The FIRESIDE Study: Optimising Fire and Rescue Service "Safe & Well" visits to support detection and sign-posting for mental health problems in older adults

RESEARCH PROTOCOL

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SIGNATURE PAGE

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The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol, GCP guidelines, the Sponsor's SOPs, and other regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator:

Signature: Date: 09 / 09 / 2021

Name (please print):

Carolyn CHEW-GRAHAM

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LIST OF ABBREVIATIONS

CTU	Clinical Trials Unit
DPIA	Data Protection Impact Assessment
FRS	Fire and Rescue Service
GCP	Good Clinical Practice
MPFT	Midlands Partnership NHS Foundation Trust
NHS	National Health Service
NIHR	National Institute for Health Research
PPIE	Patient and Public Involvement and Engagement
RfPB	Research for Patient Benefit
SoM	School of Medicine, Keele University
SOP	Standard Operation Procedures
SPCR	School for Primary care Research
S&W	Safe and Well Visits
UK	United Kingdom
WP	Work Package

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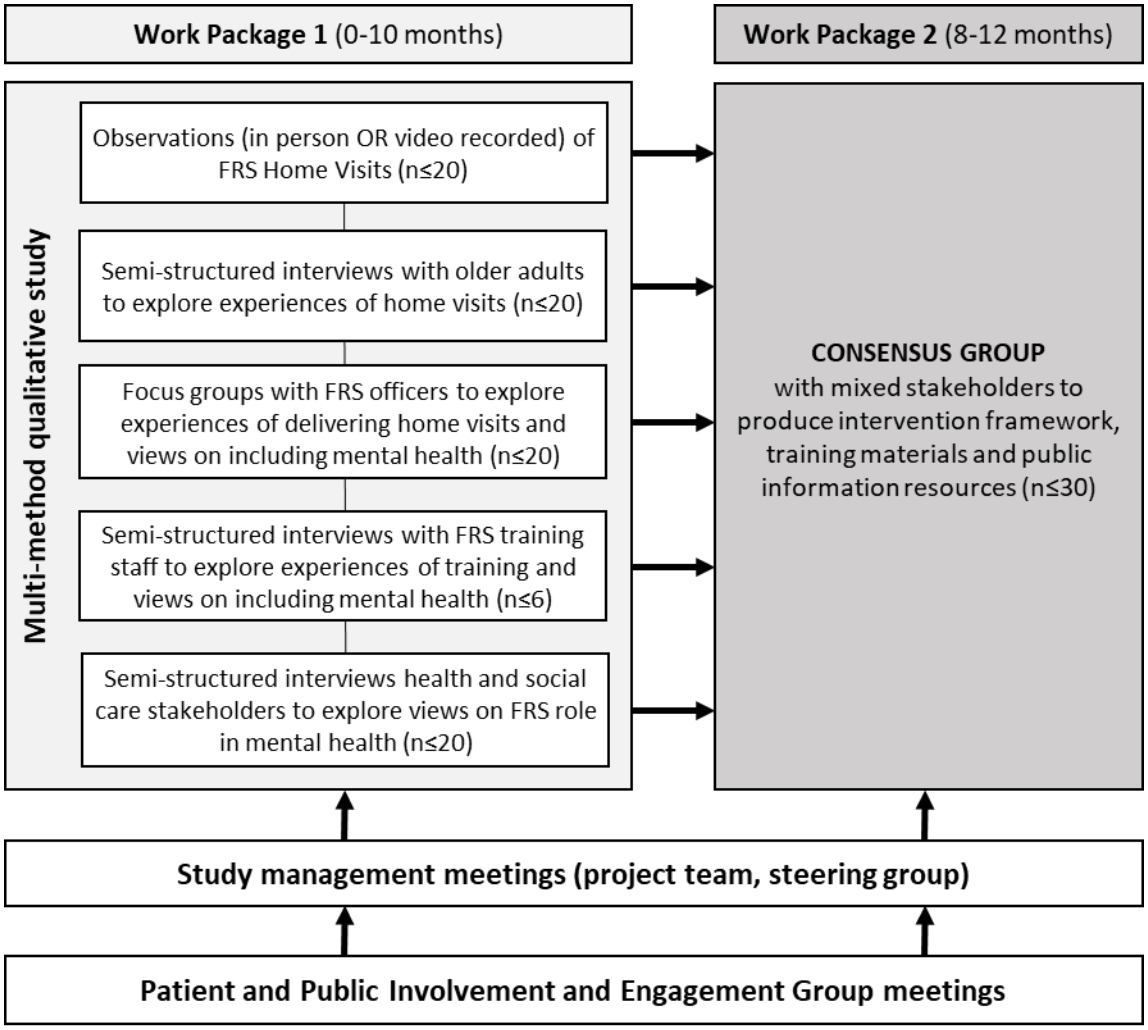
STUDY SUMMARY

