in approaches from the fire service were included in the trial. Despite this, participants often reported possessing various characteristics that made the visit less appropriate to them, such as being independent, mobile, and well supported in terms of home safety. Most participants commented that they consider themselves independent and are able to do day-to-day activities with ease, and that they consider themselves fit and active with no particular mobility issues.

> *Someone actually taking an interest in the oldies do you know what I mean, so yeah, real good, that's why I responded but it doesn't really affect me. I'll repeat that because I'm quite fit, do you know what I mean. I ride a bike every day. I exercise every day and I've no ill health.*

Participants generally felt well supported by family, friends or neighbours and participants reported few support needs with regard to home safety. Some participants believed themselves to already be knowledgeable about home safety issues and, as such, did not gain any new knowledge from the visit. Most participants reported that they had no particular desires for home safety-related support before the visit. Participants sometimes commented that HFSV were a good idea for others who may be less knowledgeable, independent or mobile. Most participants talked about wanting to take part in the study in order to be helpful to others rather than to gain support themselves. For some, there was confusion between the trial and the visit, and when asked about the utility of the visit some participants discussed hoping that their participation in the trial is helpful. Some participants expressed feeling that their participation in the trial was fraudulent due to concerns that they were not an appropriate person to receive the visit.

> *I don't really feel that I need any help, I'm lucky. But it's nice to know that this kind of thing goes on because there must be people that need this kind of thing more than I do.*

While all participants in the trial would have been eligible for a HFSV visit, it may be that those who agreed to participate in the trial were from a 'healthier' demographic, on average, than those who would ordinarily be in receipt of the service.

# Chapter 3 Discussion/interpretation

## Principal findings and achievements

The FIREFLI trial was designed to robustly evaluate the research question regarding the effectiveness and cost-effectiveness of HFSV to reduce the number of falls and improve quality of life in older people. Prior to this trial, there was little high-quality evidence available to answer this question. However, the study faced significant challenges. There were three main issues. First, the study set-up took 2 years – 18 months longer than the project management plan allowed for. Second was accessing the addresses of households to mail-out invitation packs to. Third, recruitment uptake was lower than anticipated. These challenges in navigating the landscape resulted in delays and ultimately to a reduced recruitment period. Only 63 participants were recruited to the study with insufficient follow-up data collected to answer the research question.

There was limited previous information on which to base anticipated response rates to postal trial invitation mail-outs from the FRS. The planned 6% recruitment rate was based on the research previously undertaken by members of the trial team in other falls prevention studies,[11,12,16] which recruited a similar aged population using postal mail-outs. However, the resulting response rate of 1.2% was much lower than expected. This is a key learning point for studies going forward. In hindsight, during the process of preparing the grant application, we could have further explored whether the DSA for GPRD allowed the data to be shared and used for research purposes, and the feasibility of adding this, and also other options such as using the open electoral list and obtaining names from the GPRD in order for us to do a personalised mail-out. At the time neither the fire service collaborators nor the wider research team were aware this was likely to be an issue, therefore, it should be considered in future research applications.

The use of postal communication is decreasing, in part, due to environmental concerns, rising postage costs and an increase in online communications. Also there has been an increase in concerns relating to scamming, which might have increased recipients' suspicion of the postal invitation pack. In addition, feedback from the FRSs suggests some potential participants found the recruitment information too lengthy and complex. We tried to address this by producing a shorter EoI pack, but the effectiveness of this could not be evaluated before the closure of the trial. In addition, trial governance and ethical approval are contingent on the provision of certain information, which makes it impossible to heed to PI requests for shorter and less complex provision of information as part of the study recruitment process. Similar research in the future may consider using online data collection, which may simplify the recruitment process, making it easier and quicker for participants to sign up to the study. However, this is associated with a very low response rate among a similar cohort (2.6%)[17] and would result in digital exclusion, in particular those who are older, living alone and have a limiting health condition.[18]

We interviewed 11 service leads, 15 trial participants, 18 firefighters/advocates from Humberside and Kent FRS who delivered the HFSV and 7 members of the FIREFLI trial team to better understand the challenges of delivering the trial. The trial participants found the information given to them during the visit somewhat useful and reassuring, but those delivering the visits did not always feel that they were in the correct demographic to receive the visit. Loneliness was identified as an issue for some, especially for those living alone. Service leaders and firefighters/advocates had broadly positive views of the HFSV service, though it was recognised that reaching the appropriate clients, supporting vulnerable people, and supporting officers with some of the more complex aspects of their role were challenging areas.

### *Strengths and weakness of the study*

The main strength of this study was in its planned methodological quality and rigour. It was a multicentred RCT – the 'gold-standard' method of evaluating an intervention. Randomisation was conducted by a secure, remote, web-based system with concealed allocation. The use of a run-in period in which participants had to evidence that they were willing and able to return falls calendars, which were used to collect the co-primary outcome of falls, aimed to reduce post-randomisation attrition. The falls calendars were designed to be completed and returned at regular, frequent (monthly) intervals to minimise the risk of recall bias and encourage high response rates, while not causing excessive participant burden. The trial was planned to be reported in line with CONSORT and other relevant guidelines. An

independent (joint) TSC/DMEC helped ensure the trial was conducted per protocol and that participant safety issues were considered. A further strength was the engagement with research outside of the NHS with new collaborative links made between academia and the FRS. However, despite all this, the overwhelming limitation was the landscape in which the trial was conducted resulting in recruitment that was well below target and participants not being followed up for long enough to provide sufficient follow-up data.

## *Challenges faced and limitations*

### Identifying potential households to send invitation study packs

We detailed earlier in this report the delays experienced in setting up the study and mailing out recruitment packs. These largely relate to identifying a data set on which to base the mail-out. Options included GPRD data in combination with CCP data or mailing out from GP practices. Neither proved viable. It seems unlikely that we would have been able to address the issue of accessing GPRD data for the study, as post pandemic the FRS continue to experience severe delays in obtaining updated GPRD data for routine use. We could have used the CCP data on its own from the beginning. Set up of the study would have been quicker given we would not have needed NHS Ethics, HRA or CAG approval, with approval for the study being given by the University of York, Department of Health Sciences Research Governance Committee. Yet, the downside of approval from this committee is that under the Mental Capacity Act, a University Committee is not an appropriate body[19] and would be unable to review an application including those who lack capacity to give consent to be in a study. This would mean participants lacking capacity could not have been included in the study and the results would have been less inclusive and the findings less generalisable.

