Full title: Developing the evidence and associated service models to support older people living with frailty to manage their pain and to reduce its impact on their lives: a mixed method, co-design study.

Short title: **P**ain in **O**lder **P**eo**P**le with Frailt**Y -** The POPPY Study

Study protocol: Version 1.3 (11th April, 2022) **HS&DRV2.0**

Leeds East REC approval -26 April 2022

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STUDY IDENTIFIERS

Full title: Developing the evidence and associated service models to support older people living with frailty to manage their pain and to reduce its impact on their lives: a mixed method, co-design study.

Funder: National Institute for Health Research (NIHR), Health Service and Delivery Research (HS&DR) NIHR131319

Sponsor: Bradford Teaching Hospitals NHS Foundation Trust (BTHFT).

CONTENTS

STUDY SUMMARY

Study title	Developing the evidence and associated service models to support older people living with frailty to manage their pain and to reduce its impact on their lives: a mixed method, co-design study
Short title	The POPPY Study **P**ain in **O**lder **P**eo**P**le with Frailt**Y**
Study design	A mixed method, co-design study including mapping research evidence from systematic reviews It will include: • qualitative interviews with older people (≥ 75 years), and some interviews will include spouses and partners • telephone/video interviews with a range of health-care professionals • Co-design workshops to include a range of stakeholders. The study will have input across the whole project from a dedicated Oversight Patient and Public Involvement group.
Study participants	Older people will be invited from the Community Ageing Research Study (CARE75+). They will be over 75 years and will be living with pain and frailty.
Planned sample size	Qualitative interviews: Up to 30 older people. Some will be dyadic interviews with their partners. Telephone/video interviews: Up to 96 interviews with health-care professionals
Follow up duration	Not applicable
Planned study period	April 2022 – March 2025
Research question/aim	To develop the content, mode of delivery, implementation strategies, service and professional support and guidance to enable older people with frailty to better manage their pain and reduce its negative impact on their lives, relationships, functioning and quality of life.

1. BACKGROUND

Chronic pain - persistent pain of at least three months duration - is common amongst older people as a consequence of arthritis and related diseases [1]. Prevalence ranges from 25% to 76% reflecting different populations and methodological study variation [1, 2]. Chronic pain is a major contributor to disability and emotional distress [1, 2]. The cumulative and interactive impact of the physical, functional, and psychological effects of chronic pain increases the risk of depression which also exacerbates pain [3]. Pain is associated with substantial disability from reduced mobility, avoidance of activity, falls, depression and anxiety, sleep impairment and isolation [1, 4].

Pain is more common in older people with other chronic diseases [5] and chronic pain is particularly associated with a number of diseases including musculoskeletal disorders, painful neuropathies from diabetes, herpes zoster [4] and pain from joint repair and replacement [6]. Socially disadvantaged older people are more likely to report pain [7]. Nociceptive and neuropathic pain may coexist [4].

Frailty is characterised by age-related decline across multiple physiological systems and vulnerability to disproportionate changes in health after relatively minor health events, such as a minor infection or a minor operation [8]. It affects around 10% of people aged ≥ 65 years, rising to between 25% and 50% in those ≥ 85 years [8]. In the last 20 years there has been a conceptualisation of frailty as an abnormal health state in relation to the ageing process, resulting in the development of robust models and tools to identify and grade the severity of frailty [9, 10]. Frailty is considered a long-term condition requiring long-term strategies and interventions [11, 12].

Pain prevalence is high in people with frailty: median pain prevalence of 44% (range 31-60%) was reported in a systematic review of cohort and cross-sectional studies of community dwelling older people aged ≥ 65 years [13]. Pain is more intrusive in community dwelling older people (≥ 75 years) living with frailty compared to fit older people (adjusted OR 3.53 (95% CI 2.47, 5.04)) [14]. Impact is reported across multiple domains including mobility, ability to accomplish tasks, ability to socialise, and to sleep [14]. Pain increases the risk of developing frailty in older adults with osteoarthritis [15] and a meta-analysis of pain and frailty from prospective longitudinal studies found that pain was associated with an increased risk of incident frailty and worsening frailty [16].