Study title	**The FIRESIDE Study: Optimising Fire and Rescue Service "Safe & Well" visits to support detection and sign-posting for mental health problems in older adults**
Short title	**The FIRESIDE Study**
Abstract	**RESEARCH QUESTION:** Can current "Safe & Well" (S&W) visits delivered by the Fire and Rescue Service be extended to support detection and sign-posting for mental health problems among older people living in the community? **BACKGROUND:** Mental ill-health is a leading cause of disability worldwide. One-in-four older adults experience symptoms of mental ill-health. Anxiety and depression in later life are associated with distressing life events, such as bereavement, loss of meaningful roles, physical function or decline in cognitive capacity. Loneliness and social isolation, experienced by up to 50% of older adults, are associated with depression and suicide. However, fewer than one-in-six older adults consult a healthcare professional about symptoms of a mental health problem. Attitudes and beliefs about mental health prevent older people from seeking and accessing appropriate healthcare, such as: a lack of mental health awareness, perceived stigma, prioritising physical over mental health, and reluctance to add additional burden on NHS resources. Early detection of mental health problems remains a key NHS priority. Thus, "non-traditional" providers of healthcare may provide innovation solutions to support detection and help-seeking among this population. **AIM:** To examine whether and how Fire and Rescue Service S&W visits can be optimized to include detection and sign-posting for mental health problems (anxiety and depression) in older people. **METHODS:** Multi-method qualitative study designed in two sequential work packages (WPs). WP1 includes: non-participant observation of S&W visits (as currently designed) to better understand delivery processes, interactions and receptiveness among the public; focus groups with Fire and Rescue Service officers to explore acceptability and identify training needs, and; interviews with older people and health and social care stakeholders to establish in-depth contextual understanding of barriers and facilitators to inform design and implementation. WP2 includes a consensus workshop with a diverse range of stakeholders; findings from WP1 will be used to facilitate and inform workshop discussion to agree core components of the extended S&W visit. **ANTICIPATED IMPACT AND DISSEMINATION:** A variety of research outputs will be generated to engage a range of different audiences including conference and meeting papers, peer-reviewed publications in high-impact journals and social media content. To maximise reach, we will engage members of our existing networks: National Fire Chiefs Council, Age UK, Primary Care Networks, Public Health England, Royal Colleges of General Practitioners and Psychiatrists, and the Society for Academic Primary Care. Outputs are intended to inform, generate interest in the next stage of testing and promote future scalability.
Study design	Qualitative research
Protocol scope	Qualitative research methods (interviews, focus groups, and non-participant observation) and stakeholder engagement workshops
Study participants	Older adults living in the community, Staffordshire Fire and Rescue Service staff, clinical health and social care stakeholders (healthcare practitioners, managers, commissioners, third sector).
Sample size	Observations of Safe & Well visits with recipient's permission (n=20); Interviews with older adults living in the community (n=20); Interviews and/or

	focus groups with Staffordshire Fire and Rescue Service staff (n=26), and; Interviews and/focus groups with clinical health and social care stakeholders (n=20). Stakeholder engagement workshops (n=30)
Planned period	01 September 2021 to 31 August 2022
Study objectives	(A) To explore the current delivery model and content of S&W visits in Staffordshire; (B) To examine the broad-level acceptability of plans to extend S&W visits to include mental health checks and sign-posting (the S&W+ intervention); (C) To develop, through consensus, resources to support delivery of S&W+ visits, including a new schedule of events and training materials, and; (D) To refine a theoretical framework to explain the different components of the S&W+ intervention, how they would fit together, and key contextual factors.

STUDY FLOW CHART



1 INTRODUCTION

This protocol relates to the qualitative aspects of the FIRESIDE study and outlines stakeholder engagement workshops. The protocol is structured as follows: we provide the background and rationale for the research and then describe the plan for the methods: design, methods, analysis, data management, ethical considerations, and dissemination and impact.

2 BACKGROUND

Mental ill-health is a leading cause of disability worldwide.[1] One-in-four older adults (60 years of age or more) experience symptoms of mental ill-health; however, fewer than one-in-six consult a healthcare professional about these symptoms.[2] Loneliness and social isolation, which are reported by as many as 50% of older adults,[3] are key risk factors for mental health problems such as depression, self-harm and suicide.[4] Older people that report loneliness have a reduced life expectancy, are 30% more likely to die from heart disease or stroke[5] and are at increased risk of depression.[4] Anxiety and depression may also be associated with common distressing life events such as bereavement, loss of role and/or physical function.[6,7] Anxiety and depression often occur alongside long-term physical health conditions,[8] which can lead to poorer outcomes for these physical conditions, increased use of health and social care services and increased risk of disability and death.[9] Depression is associated with frailty with a reciprocal interaction between depression and frailty in older adults apparent.[10] Depression and frailty are associated with an increased prevalence and incidence of the other and may be a risk factor for the onset of the other.[11] The mental health impact of the Covid-19 pandemic on older people should also be considered here, with prolonged periods of isolation, disrupted routines, financial concerns, and fear about infection expected to have short and/or long-term impacts.[12]

Key barriers that prevent older people from accessing healthcare and support for mental health problems include: a lack of mental health awareness, stigma, and unwillingness to seek help from healthcare professionals.[13] Older people and practitioners may view psychological difficulties as part of normal ageing, or believe that psychological treatments are not effective,[14] which may affect uptake of treatments, for example, in 2014/15 only 7% of people completing treatment in Improving Access to Psychological Therapies were older adults.[15] Inequalities linked to deprivation and rurality may also restrict access to mental health services by older adults.[16] Without adequate management, mental ill-health negatively affects morbidity and mortality.[6] New interventions are therefore needed to support early detection of mental health problems among older people and to facilitate access to appropriate services. Interventions should focus on overcoming multi-level barriers that are reported (e.g. lack of awareness, social stigma, geographical challenges) that prevent older people from seeking help. Public sector services, where delivery of healthcare does not form part of their traditional function, such as the Fire and Rescue Service (FRS), Police, postal and library services are well positioned to support positive impacts on the health of members of the public. However, the evidence for interventions delivered by such “non-traditional” services and that target mental health remains scant and lacks theoretical robustness and methodological rigor.