We did not include a formal internal pilot phase in FIREFLI, which is very common in more recently funded trials to assess key aspects such as recruitment, retention and intervention adherence against pre-agreed progression criteria. The pilot phase tends to be defined as the first 6–12 months of recruitment, after which progress is considered by the funder and external oversight committees then a decision made about the feasibility and viability of the trial going forward to meet its objectives. Recommendations about changes or strategies to improve progress may be made and implemented. Although a formal internal pilot phase would not have necessarily picked up on issues with recruitment any earlier than they were already identified in this trial, we advise their inclusion in any future trial as good practice.

### Comparison of trial participants to clients routinely seen by the fire and rescue service

FIREFLI was a pragmatic trial, the design of which aimed to reflect how the FRS routinely delivers HFSV in everyday practice. However, there was one group of people who are routinely offered HFSV who were not included in the study. We were unable to recruit those deemed at high risk as the FRS have a duty of care to deliver a HFSV to them as soon as possible. While this group may potentially have derived greater benefit from a HFSV compared to those at lower risk, it would have been unethical to ask those at high risk and allocated to the control group to wait 12 months before receiving a visit. This is a limitation the study team acknowledge. Further to this, as alluded to in some of the qualitative interviews, there is the possibility that the trial was susceptible to volunteer bias. This is where people who take part in research are likely to differ from those who do not, for example, some participants in the trial did not feel they needed the HFSV as they considered themselves to be fit and well and felt safe in their homes.

### Provision of information

At recruitment, study information was provided in paper format with the option for potential participants to telephone the study team at YTU for further information. At the point of writing the study protocol (2019), this was the standard method used within the YTU and had been used to recruit participants on other falls prevention studies run by the unit, even though one study required significant additional funding and time to reach its recruitment target. Randomisation rates on these studies ranged from 2.7% in the NIHR-funded REFORM study[5] to 6.9% for the NIHR-funded OTIS study.[12] Following the closure of FIREFLI, some members of the team worked on the Research for Patient Benefit CASCADE[17] study. In this study, community-dwelling participants aged 65 years and over were recruited to this screening for depression study by two methods (1) postal recruitment and (2) personalised text message with a link to online information, consent form and baseline questionnaire. The overall recruitment rate was 9.2% using paper recruitment packs, which was in line with our expected response to FIREFLI, and 2.6%[5] using text recruitment. The burden on GPs to send out text messages was relatively low in terms of cost and time. Future studies could explore the feasibility of involving large numbers of GP practices or the Research Delivery Networks to send out invitation texts and

e-mails. To overcome concerns that using online recruitment may not be inclusive, paper recruitment packs should be offered if needed. This would provide useful information for designing and costing future research studies in this area. Alternative data sets could be piloted, for example, using the open electoral list in combination with CCP data to see if a more personalised mail-out could also be achieved. Providing study information in other formats such as animations, 'talking heads' or online videos could be tested against more traditional means of providing study information, for example paper participant information's within several SWATs and the results pooled in a meta-analysis.

## Public involvement

We wanted to ensure that the views of older people were woven into the research so that the results of the study would be of direct benefit to them. We were not only able to draw on the PI group set up specifically for the study, but also on the experiences of the OTIS trial PI group and Kent FRS's HFSV customer satisfaction survey which reported the majority of those surveyed as being very satisfied with the HFSV and would recommend having a visit to a friend.

As members of the PI group were geographically dispersed, it was not possible to hold face-to-face meetings, so our PI meetings were held remotely via an online platform with the option for one-to-one catch-ups on the telephone. While some members of the group were familiar with using online platforms, others were not and required support. Some PI members preferred family members to support them through the process of using these platforms. We are grateful to the family members who provided this support. Others were happy for the study team to support them, and PI members found the 'practice meetings' before the actual meeting helpful.

Our PI group advised us on potential recruitment strategies we could implement and were supportive of the research team's suggested strategies. Unfortunately, they were unable to suggest any further strategies the team could implement in order to improve recruitment. They also raised the issue potential participants may experience when received the study invitation pack, in that it may be considered a 'scam'.

## Engagement with partners and stakeholders

At the time of designing the study, the FRS had developed, and were routinely delivering, the HFSV to households in the community. Within this trial, a collaborative approach was adopted with members of the FRS which included a data analyst, a Customer Experience Strategic Lead/Customer Engagement and Safety Officer, and a Prevention Inclusion Manager as well as academics from several organisations in addition to the lead organisation, all of whom were included as co-applicants on the grant and were members of the Trial Management Group. This was essential to ensure that those with detailed knowledge of the context in which the research was being undertaken were involved in trial design. For example, the FRS worked closely with the academic members to develop feasible recruitment strategies and outcome measures such as the fire risk-taking behaviours questionnaire, to ensure the outcome measures used within the trial reflected the intervention. The data analyst was knowledgeable about the availability and accuracy of the data and was able to quickly extract data when required. They were also aware of the potential issues around the use of the procured CCP data. Members of the FRS and academics from organisations in addition to the lead organisation were co-authors on the trial papers and aided with the interpretation and reporting of trial findings.

In October 2022, a new Academic Collaboration, Evaluation and Research Group (ACER)[20] was set up and the FIREFLI Chief Investigator is a member of this group. ACER is an independent forum, convened by the National Fire Chief Council, that aims to create better links between the FRS and academia. This group have developed a new research portal where it is now possible for the FRS and researchers to include information about ongoing or completed research linked to FRS's interest. Going forward, future researchers should approach this group to include information about their research on the portal and ask for assistance in identifying FRSs which may be interested in taking part. In addition to developing collaborations between the FRS and academia, collaborations between local authorities, NHS, social care and housing and other voluntary agencies would be beneficial.

### *Take-home message*

Conducting a RCT within this setting is very challenging and sufficient lead time should be allowed for the setup of a study. We consider an urgent review of research governance issues relating to the type of personal data that can be used for research and its access to be warranted. One option could be for the DSA between NHS England and the FRS to be amended to allow for the use of GP registration data for research purposes and for these data to be extended

to include access to householder's names. Alternatively, recruitment strategies such as text or e-mail invitations sent by GPs or use of the open electoral list in combination with FRS databases could be piloted. Advertisements for participants posted on Twitter and neighbourhood social media (Nextdoor) resulted in 89 enquiries, though we cannot know how many people these adverts actually reached. However, this provides some optimism that older people can be reached about research through social media and the internet despite concerns of scamming. We also had approval to advertise on the TV, radio and in newspapers, but we did not utilise these avenues in the timescale we had. These low-cost forms of advertisements may have resulted in more interest and could have reached a wider population than social media. Researchers should make use of the ACER group and their research portal to help facilitate the process of identifying collaborators within the FRS for future research.

# Chapter 4 Public involvement

We worked with PI representatives from grant preparation through to dissemination of study findings. At the grant application stage, we asked members of the PI group from the NIHR HTA-funded OTIS falls prevention study[6] to provide input into FIREFLI. The OTIS study was conducted by several members of the FIREFLI team and was run in a similar way to that proposed for FIREFLI and recruited a similar population. The PI group identified falls as an area of concern affecting many older people and considered it an area of research worth undertaking. They were supportive of members of the FRS delivering the HFSV and said they would be happy to talk to them about falls around the home. Further evidence of the acceptability of the HFSV was provided from the findings of Kent FRS's HFSV customer satisfaction survey. The majority of those surveyed (98%) reported being very satisfied with their HFSV and would recommend it to a friend.

We wanted to ensure that advice was sought on the number and type of contacts that would be acceptable when collecting data via postal questionnaires and how to collect data from participants who report falling during the study. The PI group confirmed that the two proposed reminders were acceptable and agreed that postal questionnaires to collect further information on reported falls was not too burdensome for participants. The PI group suggested participants should be sent a newsletter to keep them informed about study progress. This was incorporated into the study design with three newsletters sent out at 3, 7 and 11 months post randomisation.

The FIREFLI study, from setup onwards, was informed by the involvement of a PI group, made up of nine older people aged 70 years and over (five female and four male) and identified by the University of York PPI network, Involvement@York, and Engage Kent and Older People's Forum in the Kent. They provided the following feedback:

i. They considered it acceptable for the FRS to use their GP registration data for the purposes of research.
ii. The PI group considered mailing out postal recruitment packs as an appropriate method of inviting large numbers of people to take part in the study. They did voice concerns that recipients may consider the invitation pack a scam and provided advice on how to legitimise the mail-out.
    They provided advice and input into the phrasing, content and format of patient-facing documents, such as information sheets, case report forms and newsletters. The documents were well received, although they thought the information sheet could be shorter. We shortened the information sheet where possible, but due to Sponsor's requirement we were unable to shorten the section on GDPR and confidentiality. Further PI input was provided during the study when one member of the PI group sat on the TSC/DMEC. At the end of the study, a member of the PI group gave input into the content of the study closure letter, which was sent to all participants.

Public involvement members gave their input through group meetings or one-to-one feedback with a member of the team. Our PI strategy was successful in engaging older people in the research, but as this was a slow-progressing trial, contact was often sparse. A key learning point was the need to provide PI members with technical support with the videoconference calls to make the meetings as accessible as possible and offer telephone calls as an alternative.

# **Chapter 5** Equality, diversity and inclusion

The trial recruitment strategy used to identify potential participants for FIREFLI replicated, as far as possible, the process routinely used by Kent and Humberside FRSs to offer HFSV to households. The same risk factors were used to prioritise which households should be offered a HFSV. This was done to ensure the trial population reflected those routinely offered a HFSV. Participants had to be over 65 years or age (or over 70 in Kent) and therefore included a population (i.e. age extremes) identified by the NIHR as being underserved. Falls occur in elderly people from all backgrounds and there was no reason to believe that a falls intervention should work differently in different groups. We acknowledge the trial recruited participants from only two geographical areas, and including more FRS would have made the trial's findings more representative, but this would not have overcome the issues we faced with accessing data. However, the areas covered by both FRSs were diverse and included areas of deprivation as well as less deprived areas, cities, rural and coastal areas.

The fact that the HFSV were delivered in people's homes meant that the study was more inclusive for those who were frail, did not wish to leave their home, or were unable to travel. Not having to travel helped minimise participant burden, as did being able to collect falls and other data over the telephone. The study team would telephone the participant or participants could telephone a Freephone number, thereby ensuring they were not out of pocket. To further reduce burden, participants were due to be given an unconditional £5 with their final questionnaire, as an acknowledgement of their help and to cover any unforeseen expenses.

While the eligibility criteria for the study were wide, it was necessary to exclude people who were bedbound or had an OT visit within the last 12 months as they would not have benefited from the falls prevention aspect of the HFSV. In addition, people who were unable to read English were excluded from the study unless they had a family member or friend to translate/interpret study materials for them. The eligibility criterion that had the largest impact on the generalisability of the study's findings was the necessary exclusion of households that the FRS deemed to be at a high risk of fire. In such cases, the FRS have a duty of care to deliver a HFSV as a priority, and it would have been unethical to make participants from these households, if allocated to the usual care group, wait 12 months for a HFSV. It is possible that this is the group that benefits the most from the HFSV.

As recruitment to the study was via the post, we had to make the assumption that any participant who returned a valid consent form and competed a screening questionnaire had capacity to make a decision about their own participation in the trial. People who lacked capacity to consent were eligible for inclusion, provided there was agreement from a Consultee who lived with them and was willing to provide outcome data by proxy. It was important to include this group in the study as people with reduced cognitive function such as dementia are at a higher risk of falling, may be at higher risk of having a fire, and may find it more difficult to escape their home if there is a fire. Assessment of capacity to give consent via postal recruitment is extremely challenging. We are grateful to the ethics committee for working with us to put a process in place, which enabled us to recruit these participants. However, we were reliant on potential participants (or their carers) being able to self-report they had a condition or impairment that affected their memory or ability to make decisions on their screening questionnaire. If this was indicated on the screening questionnaire, this then alerted the study team to send out participant-facing documents adapted for consultees. If the consultee agreed, a capacity assessment for the potential participant would be arranged. Ethically we were unable to include those who lacked capacity and did not have a family member to act as a consultee.

The study enrolled 63 participants from England, of which 51% were male and all bar one (who did not provide data) were from White ethnic groups. In Humberside, 97.7% of the HSFVs undertaken in 2021–2 were to households of White British/White Irish/white other groups with 0.4% Asian, 0.4% Black, 0.6% other and 0.4% not recorded. Data on ethnicity of residents in the area covered by Kent FRS indicate that 94.3% of people are from a White ethnic group and 5.7% from a non-White group. These data suggest that non-White ethnic groups may be under-represented in our trial sample but given the fact that we had such limited recruitment we may not have expected to have recruited more than three non-White participants based on these percentages. Had we recruited to target, we may have seen that we had obtained a more representative sample.