3 RATIONALE

Our research seeks to address: (1) the gap in older adult services that support proactive detection and sign-posting for mental health problems, and (2) the gap in evidence for the role of “non-traditional” providers in this regard. Specifically, our study seeks to adapt and extend an existing intervention

called Safe & Well (S&W) delivered by FRSs across England. The extended S&W initiative (from this point on referred to as S&W+) will seek to optimize these points of contact between the FRS and older adults to support early detection and signposting for mental health problems (anxiety and depression). We will use a mixture of qualitative methods to explore the acceptability of the proposed S&W+ intervention among FRS staff, the public and health and care stakeholders and agree ways to optimize the intervention content and delivery model. We will develop new training resources for FRS staff to support delivery of S&W+.

This research will complement and build upon an existing study funded by National Institute for Health Research School for Primary Care (NIHR SPCR grant reference: 472) entitled: 'A Realist review of Interventions for Depression Delivered by "non-traditional" providers for oLder pEople' (short title: the RIDDLE study. In combination, this research will establish a trial ready intervention that will form the basis of a future funding application to assess effectiveness and cost effectiveness.

4 STUDY AIM AND OBJECTIVES

The proposed research aims to examine whether and how Fire and Rescue Service (FRS) Safe & Well (S&W) visits can be optimized to include detection and sign-posting for mental health problems (anxiety and depression) in older people.

The following objectives have been set:

(A) To explore the current delivery model and content of S&W visits in Staffordshire;
(B) To examine the broad-level acceptability of plans to extend S&W visits to include mental health checks and sign-posting (the S&W+ intervention);
(C) To develop, through consensus, resources to support delivery of S&W+ visits, including a new schedule of events and training materials, and;
(D) To refine a theoretical framework to explain the different components of the S&W+ intervention, how they would fit together, and key contextual factors.

5 STUDY DESIGN

The study has been designed as a multi-method case study approach. A case study approach will be applied to establish deep contextual understanding of a single Fire and Rescue Service acting within a single, yet diverse, geographical setting, in this case the Staffordshire Fire and Rescue Service. [17] The work is planned in two sequential work packages (WPs). WP1 comprises qualitative and observational methods to support exploration and understanding. WP2 comprises stakeholder engagement workshops to support consensus building and co-design of the S&W+ intervention with training package. See study flowchart for an overview of the work (page viii). See Appendix A0 for a participant flow chart.

6 WORK PACKAGE 1

6.1 Overview

In WP1, primary data will be gathered using a mixture of qualitative methods to explore different perspectives and generate understanding about current service provision. Data gathered in WP1 will inform objective s(A), (B) and (D).

6.2 Non-participant observations of Safe & Well visits

6.2.1 Data collection

To understand the current provision of S&W visits, non-participant observational methods will be used; this ethnographic research method will enable direct access to the intervention as it is delivered, as experienced by providers and receivers, to observe participant behaviour and interactions.[18]

The RA will accompany a member of the FRS team during S&W visits (n=~20) to observe in real-time the delivery of these visits (as currently designed) and interaction with members of the public. In the event that Covid-19 related restrictions prohibit data collection by direct observation, we will ask the FRS staff to use a wearable video-recording device (such as a GoPro™); this provides an alternative means of capturing data via 'real-time sequential medium' [19] in the absence of the RA accompanying them on home visits.

The RA will record observations from S&W visits in fieldnotes either directly after having attended in-person, or by reviewing the digital recording captured by the FRS staff member's wearable device. A framework, developed by the research team, will be applied to guide notetaking and support the capturing of rich contextual information, to include: verbal/visual interactions, engagement with advice and information, receptiveness to FRS officer, and characteristics of the domestic setting. Observational data will be used to generate understanding about S&W visits (as currently designed), support understanding of potential mechanisms of action for the extended version of S&W (such as, public-FRS relationship, trust, level of engagement), and inform further refinement of the intervention programme theory.

6.2.2 Selection of visits to observe

The selection of visits will be purposively sampled based on type of visit conducted by the FRS (either a first visit or an extended second visit) and service receiver characteristics (age, gender, household composition, geographical location [rural/urban], area level deprivation) to ensure data from a diverse range of contexts is observed. Co-applicant Walchester will facilitate the arrangement of S&W observation visits.

6.2.3 Consent procedures

People in receipt of a S&W visit will be informed about the potential presence of the RA (or wearable technology and its purpose) prior to S&W visit by verbal explanation over the telephone by the FRS officer responsible for scheduling the visit, and a written information leaflet distributed by post or e-mail (with research team contact details to enable them to contact the research team should they have questions about the study). People in receipt of S&W visits will have the opportunity to decline the presence of the RA or the use of wearable technology, up to and including on the day. The RA (where present) will avoid recording personal-identifiable information about the People in receipt of the S&W visit in fieldnotes. A written consent form will be completed by the householder in the presence of the researcher and/or the member of the FRS team.

Relevant study documents:
A1 Study information leaflet for observations
A2 Consent form for observations
A3 Home visit observation framework
A4 Home visit booking script
A5 Invitation cover letter

6.3 Semi-structured interviews with people in receipt (older adults) of Safe & Well visits

Data gathered through interviews will inform our understanding about key barriers and facilitators to the proposed S&W+ intervention (from intended receiver perspectives), FRS staff training (to engender a sensitive and acceptable approach) and the design of intervention materials.

6.3.1 Data collection

One-to-one semi-structured interviews will be conducted with older adults (up to 20) who have received a S&W visit (as currently designed) in Staffordshire. A topic guide will be developed with input from the patient advisory group to capture key demographic information, experiences of S&W visits, interactions with FRS staff, and views on the acceptability (benefits and consequences) of expanding visits to include mental health. Interviews will last for ~60 minutes and take place either face-to-face in the participant's home or at Keele University, or via telephone or a suitable video-conference platform such as Microsoft Teams (whichever is permitted by COVID-19 restrictions and preferred by participants).

6.3.2 Recruitment

Inclusion criteria:

- 60 years of age and over
- Living in the community
- Capacity to provide consent
- English-speaking
- Received a Safe & Well visit in last 6 months

Participants will be excluded if they do not meet the inclusion criteria (no additional exclusion criteria are specified).

We will seek to interview a diverse range of older people in terms of age, gender, geographical characteristics (urban/rural, area-level deprivation). Potential interviewees will be identified and invited to participant by FRS staff, who will distribute information about interviews during routine S&W visits (including but not limited to those visits observed [see 6.2.1]). Potential participants will be invited to express their interest in participating by contacting the research team directly (by telephone, email or post). No reminder letters or telephone calls are planned. A member of the research team will then make contact to arrange the interview. Participants will be offered online shopping vouchers as recompense for time (£20); appropriate travel costs will also be reimbursed where applicable.

Following the interview, a 'thank you' email or letter will be sent to participants with details about the voucher, opportunities to maintain involvement, and a link to the study website where a summary of findings will be made publicly available.

6.3.3 Consent procedures

Participants will be asked to complete a consent form prior to the commencement of data collection. The consent form will be completed either in writing at the beginning of the interview (if conducting face-to-face), or by post (a pre-paid return envelope will be provided) if conducting via telephone or via video conference.

Older adults that participate in this interview may be potentially vulnerable. At any point during the interview, should the researcher become concerned that the participant poses a risk to themselves or others, the interview will be stopped and these concerns will be discussed. Individuals will be sign-posted to appropriate services (e.g. GP, adult mental health services) where necessary. A risk protocol is in place for instances of suicide ideation. During the interviews, should the participant give any reason that they are a threat to themselves or others the RA will initiate the risk protocol (see Appendix C4).

Relevant study documents:
B1 Study information sheet for interviews with older adults
B2 Consent form for interviews with older adults
B3 Interview topic guide
B4 Risk protocol
B5 Generic 'thank you' letter / email

6.4 Focus groups with FRS Staff

Data gathered during focus groups will inform our understanding about key barriers and facilitators to the proposed expansion of S&W visits (from intended provider perspectives) and the design of training materials.

6.4.1 Data collection

Focus groups with FRS staff (n=~20 individuals) currently responsible for delivering S&W visits in Staffordshire will be conducted. TK and the RA will facilitate focus groups using a topic guide to explore FRS staff views on barriers and facilitators to the proposed expansion of S&W visits, such as, current mental health awareness, training needs and any other preparation required, views on risk management and inter-agency working. Four focus groups will be conducted, each with 4-6 participants, lasting ~60minutes. Focus groups will be conducted either face-to-face at a central location (Keele University, FRS or appropriate community setting) OR via video conference technology (e.g. Zoom, Google Hangouts, Microsoft Teams) OR telephone (whichever is permitted and preferred) depending on COVID-19 restrictions.

6.4.2 Recruitment

Potential participants will be identified from across FRS Staffordshire through existing networks, supported by co-applicant Walchester, invited in person or via post, email, and/or social media and provided with written information about the study (with research team contact details should they have questions). Potential participants will be invited to express their interest in participating by contacting the research team directly (by telephone, email or post); they retain the option to decline this invitation. A member of the research team will then make contact to arrange the focus group. Participants will be offered online shopping vouchers as recompense for time (£20 per hour); appropriate travel costs will also be reimbursed where applicable.

Following the focus group, a 'thank you' email will be sent to participants with details about the voucher, opportunities to maintain involvement and a link to the study website where a summary of findings will be made publicly available.

6.4.3 Consent procedures

Participant will be asked to complete a consent form prior to the commencement of data collection. The consent form will be completed either in writing at the beginning of the focus group (if conducting face-to-face), or electronically (if conducting an online focus group) ahead of the focus group via an online consent form using MS Forms. At any point during the focus group/interview, should the researcher become concerned that the participant poses a risk to themselves or others, the interview will be stopped and these concerns will be discussed. Individuals will be sign-posted to appropriate services (e.g. GP, adult mental health services) where necessary.