The study relied heavily on written information as a means to provide information, although there was the option for potential participants to telephone the study team and discuss the study. To support an inclusive approach to recruitment, we worked with our PI group to co-develop our participant information sheets. This may have excluded some people with literacy problems. While potential participants could have asked family members or friends to help read study documentation, this may not be ideal, but it may have reflected how they would usually communicate. The team acknowledge the heavy reliance on written information. Providing information in the forms of infographics, audio sound bites, videos or animations may have helped overcome this issue.

The research question outlined in the commissioning brief stipulated the requirement to evaluate which fire and rescue safety and health-related interventions were effective at improving health outcomes. To collect robust data on health outcomes and to evaluate the cost-effectiveness of the intervention required the use of questionnaires to collect participant- reported outcomes. We used prospective monthly falls calendars to collect falls data, as this is considered the 'gold standard' method of collecting falls data. Questionnaires have been used successfully in many trials conducted by the study team to collect outcome data, as we consider this to be a feasible method of collecting large amounts of data from a geographically disperse population. To minimise participant burden, participants were given the option to telephone the research team to report falls and other data. However, due to the large sample size and multiple time points, this would not have been a feasible as the sole method of data collection from all participants. An alternative to collecting data from the participant, which we explored during the grant application stage, would be to access routine healthcare records. Use of these data is limited and not without issues. For example, < 20% of falls are reported by patients;[21] therefore, reliable data on the number of falls participants had (our co-primary outcome) would not have been available.

From the start of the study, we assembled a research team with a wide range of experience and expertise. The team included a diverse mix of members of the FRS (the Head of Prevention, Head of Risk and Intelligence and Customer Experience and Behaviour Change Lead), as well as trial methodologists, statisticians, qualitative researchers, health economists and academic and clinical OTs, with representation across England and Australia. The FRS work closely with social care services and, if needed, we could have accessed their services. Members of the study team based at YTU included a trainee trial co-ordinator and trainee trial statistician. Supported by other members within the YTU, these staff received hands-on experience of day-to-day management/undertaking statistical tasks required to conduct large pragmatic RCTs. Gaining such experience helps facilitate their career progression.

Members of our PI group were representative of the trial population in terms of age, with all being aged 65 years or over. They were living in the community within the recruiting areas of Kent and Yorkshire. Their input into the study is detailed in the above section.

# **Chapter 6** Impact, learning and implications for decision-makers

Due to poor recruitment and insufficient follow-up data, we are unable to determine the effectiveness or cost-effectiveness of the HFSV to reduce the number of falls people have or improve quality of life. Therefore, we are unable to provide the FRS with recommendations around the effectiveness of the HFSVV to inform their everyday practice. However, the issue of loneliness was highlighted for those in particular who lived alone. Had we shown that the HFSV were insufficiently effective at reducing falls and improving quality of life to offer good value for money, the FRS may have concluded that resources could be diverted elsewhere. However, in the event, we are unable to draw any such conclusions from the study.

We plan to publish a paper in a peer-reviewed journal detailing the challenges of delivering the FIREFLI study so that others can learn from our experiences. As a direct result of conducting this trial, the Chief Investigator was invited to become a member of ACER.[13] The group has been established to create better links between the FRS and academia. It consists of academic representatives from a range of disciplines that have relevance to FRS. The group aims to maximise the benefits of academic research with relevance for FRS to contribute to improved public and firefighter safety. A briefing document will be produced and shared with the National Fire Chief Council. Through the ACER group, the Chief Investigator (SC) will feed back about the challenges faced during the FIREFLI study to any research group planning to undertake further work. Participants have been sent a short summary of the findings of the study.

The findings from the qualitative study were presented at the 2023 Society for Social Medicine and Population Health conference, in the form of an oral presentation entitled, 'A qualitative exploration of Safe and Well Visits by the fire and rescue service: perspectives of service leaders, firefighters and advocates'. A paper on the same subject has been submitted for publication.

# Chapter 7 Research recommendations

The research question of whether HFSV are effective at reducing falls and improving quality of life in older people remains unanswered. Recruitment strategies need to be identified/tested prior to another trial taking place in order to ensure recruitment to the study can occur.

Identifying effective and cost-effective falls prevention strategies continues to be a priority given the prevalence of falls in older people, the potential negative impact falling can have and the fact that the UK has an ageing population.

Given the continuing cost of living crisis and increasing energy costs, the issue of how to heat homes efficiently remains an issue.

Loneliness can have an adverse impact on an individual's health and can put people at increased risk of poorer mental health including depression and suicide. Therefore, research into identifying effective interventions to reduce this is required.

# **Chapter 8** Research policy-makers recommendations

We recommend an urgent review of the regulatory processes required to undertake research outside of the NHS. In FIREFLI, we were required to adhere to regulatory processes designed for NHS settings. A more streamlined less bureaucratic process which can be undertaken in shorter time frame is required. For example, review of the items to be undertaken to meet the requirements of the Data Protection Toolkit for research purposes. NHS England should consider amending their DSAs with the FRS to allow the use of its GPRD for research purposes.

# Chapter 9 Conclusions

Conducting trials in the FRS setting poses a number of methodological and practical challenges. However, it is important that RCTs are undertaken to ensure the health-related interventions delivered by the FRS are informed by a strong evidence base.

At the current time, recruitment to a trial assessing the effectiveness and cost-effectiveness of HFSV to reduce falls and improve quality of life in older people is not feasible. Further research to establish more robust recruitment strategies within this population is required prior to undertaking a future trial. We also recommend an urgent review of research governance issues relating to the type of personal data that can be used for research and its access, to provide support and not present additional obstacles to research in this area.

# Additional information

## CRediT contribution statement

**Sarah Cockayne (https://orcid.org/0000-0002-1288-5497)**: Conceptualisation, Funding acquisition, Methodology, Writing – original draft.

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### *Members of the FIREFLI team*

The FIREFLI team consisted of the named authors and Helen Anderson, Dr Daniel March and Zohaib Akhter.

## Data-sharing statement

All data requests should be submitted to the corresponding author for consideration in line with current York Trials Unit Standard Operating procedures. Access to available anonymised data may be granted following review.