Relevant study documents:
C1 Study information sheet for focus group with FRS staff
C2 Consent form
C3 Focus group topic guide

6.5 Semi-structured interviews with FRS trainers

Data gathered through interviews with FRS trainers will inform our understanding about key barriers and facilitators to the proposed expansion of S&W visits from an education and training perspective.

6.5.1 Data collection

One-to-one semi-structured interviews or a focus group with FRS staff (n=~6) responsible for delivering current S&W training will be conducted. A topic guide will support exploration of the current delivery of S&W training, content, associated training materials, and anticipated barriers and facilitators to extending this training. Interviews are expected to last ~60 minutes and will take place face-to-face at FRS sites OR Keele University OR via video-conference OR telephone (whichever is permitted and preferred).

6.5.2 Recruitment

Potential participants will be identified from across Staffordshire through existing networks, supported by co-applicant Walchester, and invited via post, email, and/or social media and provided with written information about the study. Potential participants will be invited to express their interest in participating by contacting the research team directly (by telephone, email or post); they retain the option to decline this invitation. Once an expression of interest has been received, a member of the research team will make contact to arrange the interview or focus group. Participants will be offered online shopping vouchers as recompense for time (£30 per hour); appropriate travel costs will also be reimbursed where applicable.

Following the interview, a 'thank you' email or letter will be sent to participants with details about the voucher, opportunities to maintain involvement, and a link to the study website where a summary of findings will be made publicly available.

6.5.3 Consent procedures

Participants will be asked to complete a consent form prior to the commencement of data collection. The consent form will be completed either in writing at the beginning of the interview/focus group (if conducting face-to-face), or electronically (if conducting an online interview/focus group) ahead of the data collection via an online consent form using MS Forms or Keele Health Survey. At any point during the interview, should the researcher become concerned that the participant poses a risk to themselves or others, the interview will be stopped and these concerns will be discussed. Individuals will be sign-posted to appropriate services (e.g. GP, adult mental health services) where necessary.

Relevant study documents:
D1 Study information sheet for interviews with older people
D2 Consent form
D3 Interview topic guide

6.6 Semi-structured interviews with health and social care service stakeholders

Interviews with health and social care stakeholders will help to establish a view of the complex local health and social care landscape in which the S&W+ intervention is intended to operate; all of which will inform intervention design and future implementation.

6.6.1 Data collection

One-to-one semi-structured interviews with stakeholders from health and social care (e.g. general practitioners, social workers, NHS service commissioners, home care workers) and third sector services (e.g. Age UK; Social Prescribing link workers) (n=~20). Interviews will explore the acceptability of extending the FRS role into mental health, barriers and facilitators relating to integrated and collaborative working, local service infrastructure, and feasibility of implementation in the future. Interviews are expected to last ~60 minutes and will take place face-to-face at the participant's place of work, Keele University or via video-conference or telephone (whichever is permitted and preferred).

6.6.2 Recruitment

Potential participants will be identified across Staffordshire through existing professional networks and contacts, supported by co-applicants and Steering Group members (including third sector representatives), invited via post, email, and/or social media and provided with written information about the study. Potential participants will be invited to express their interest in participating by contacting the research team directly (by telephone, email or post); they retain the option to decline this invitation. Once an expression of interest has been received, a member of the research team will make contact to arrange an interview. Participants will be offered online shopping vouchers as recompense for time (approximately £50 per hour); appropriate travel costs will also be reimbursed where applicable.

Following the interview, a 'thank you' email or letter will be sent to participants with details about the voucher, opportunities to maintain involvement, and a link to the study website where a summary of findings will be made publicly available.

6.6.3 Consent procedures

Participants will be asked to complete a consent form prior to the commencement of data collection. The consent form will be completed either in writing at the beginning of the interview/focus group (if conducting face-to-face), or electronically (if conducting an online interview/focus group) ahead of the data collection via an online consent form using MS Forms or Keele Health Survey. At any point during the interview, should the researcher become concerned that the participant poses a risk to themselves or others, the interview will be stopped and these concerns will be discussed. Individuals will be sign-posted to appropriate services (e.g. GP, adult mental health services) where necessary.

Relevant study documents:
E1 Study information sheet for interviews with health and social care stakeholders
E2 Consent form

6.7 Analysis

Interviews and focus groups will be digitally recorded with permission and transcribed for analysis by an external company (http://www.thetranscription.co.uk/). Data from the non-participant observations of S&W home visits in the form of fieldnotes will also be included as part of an integrated approach to analysis.

Interview and focus group data across WP1 will be analysed using an inductive thematic approach [20] to identify key themes, with analysis and data collection conducted as part of an iterative process. We anticipate the stated sample sizes to provide an appropriate range and depth of insights for analysis and to achieve saturation; we will be guided by this concept during analysis.[21] Priority will be given to the identification of themes that support the answering of the research aim and objectives, as reflected in the design of topic guides. Constant comparison will be applied to examine cross-cutting themes in the data with visual thematic maps and data tables used to support interpretation and presentation of the data.[22] The RA will analyse all transcripts, TK and CCG will analysis a sub-set of transcripts and interpretations of the data will be compared and discussed in analysis meetings. Preliminary analyses will be presented to the study team and PPIE advisory group to ensure a broad range of perspectives are considered.

Analysis will help to contextualise and further refine the programme theory (or theories), developed in the preparatory research (the RIDDLE study; SPCR grant reference: 472), and inform development of the schedule for the S&W+ intervention and accompanying training package. Findings from WP1 will be taken forward to inform discussions in WP2.

7 WORK PACKAGE 2

7.1 Overview

WP2 will use findings from WP1 (and the RIDDLE study; SPCR grant reference: 472) to inform consensus building methods to agree and co-design adaptations to the S&W visits to develop the S&W+ intervention. WP2 will establish an intervention delivery model and training package. Activities in this WP will inform objective (C) and (D).

7.1.1 Consensus building approach

A diverse range of health and social care stakeholders (up to 30) (listed below) will be invited to participant in a 6-hour expert consensus workshop, designed to facilitate meaningful dialogue between researchers and stakeholders to identify and address real world concerns that may influence implementation of the S&W+ intervention.[23,24] The workshop will be either be held face-to-face at Keele University or in a central location convenient for the majority of participants or (if COVID-19 restrictions remain in place) virtually via video-conferencing (e.g. Zoom, Google Hangouts, Microsoft Teams).

The research team will present WP1 and RIDDLE study findings and use these to prompt discussion and facilitate agreement among participants in the co-design of specific components of the proposed S&W+ intervention, including: delivery model (including integration within the wider healthcare network), schedule of events and content, training materials, manuals for FRS, resources for older adults as identified from WP1 and identification of relevant outcome measures for a future trial. The

model for S&W+ intervention will be developed in line with the TIDiER checklist.[25] As the workshop is to involve a mixed group of stakeholders, principles of coproduction will be used to facilitate collaboration, promote equal status, and protect the value of the unique perspective that each stakeholder has to offer based on their skills and experiences.[12]

7.1.2 Identification of stakeholders

Stakeholders will be invited from the pool of participants who took part in WP1 (FRS staff, health and social care representatives including third sector, and older adults), the study steering group (described below), and PPIE advisory group (also described below). Other groups of interest may also emerge from the preparatory RIDDLE study (e.g. public health, local government); stakeholders representing these additional groups will be identified within existing professional networks and recruited as and where appropriate. Potential participants will be invited to express their interest in participating by contacting the research team directly (by telephone, email or post); they retain the option to decline this invitation.

Participants will be offered online shopping vouchers as recompense for time; appropriate travel costs will also be reimbursed where applicable. Refreshments will also be provided during the workshop.

Following the workshop, a 'thank you' email or letter will be sent to participants with details about the voucher, opportunities to maintain involvement, and a link to the study website where a summary of findings will be made publicly available.

7.1.3 Consent procedure

Participants will be asked to complete a consent form prior to the commencement of the workshop. The consent form will be completed either in writing at the beginning of the workshop (if conducting face-to-face), or by post (a pre-paid return envelope will be provided) if conducting via telephone or via video conference. Permission will be obtained to record discussion at the workshop and to use comments as data to be anonymised and analysed for reporting in publications and reports. At any point during the workshop, should the researcher become concerned that the participant poses a risk to themselves or others, the interview will be stopped and these concerns will be discussed. Individuals will be sign-posted to appropriate services (e.g. GP, adult mental health services) where necessary.

See appendix for study documents:
F1 Study information sheet for stakeholder workshop
F2 Consent form
F3 Workshop outline structure

7.2 Analysis

A framework approach to compare different perspectives and document reasoning for the design of specific components of the intervention.[26] Participants from the consensus workshop will be invited to provide further input on progressive versions of materials for the S&W+ intervention. The RA will analyse all transcripts, TK and CCG will analysis a sub-set of transcripts; individual interpretations of the data will be compared and discussed in analysis meetings. Preliminary analyses will be presented to the study team and PPIE advisory group to ensure a broad range of perspectives are considered.

8 DATA MANAGEMENT

8.1 Data processing and storage

Sensitive and personal data will be held and managed in line with the study HRA requirements, the UK Policy for Health and Social Care Research, the Data Protection Act, the University, Research Institute and CTU policies. Anonymisation of electronic sensitive data will be undertaken in accordance with the procedure described in Standing Operating Procedure (SOP) 42 Database Locking and POL02 Data Security Policy.

Where data is collected over the telephone or internet, this will be take place either in a private room at the researchers own home or from a meeting room at Keele University. A notice will be displayed on the outside of the door to the room to signal 'do not disturb'. This will maintain confidentiality, avoid unnecessary interruptions and ensure the quality of the recording/data. Data will be recorded using a Dictaphone and uploaded to the secure network area at the end of the interview. Once checked, it will be deleted from the Dictaphone.

Participants' personal data will only be accessible by authorised members of the research team based at Keele University during data collection phase of the study. A study database containing participant information will be housed on Keele University's network, which requires a log-in and password to access. Digital audio files from the interviews and focus groups will be stored on a secure university network. The building that houses the School of Medicine operates a key code entry system to ensure only appropriate persons have entrance to the building. Roles and permissions are applied to users within the network as well as within an application to restrict what data a user can access. Personal data will be kept for up to 6 months after the end of the study.