## Ethics statement

The FIREFLI study and subsequent amendments were approved by Health Research Authority – West Midlands – Coventry and Warwickshire Research Ethics Committee (REC reference number 21/WM/0050) on 27 April 2021. Confidentiality Advisory Group (CAG) approval (CAG reference number 21/CAG/049) was given on 20 July 2021. The study was approved by the Health Research Authority (HRA) and Care Research Wales (HCRW) on 29 July 2021. Details of protocol amendments submitted to the REC are provided in *Appendix 2*.

## Information governance statement

The University of York, Humberside Fire and Rescue Service and Kent Fire and Rescue Service are committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679. Under the Data Protection legislation, The University of York is the Data Controller, and you can find out more about how we handle personal data, including how to exercise your individual rights and the contact details for our Data Protection Officer here: www.york.ac.uk/healthsciences/research/trials/trials-gdpr/. Under the Data Protection legislation, Humberside Fire and Rescue Service and Kent Fire and Rescue Service are the Data Processor; the University of York is the Data Controller and we process personal data in accordance with their instructions. You can find out more about how we handle personal data, including how to exercise your individual rights and the contact details for Humberside Fire and Rescue Service's and Kent Fire and Rescue Service's Data Protection Officer here: https://humbersidefire.gov.uk/about-us/access-to-information/data-protection and www.kent.fire-uk.org/report/data-protection-and-information-security-policy

## Disclosure of interests

***Full disclosure of interests:*** Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/DJHF6633.

***Primary conflicts of interest:*** Sarah Cockayne declares part of her salary was funded by the PHR NIHR128341 grant.

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Avril Drummond declares that she is a Senior Chair, NIHR Doctoral Clinical Academic Fellowship (DCAF) Panels. (2022–current) and part of her salary was funded by the PHR NIHR128341 grant.

Catherine E Hewitt declares that she has a NIHR Senior Investigator Award NIHR205100, is a member of the NIHR HTA commissioning board, a member of the NIHR CTU Standing Advisory Committee, a member of the HTA Post-Funding Committee teleconference (POC members to attend), a member of the HTA Funding Committee Policy Group (formerly CSG), a member of the HTA – Fast Track -Funding Committee, a member of the HTA Fast Track Committee – June 2021 and part of her salary was funded by the PHR NIHR128341 grant.

Alison Pighills declares no conflict of interests.

Gareth Roberts declares part of his salary was funded by the PHR NIHR128341 grant.

Sarah Ronaldson declares part of her salary was funded by the PHR NIHR128341 grant.

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All authors declare that Humberside Fire and Rescue Service and Kent Fire and Rescue Service covered the cost of delivering the Safety Home Visits in their region.

## Publications

Carr R on behalf of the FIREFLI study. *Impact on Recruitment of Using an Invitation Letter Informed by Self-determination Theory*. UK Trial Manager's Network Annual on-line Conference, UK, 1 March 2021.

Cockayne S. *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*. Hull CCG Humber Business Intelligence Project Group Meeting, UK, 1 November 2021.

Cockayne S on behalf of the FIREFLI team. *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*. National Fire Chiefs Council Prevention Evaluation Sharing Session, on-line, UK, 18 July 2022.

Cockayne S, Cunningham-Burley R, Fairhurst C, Mann J, Stanford-Beale R, Adamson J, *et al.* Do Safe and Well Visits delivered by the Fire and Rescue Service reduce falls and improve quality of life among older people (FIREFLI): study protocol for a randomised controlled trial. *Open Science Framework* 2023. https://doi.org/10.17605/OSF.IO/GYNCE

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%3d&_t_uuid=mOVTCZ4uSvyIsBM5qtF9YQ&_t_q=how+many+people+don%27t+have+a+computer&_t_tags=language%3aen%2csiteid%3ac4f4b17c-5d8d-455f-9d6a-a18c1121c646%2candquerymatch&_t_hit.id=AgeUK_Web_Models_Media_PdfFile/_467d4c85-dc17-4ffb-9e1e-ccd51c5c978a&_t_hit.pos=4 (accessed December 2023).

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# **Appendix 1** Details of the Home Fire Safety Visits intervention

Participants in the intervention group were offered a SWV within approximately 3 weeks of being randomised. A firefighter, day duty advocate or Safe and Well Officer delivered the SWV at a date and time convenient to the participant. The aim of the SWV was 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. Delivery of the SWV between the two FRS varied slightly; however, the SWV were delivered in each area, as per usual practice. Therefore, training in how to deliver the SWV was not required. For each appropriate element, a risk assessment was conducted and, if appropriate, an intermediate intervention is undertaken with referral to specialist help in line with their FRSs' routine practice. The visit lasted between 45 and 60 minutes.

**TABLE 8** Details of the Home Fire Safety Visits intervention

| Element of the HFSV | Possible actions |
|---|---|
| Fire safety issues | A person-centred fire risk assessment by talking to the participant and taking into account 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.)<br>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 |
| Falls prevention | A record of health conditions; dementia; mental health<br>Information about number of medications<br>History of falls; balance issues; conditions limiting mobility; fear of falling<br>Ability to get out of a chair; ability to undertake exercises; removal of trip hazards; safe use of mobility aids and footwear advice<br>An Age UK falls prevention booklet provided by the YTU<br>Onward referral to falls service or occupational therapy or postural stability services |
| Smoking cessation | An assessment of smoking practices<br>Use of the Making Every Contact Count (or similar behaviour change approaches)<br>Referral on to local stop smoking services<br>Provision of fire-retardant bedding and other equipment |
| Social isolation | Assessment of living arrangements<br>Assistance from carers and assessment of social isolation (in Humberside FRS only) |
| Cold homes and housing conditions | Discussion about room temperature, safe use of heating appliances, advice about financial schemes and how to keep the home warm<br>Advice given regarding any concerns about housing conditions, for example damp, vermin infestations and unsafe electrical systems<br>Referrals to other agencies where appropriate |