There are secure physical storage arrangements for hard copies within the School of Medicine in lockable filing cabinets. Hard copies of research data will be stored for 10 years after the publication of findings; it is anticipated that hard copy material will be kept to a minimum. Any hard copy research data that has been printed for checking will be destroyed by shredding. Research data will be pseudo-anonymised prior to analysis through the use of a unique study code, only members of the study team will have access to the link to identify data. Electronic copies of anonymised transcripts will be stored for 10 years on a secure university network in order to be accessible for future research.

8.2 Data Sharing Agreements

Digital recordings of interviews and focus groups in WP2 will be transferred via a secure online system (www.sendthisfile.com) to The Transcription Company (www.thetranscription.co.uk) for transcription. A data sharing and confidentiality agreement is in currently in place between Keele University and The Transcription Company to control data use in line with GDPR.

8.3 Archiving

Data archiving and data destruction will be undertaken in accordance with the procedure described in SOP 17 Archiving and Destruction and POL02 Data Security Policy. All data will be maintained in such a form that they cannot be linked with identifiable participants and will be anonymised in the reports.

9 MONITORING & AUDIT

9.1 Study Management

A multidisciplinary project management group consisting of investigators from Keele University, University of Chester, and Staffordshire Fire and Rescue Service will be established and convened in advance of the funding start date to finalise the protocol. The group will meet every 4-6 weeks throughout the project to ensure timely delivery according to the protocol, and to discuss and resolve any issues.

A study steering group will be established to provide high level advice and guidance. The study steering group will comprise the co-applicants, the appointed RA and a subgroup of key advisors including: Professor Simon Pemberton (Professor of Human Geography [expertise in local planning partnerships], Keele University), Professor Mo Ray (Professor of Social Work, University of Lincoln), Ivan Annibal (National Centre for Rural Health and Care), John Wynn-Jones (Keele University Medical School, National Centre for Rural Health and Care), Jan Bailey (Research Fellow, University of Chester), Dean Stevens (doctoral researcher in fireology, University of Chester), and Lynne Wealleans (Beth Johnson Foundation). The steering group will meet quarterly to provide guidance on all aspects as required and ensure the project is managed to time.

9.2 Monitoring arrangements

The following central monitoring procedures will be put in place as part of an ongoing monitoring plan (as described in HSCR SOP14):

- To check that all consent forms are completed in full and accurately and are stored separate to any research data.
- To check that completion of eligibility criteria has been confirmed and expression of interest has been received, prior to the participant being entered into the study. The participant database (in excel) will include a column header to record verification information for review.
- To check contact procedures are followed for interviews and focus group recruitment related to follow-up contacts. A participant recruitment database (in excel) will be developed to record this information for review.

9.3 Safety Reporting

Safety reporting procedures for non-CTIMP studies will be undertaken as per HSCR SOP20b. The research team consider the research study low risk in relation to safety concerns; this is not an intervention study; qualitative methods do not seek to explore in-depth experiences of potentially distressing events. The research team will conduct a thorough risk assessment prior to the commencement of the research.

9.4 Study timeline

Pre-award: Obtain ethical approval for qualitative data collection in WP1 and WP2

Month 1: Start data collection in WP1 for non-participant observations and conduct concurrent analysis. Start recruitment for focus groups and interviews with FRS staff, older people, and health and social care stakeholders.

Month 2: Continue data collection in WP1 for non-participant observations and concurrent analysis. Start data collection for focus groups with FRS staff and concurrent analysis. Continue recruitment of older people, and health and social care stakeholders for interviews.

Months 3-7: Continue data collection in WP1 for non-participant observations and focus groups with concurrent analysis. Start data collection for FRS trainers, older people and health and social care stakeholder interviews with concurrent analysis.

Month 8-10: Finalise analysis and write-up main findings from WP1. Recruit participants to and schedule consensus workshop. Hold meeting. Produce S&W+ intervention delivery model, programme theory/theories, and training materials. Share for further stakeholder input.

Month 11: Produce S&W+ intervention delivery model, programme theory/theories and training materials. Share for further stakeholder input. Write-up main findings from WP2 and create infographics and animation.

Month 12: Finalise S&W+ intervention delivery model, programme theory/theories, and training materials. Finalise and share infographics and animation.

Beyond award: Complete publication of findings in peer-review journals and deliver conference presentations (as and where opportunities arise).

10 ETHICAL AND REGULATORY CONSIDERATIONS

10.1 Research Ethics Committee (REC) review and reports

As data collection does not include the recruitment of NHS patients, ethical approval will be sought from the Faculty for Medicine and Health Sciences Ethic Panel at Keele University. No data collection is planned to take place on NHS sites, so Health Research Authority (HRA) approval will not be sought. The research team will follow Keele University procedures for reporting.

Any subsequent amendments to the study design and/or process will be submitted via Keele ethics procedures.

The following areas of risk have been identified and will be accounted as part of the ethics process:

- SAFETY REPORTING: Safety reporting procedures for non-CTIMP studies will be undertaken as per HSCR SOP20b. The research team consider the research study low risk in relation to safety concerns; this is not an intervention study; qualitative methods do not seek to explore in-depth experiences of potentially distressing events. We have attempted to minimise burden where possible, offer flexibility to support participation and offer appropriate incentives.
- CONCERN RAISED BY PARTICIPANT DURING DATA COLLECTION: We recognise that as we are seeking to interview potentially vulnerable older adults about mental health, we have a process in place should concerns about risk to self and/or others be raised. We have also developed a risk protocol (Appendix B4) should the individual raise any concerns about suicide ideation. The researcher is an experienced qualitative interviewer in mental health.
- LONE WORKING (CONDUCTING DATA COLLECTION OFF-SITE): In instances where researchers conduct fieldwork alone, Keele's lone working policy will be used. Researchers will be referred to the Personal Risk Assessment Checklist to protect their own safety. A nominated colleague will check-in with the researcher before, during and after fieldwork visits.
- COVID-19 INFECTION: Risk presented by COVID-19 is a key concern. As the situation continues to change, the research team will continually review public health advice.

- MAINTAINING PRIVACY/CONFIDENTIALITY WHEN WORKING FROM HOME: During this study, researchers may conduct data collection activities from their own home. To protect the privacy of participants during data collection, researchers are to work from a private room and clearly display 'do not disturb' on the outside of the door (see section 8.1). Should the researcher not be in a position to accommodate this, then data collection will take place from a private meeting room at Keele University.
- IMPACT OF A DISTRESSING INTERVIEW ON THE RESEARCHER: Processes are in place to support researchers in instances where data collection raises issues that are experienced as distressing. Researchers will have the opportunity for a debrief with a senior clinical-academic colleague, should they feel they need to discuss topics raised during data collection.

10.2 Peer review

The research design has undergone peer review as part of the application process; this process was overseen by NIHR Research for Patient Benefit committee. The NIHR Research Design Service also reviewed the original funding application.

10.3 Public and Patient Involvement

Members of the public supported the development of the funding application and will inform the ongoing work.

We will seek to establish a patient advisory group comprising members of existing networks (RUG and previous contributors) to support ongoing development and conduct of the research. We have maintained contact with the 6 participants from the PPIE meeting (June 2018) and will invite these to join the group. To support wider inclusion, we will explore opportunities to involve members of patient participation groups linked to local GP practices and carers identified via Beth Johnson Foundation. All patient advisory group members will receive an appropriate induction to PPIE in research and will receive on-going support provided by a member of the PPIE team and the research team.

PPIE contributors will be briefed at the start of the project, with each member having the opportunity to discuss and agree the level of involvement that is right for them. Meetings will be held 4 times across the study, at key points. Communication between PPIE group meetings will be maintained via newsletter (postal or electronic); this will support ongoing information sharing and invite contributions and comments from members about study progress. Members will be asked to support specific activities, including: development of the ethics application and supporting documents, review preliminary findings from WP1, and prepare content for WP2. Members will be paid for their time reading documents and attending meetings, and reimbursed for expenses, in line with national INVOLVE guidelines. The advisory group will also identify pathways, including via their own networks, to maximise the reach of key messages from the research to members of the public. This will enable members to play a more meaningful role in dissemination thereby enriching their experience and engagement with the research.

10.4 Data protection and patient confidentiality

Consent procedures are explained above. Briefly, prior to data collection, written informed consent will be obtained, using a consent form, by Good Clinical Practice (GCP) trained interviewers (a member of the research team). Participation in the study will be kept confidential and data will be pseudo-anonymised through the use of a unique study code. See Section 7 for description of Data

Management procedures. A Data Protection Impact Assessment (DPIA) may also be required to confirm data management procedures for digital video recording of home visits.

10.5 Indemnity

Keele University carries professional liability and medical malpractice insurance to indemnify it, subject to the terms and conditions of the policy, for its legal claims or damages arising out of any bodily injury, mental injury, illness, disease or death or any harm caused by negligent act, error or omission by the university in the course of its business.

11 DISSEMINATION POLICY

Dissemination and impact generation will be supported by the Impact Accelerator Unit (IAU) (Keele University); a member of the IAU (Stevenson) has agreed to join the steering group to provide expertise in knowledge mobilisation and implementation science.

Findings will be shared with academic audiences within the collaborating institutions (Universities of Keele and Chester) through seminars and blogs, and externally through a range of outputs including conference papers, peer-reviewed publications in high-impact journals and social media content such as infographics shared via twitter. We will use these outputs to engage members within our existing networks who have influence at local, regional and national levels: Beth Johnson Foundation, Age UK, Primary Care Networks in the West Midlands, National Fire Chiefs Council, Public Health England, Royal Colleges of General Practitioners and Psychiatrists, and the Society for Academic Primary Care. Outputs are intended to inform, generate interest in the next stage of testing and promote future scalability.

Authorship will be discussed at an early stage. All co-applicants that were involved in the original conception of the project will be invited to co-author research outputs linked to this study. Authorship guidelines will be checked to ensure additional authors meet the required standards and eligibility criteria of the intended journal. Open access publications in high impact journals will be prioritised.

To generate wider social impact, we will seek to interweave research findings into existing political and social narratives (such as UK and global policy), particularly in the development of social media content and visual outputs such as infographics.[27]

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Appendices

Appendix A0: Participant flow chart