# Appendix 2 Protocol amendments

**TABLE 9** Protocol amendments

| Amendment number | Description | Substantial/non-substantial | Date HRA approved |
|---|---|---|---|
| 1 | Minor changes to study documents, additional questions on the Falls Data Telephone Sheet | Non-substantial | 9 August 2022 |
| 2 | Protocol amended to allow the change in data flow as requested by CAG, allow households to opt out of the mail-out, allow the HFSV to be delivered by telephone if needed to comply with local public health guidance with respect to COVID-19 and confirmation that data may be held on the University of York's cloud-based services | Substantial | 12 November 2021 |
| 3 | Protocol amended to allow the FRS to use socio-demographic data for the mail-out. Submission of a new set of study documentation to undertake the mail-out | Substantial | 3 March 2022 |
| 4 | Minor clarification to some study documentation | Non-substantial | 23 March 2022 |
| 5 | Minor clarification to some study documentation | Non-substantial | 21 April 2022 |
| 6 | Additional eligibility check with the FRS regarding direct recruitment in response to advertisement, as opposed to recruitment via mail-out. eligibility check with the FRS regarding direct recruitment in response to advertisement, as opposed to recruitment via mail-out | Non-substantial | 20 June 2022 |
| 7 | Reduction of the inclusion age to aged 65 or over at Humberside FRS (reflects their usual practice) and changing initial mail-out to include a shorter EoI letter, with only those interested in taking part/receiving more information receiving a full recruitment pack on request | Substantial | 15 September 2022 |

# **Appendix 3** Supplementary tables

**TABLE 10** Baseline smoking habits of members of household for randomised participants (*n* = 63)

| Smoking in household, *n* (%) | Intervention (*n* = 32) | Usual care (*n* = 31) | Overall (*n* = 63) |
|---|---|---|---|
| Participant smokes | 1 (3.1) | 3 (9.7) | 4 (6.3) |
| Participant vapes | 0 (0.0) | 2 (6.5) | 2 (3.2) |
| Another member of the household smokes | 2 (6.2) | 2 (6.5) | 4 (6.3) |
| Another member of the household vapes | 0 (0.0) | 1 (3.2) | 1 (1.6) |
| ***If yes to any of above, n (%)*** | ***N* = 2** | ***N* = 5** | ***N* = 7** |
| Smoke inside house | 1 (50.0) | 4 (80.0) | 5 (71.4) |
| Ever smoke in bed | 1 (50.0) | 0 (0.0) | 1 (14.3) |
| Anyone in household ever fallen asleep while smoking | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Ever vape inside the house | 1 (50.0) | 2 (40.0) | 3 (42.9) |
| Ever vape in bed | 1 (50.0) | 0 (0.0) | 1 (14.3) |
| Ever attended an NHS stop smoking service | 0 (0.0) | 1 (20.0) | 1 (14.3) |

**TABLE 11** Health problems reported by randomised participants (*n* = 63)

| Health problems, *n* (%) | Intervention (*n* = 32) | Usual care (*n* = 31) | Overall (*n* = 63) |
|---|---|---|---|
| High blood pressure | 16 (50.0) | 15 (48.4) | 31 (49.2) |
| Arthritis | 12 (37.5) | 10 (32.3) | 22 (34.9) |
| Angina or heart troubles | 9 (28.1) | 11 (35.5) | 20 (31.7) |
| Chronic lung disease | 5 (15.6) | 6 (19.4) | 11 (17.5) |
| Poor vision | 2 (6.2) | 8 (25.8) | 10 (15.9) |
| Chronic pain | 4 (12.5) | 5 (16.1) | 9 (14.3) |
| Anxiety, depression or other mental health problems | 3 (9.4) | 6 (19.4) | 9 (14.3) |
| Diabetes | 2 (6.2) | 5 (16.1) | 7 (11.1) |
| Osteoporosis | 3 (9.4) | 3 (9.7) | 6 (9.5) |
| Stroke | 1 (3.1) | 4 (12.9) | 5 (7.9) |
| Cancer[a] | 3 (9.4) | 1 (3.2) | 4 (6.3) |
| Urinary incontinence | 1 (3.1) | 2 (6.5) | 3 (4.8) |
| Meniere's disease/conditions affecting balance/dizziness | 1 (3.1) | 1 (3.2) | 2 (3.2) |
| Other[b] | 7 (21.9) | 12 (38.7) | 19 (30.2) |

a Types of cancer were prostate, skin, breast and lung.
b 'Other' participant-reported conditions include (each condition may apply to more than one participant, and participants could report more than one 'other' condition): peripheral neuropathy, liver problems, myalgic encephalomyelitis (ME), Klinefelter syndrome, Crohn's disease, poor hearing, dementia, polymyalgia rheumatica, chronic obstructive pulmonary disease, glaucoma, thyroid problems, epilepsy, arrhythmia, anaemia, mild cognitive impairment, spinal stenosis, aortic aneurysm, asthma, torn ligaments, prostrate problems, hip and knee severe arthritis, diverticulosis, vascular disease, pacemaker, venous leg ulcers, lymphoedema.

**TABLE 12** EuroQol-5 Dimensions, five-level version (EQ-5D-5L), UCLA and falls at baseline for randomised participants (*n* = 63)

| | Intervention (*n* = 32) | Usual care (*n* = 31) | Overall (*n* = 63) |
|---|---|---|---|
| ***UCLA-3*** | | | |
| Mean (SD) | 4.6 (1.8) | 4.1 (1.6) | 4.4 (1.7) |
| ***EQ-5D-5L utility index value*** | | | |
| Mean (SD) | 0.724 (0.203) | 0.718 (0.252) | 0.721 (0.227) |
| ***EQ-5D-5L visual analogue scale*** | | | |
| Mean (SD) | 75.8 (19.1) | 73.3 (20.7) | 74.6 (19.8) |
| ***Worried about falling during last 4 weeks, n (%)*** | | | |
| All of the time | 0 (0.0) | 1 (3.2) | 1 (1.6) |
| Most of the time | 2 (6.2) | 0 (0.0) | 2 (3.2) |
| A good bit of the time | 1 (3.1) | 1 (3.2) | 2 (3.2) |
| Some of the time | 5 (15.6) | 6 (19.4) | 11 (17.5) |
| A little of the time | 12 (37.5) | 9 (29.0) | 21 (33.3) |
| None of the time | 12 (37.5) | 14 (45.2) | 26 (41.3) |
| ***Fall in past 12 months, n (%)*** | | | |
| Yes | 13 (40.6) | 10 (32.3) | 23 (36.5) |
| **If yes:** | ***N* = 13** | ***N* = 10** | ***N* = 23** |
| *Number of falls* | | | |
| Mean (SD) | 2.2 (1.7) | 2.4 (2.8) | 2.3 (2.2) |
| Median (IQR) | 1.0 (1.0–3.0) | 1.0 (1.0–2.0) | 1.0 (1.0–3.0) |
| Minimum–maximum | (1.0–6.0) | (1.0–10.0) | (1.0–10.0) |
| *Number of falls at home* | | | |
| Mean (SD) | 1.0 (0.7) | 1.5 (2.4) | 1.2 (1.7) |
| Median (IQR) | 1.0 (1.0–1.0) | 1.0 (0–2) | 1.0 (0–2) |
| Minimum–maximum | (0.0–2.0) | (0.0–8.0) | (0.0–8.0) |
| Attended hospital for a fall, *n* (%) | 4 (30.8) | 0 (0.0) | 4 (17.4) |
| Broke a bone as a result of a fall, *n* (%) | 2 (15.4) | 0 (0.0) | 2 (8.7) |

IQR, interquartile range.

**TABLE 13** Fire risk behaviours in the household at baseline for randomised participants (*n* = 63)

| Fire risk, *n* (%) | Intervention (*n* = 32) | Usual care (*n* = 31) | Overall (*n* = 63) |
|---|---|---|---|
| ***Does anyone in your household*** | | | |
| *Leave the room without extinguishing candles, tealights or oil burners* | | | |
| Never | 10 (31.2) | 19 (61.3) | 29 (46.0) |
| Sometimes | 3 (9.4) | 1 (3.2) | 4 (6.3) |
| We don't use candles, tealights or oil burners | 19 (59.4) | 11 (35.5) | 30 (47.6) |
| Use a portable heater | 4 (12.5) | 4 (12.9) | 8 (12.7) |
| *Use a paraffin-based skin cream* | | | |
| Yes | 6 (18.8) | 9 (29.0) | 15 (23.8) |
| No | 26 (81.2) | 21 (67.7) | 47 (74.6) |
| Don't know | 0 (0.0) | 1 (3.2) | 1 (1.6) |
| Use an open chip pan full of oil | 5 (15.6) | 2 (6.5) | 7 (11.1) |
| Ever leave cooking unattended for more than a few minutes | 2 (6.2) | 3 (9.7) | 5 (7.9) |
| *In the past 4 months, has anyone in the household experienced a fire while cooking?* | | | |
| No | 32 (100.0) | 31 (100.0) | 63 (100.0) |
| ***Within the household*** | | | |
| Anyone used an adaptor to use more than one plug in a socket | 28 (87.5) | 24 (77.4) | 52 (82.5) |
| Anyone ever noticed any scorch marks on a plug socket, had any electrical appliances overheat, or had electrics tripped | 2 (6.2) | 2 (6.5) | 4 (6.3) |
| At least one working smoke alarm on each level of the home | 29 (90.6) | 28 (90.3) | 57 (90.5) |
| *Smoke alarm(s) last tested* | | | |
| Within the last week | 3 (9.4) | 3 (9.7) | 6 (9.5) |
| Within the last month | 16 (50.0) | 10 (32.3) | 26 (41.3) |
| Within the last year | 9 (28.1) | 15 (48.4) | 24 (38.1) |
| Over a year ago | 1 (3.1) | 2 (6.5) | 3 (4.8) |
| Never | 3 (9.4) | 0 (0.0) | 3 (4.8) |
| I don't have any smoke alarms | 0 (0.0) | 1 (3.2) | 1 (1.6) |
| Had fire in property that FRS attended | 1 (3.1) | 0 (0.0) | 1 (1.6) |
| Had fire in property that FRS did not attend | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| *Someone in household closes all internal doors before bed* | | | |
| Never | 9 (28.1) | 13 (41.9) | 22 (34.9) |
| Sometimes | 12 (37.5) | 3 (9.7) | 15 (23.8) |
| Often | 11 (34.4) | 15 (48.4) | 26 (41.3) |
| *Escape plan for home in the event of a fire* | | | |
| There is a written or verbal escape plan that everyone in the household understands | 12 (37.5) | 16 (51.6) | 28 (44.4) |
| There is no escape plan | 20 (62.5) | 15 (48.4) | 35 (55.6) |

continued

**TABLE 13** Fire risk behaviours in the household at baseline for randomised participants (*n* = 63) (*continued*)

| Fire risk, *n* (%) | Intervention (*n* = 32) | Usual care (*n* = 31) | Overall (*n* = 63) |
|---|---|---|---|
| *If there was a fire in your home, are you confident that you could escape safely?* | | | |
| Yes | 19 (59.4) | 21 (67.7) | 40 (63.5) |
| No | 3 (9.4) | 4 (12.9) | 7 (11.1) |
| Don't know | 10 (31.2) | 6 (19.4) | 16 (25.4) |
| *Members of the household feel safe in the home* | | | |
| Yes | 30 (93.8) | 30 (96.8) | 60 (95.2) |
| Not sure | 2 (6.2) | 1 (3.2) | 3 (4.8) |
| *Knowledge of members of household on fire safety issues (1 = poor knowledge, 10 = excellent knowledge)* | | | |
| Mean (SD) | 7.9 (1.8) | 8.3 (1.4) | 8.1 (1.6) |

**TABLE 14** Baseline healthcare resource use for randomised participants (*n* = 63)

| Care received as an NHS patient NOT in hospital, in past 4 months | Intervention (*n* = 32) | | Usual care (*n* = 31) | | Overall (*n* = 63) | |
|---|---|---|---|---|---|---|
| | About a fall | Other reason | About a fall | Other reason | About a fall | Other reason |
| ***How many times have you. . .*** | | | | | | |
| Seen a GP (doctor) at your GP practice? | 20, 0.0 (0.0), 0–0 | 29, 0.5 (0.7), 0–2 | 24, 0.0 (0.0), 0–0 | 26, 0.8 (1.5), 0–5 | 44, 0.0 (0.0), 0–0 | 55, 0.6 (1.1), 0–5 |
| Seen a GP (doctor) at home | 22, 0.0 (0.0), 0–0 | 30, 0.0 (0.2), 0–1 | 24, 0.0 (0.0), 0–0 | 25, 0.1 (0.4), 0–2 | 46, 0.0 (0.0), 0–0 | 55, 0.1 (0.3), 0–2 |
| Spoken to a GP (doctor) over the phone/online? | 22, 0.2 (0.4), 0–1 | 27, 1.4 (2.1), 0–9 | 23, 0.1 (0.3), 0–1 | 26, 1.0 (1.5), 0–6 | 45, 0.1 (0.3), 0–1 | 53, 1.2 (1.8), 0–9 |
| Seen a nurse at your GP practice? | 20, 0.2 (0.7), 0–3 | 28, 0.9 (1.2), 0–4 | 21, 0.0 (0.0), 0–0 | 28, 1.4 (2.4), 0–10 | 41, 0.1 (0.5), 0–3 | 56, 1.1 (1.9), 0–10 |
| Seen a nurse at home? | 23, 0.0 (0.0), 0–0 | 28, 0.0 (0.0), 0–0 | 23, 1.3 (6.3), 0–30 | 28, 1.2 (6.2), 0–33 | 46, 0.7 (4.4), 0–30 | 56, 0.6 (4.4), 0–33 |
| Spoken to a nurse over the phone/ online? | 24, 0.2 (0.6), 0–3 | 27, 0.4 (0.6), 0–2 | 22, 0.0 (0.0), 0–0 | 27, 0.2 (0.6), 0–3 | 46, 0.1 (0.5), 0–3 | 54, 0.3 (0.6), 0–3 |
| Seen a social worker? | 23, 0.0 (0.0), 0–0 | 27, 0.0 (0.0), 0–0 | 23, 0.0 (0.0), 0–0 | 27, 0.0 (0.0), 0–0 | 46, 0.0 (0.0), 0–0 | 54, 0.0 (0.0), 0–0 |

**TABLE 14** Baseline healthcare resource use for randomised participants (*n* = 63) (*continued*)

| Care received as an NHS patient NOT in hospital, in past 4 months | Intervention (*n* = 32) | | Usual care (*n* = 31) | | Overall (*n* = 63) | |
|---|---|---|---|---|---|---|
| | About a fall | Other reason | About a fall | Other reason | About a fall | Other reason |
| ***In the past 4 months, number of appointments with*** | | | | | | |
| An OT at home, their practice, or over the phone/online | 25, 0.0 (0.0), 0–0 | 30, 0.1 (0.7), 0–4 | 24, 0.0 (0.0), 0–0 | 28, 0.0 (0.0), 0–0 | 49, 0.0 (0.0), 0–0 | 58, 0.1 (0.5), 0–4 |
| A physiotherapist at home, their practice, or over the phone/online | 25, 0.0 (0.0), 0–0 | 30, 0.0 (0.2), 0–1 | 23, 0.0 (0.0), 0–0 | 28, 0.0 (0.2), 0–1 | 48, 0.0 (0.0), 0–0 | 58, 0.0 (0.2), 0–1 |
| ***Care received as an NHS patient IN hospital, in past 4 months*** | | | | | | |
| *How many times have you. . .* | | | | | | |
| Attended an outpatient appointment in person? | 22, 0.1 (0.3), 0–1 | 30, 0.8 (1.4), 0–6 | 22, 0.0 (0.0), 0–0 | 28, 0.5 (1.0), 0–4 | 44, 0.0 (0.2), 0–1 | 58, 0.6 (1.2), 0–6 |
| Had an outpatient appointment over the phone/online? | 23, 0.0 (0.2), 0–1 | 30, 0.2 (0.5), 0–2 | 24, 0.0 (0.0), 0–0 | 27, 0.3 (0.7), 0–2 | 47, 0.0 (0.1), 0–1 | 57, 0.2 (0.6), 0–2 |
| Visited accident and emergency? | 24, 0.1 (0.3), 0–1 | 30, 0.2 (0.4), 0–1 | 24, 0.0 (0.0), 0–0 | 28, 0.0 (0.2), 0–1 | 48, 0.0 (0.2), 0–1 | 58, 0.1 (0.3), 0–1 |
| Visited hospital as a day case? | 24, 0.0 (0.0), 0–0 | 30, 0.1 (0.3), 0–1 | 24, 0.0 (0.0), 0–0 | 28, 0.1 (0.5), 0–2 | 48, 0.0 (0.0), 0–0 | 58, 0.1 (0.4), 0–2 |
| Stayed in hospital overnight as an inpatient? | 22, 0.0 (0.2), 0–1 | 28, 0.3 (0.9), 0–4 | 24, 0.0 (0.0), 0–0 | 28, 0.0 (0.2), 0–1 | 46, 0.0 (0.1), 0–1 | 56, 0.2 (0.6), 0–4 |
| If yes, number of nights (*n*, median, minimum–maximum)[a] | 5, 5 (1–21) | | 1, 7 (7–7) | | 6, 6 (1–21) | |

a Reasons for hospital stay included hip replacement, plastic surgery following a fall, heart failure, collapse, haemorrhaging, and heart monitoring.

**Note**
Data are *N*, mean (SD), minimum–maximum unless otherwise stated.

**TABLE 15** Return rates of falls calendars post randomisation

| Month post randomisation | Intervention (*n* = 32), *n* (%) | Usual care (*n* = 31), *n* (%) | Overall (*n* = 63), *n* (%) |
|---|---|---|---|
| 0 | 31/32 (96.9) | 28/31 (90.3) | 59/63 (93.7) |
| 1 | 29/32 (90.6) | 28/31 (90.3) | 57/63 (90.5) |
| 2 | 25/27 (92.6) | 24/28 (85.7) | 49/55 (89.1) |
| 3 | 18/24 (75.0) | 20/22 (90.9) | 38/46 (82.6) |
| 4 | 16/19 (84.2) | 14/17 (82.4) | 30/36 (83.3) |
| 5 | 6/7 (85.7) | 5/6 (83.3) | 11/13 (84.6) |
| 6 | 4/5 (80.0) | 1/2 (50.0) | 5/7 (71.4) |

No participants reported having received visits from a paid home care worker during the past 4 months. Only one participant reported having bought any equipment or paid to have any adaptations/changes made to their house due to ill health in the past 4 months. This was a control participant who had paid a total of £1139.93 for one-off purchases of a rise and recline chair, a walker, a portable table, a trolley, a wheelchair and two walking sticks. Fifty participants reported whether they had paid travel costs (e.g. bus fare, parking fees) to attend any appointments (e.g. to hospital, the GP) during the past 4 months. For those that had, the median cost was £25 (*n* = 7); £10 in the intervention group (*n* = 3) and £60 in usual care (*n* = 4). Fifty-four participants reporting whether they had paid for any medication or over-the-counter drugs during the past 4 months. For those that had, the median cost was £10 (*n* = 8); £8.50 in the intervention group (*n* = 6) and £38.75 in usual care (*n* = 2).

Two participants, one from each group, indicated that a family member or friend had provided care to them due to ill health over the past 4 months, which involved them stopping or reducing their usual work/activities. The participants reported that their friend or family member missed a median of 8.5 days paid work, and 8.5 days of unpaid usual activities while helping them.

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