The impact of pain on everyday life is potentially modifiable with appropriate pain management techniques and support [17]. However, this has yet to be realised in older adults living with frailty. Barriers to pain management, relevant to older adults generally, include a limited evidenced base to guide treatment decisions, concerns about treatment related harms, and older peoples' beliefs about pain and how it should be managed [4]. Some challenges are particularly pertinent to those living with frailty. For example, pharmacological pain management is particularly problematic for this population [18]. Medication changes, including new medications, and polypharmacy can have a disproportionate negative affect on an older person with frailty [8], with unpredictable reactions, greater sensitivity and higher risk of harmful side effects [18], for example falls or dizziness. Furthermore, evidenced pain management strategies for chronic pain such as exercise [19] may not always be appropriate for older people living with more advanced frailty who will be less physical active compared to younger, fitter older adults.

2. STUDY RATIONALE

The need to develop new models of care for older people living with frailty is highlighted in the NHS Long Term Plan [12]. In light of population ageing and the increasing numbers of people in advanced older age, targeted services addressing the specific needs of people with frailty are required. The presence of frailty identifies older people with multimorbidity at high risk of adverse outcomes (falls, disability, hospitalisation and care home admission) [8]. Frailty negatively impacts on quality of life [20], caregiver burden, health and social care use [8]. Frailty is a long-term condition, requiring long-term strategies [11]. UK healthcare policy has prioritised multidisciplinary and person-focused care for older people with comorbidities, and those with, and at risk of, frailty [12]. General practices are now able to readily identify older people living with frailty for appropriate services with the inclusion of the electronic Frailty Index (eFI) embedded within primary health-care records [21].

Older people living with frailty are an 'underserved population' with lower inclusion in research than expected from population estimates, and particular neglect of how frail older people respond to or engage with healthcare compared to other groups [22]. The healthcare burden of pain in frailty is not matched by the volume of research targeting this group. Pain, or pain impact, is potentially modifiable, and therefore makes an attractive target for services for older people living with frailty.

3. AIM

To develop the content, mode of delivery, implementation strategies, service and professional support and guidance to enable older people with frailty to better manage their pain and reduce its negative impact on their lives, relationships, functioning and quality of life.

4. OBJECTIVES

1. Map research evidence from systematic reviews of multi-component pain management programmes (PMPs) and psychological therapies and the studies that comprise them, to develop hypotheses about processes and change mechanisms that will inform appropriate content and implementation strategies that address the specific needs of older people with pain and frailty.

2. Explore through qualitative interviews with older people living with pain and frailty, and their families, how they experience and manage pain, the workload involved, and how they reciprocally engage with health professionals. This will determine how their pain-related needs can be met, and what service models are required to optimise access and provide tailored support with pain.

3. Identify opportunities and barriers to engaging older people with pain and frailty in pain management services and support, through service mapping and qualitative interviews with managers, health-care professionals, and service commissioners within purposively selected Clinical Commissioning Groups (CCGs).

4. Develop and operationalise theory-informed pain management guidance specific to the needs of older people with frailty in service contexts through co-design; iteratively building on evidence from each study strand and involving relevant stakeholders (health-care professionals, commissioners, older people, their relatives and carers).

5. Oversight Patient and Public Involvement group (Oversight PPI Group)

A key first step is to establish a bespoke Oversight Patient and Public Involvement group (Oversight PPI Group). Members will provide oversight and insights across the whole programme and contribute to the development of resources and outputs. The Oversight PPI Group will comprise approximately eight people including those in later life living with chronic pain, at least one family member and a carer of an older person living with pain, and third sector representation. Oversight PPI members will be identified in a number of ways:

- Presentation of this proposal to a patient group run by a GP with a special interest in pain, aligned to a Bradford General Practice
- Presentation of this proposal to the Bradford District Older People's forum
- Invitations sent to past participants of the Community Ageing Research 75+ (CARE75+) study (with post study consent to approach)[23]
- Contacts of the established Frailty Oversight Group (FOG)[24]
- Identified from the charity Versus Arthritis and from Age UK Bradford.

Terms of reference detailing the roles and responsibilities, meeting schedule and reimbursement details will be discussed with potential PPI members. We will adopt a flexible approach, being aware that not all members will contribute to all activities.

6. Study design

This study will include the mapping of research evidence from systematic reviews (to meet objective 1, reported separately), qualitative interviews, and co-design workshops. See Figure 1.
Note: The mapping review for objective 1 will be detailed elsewhere.

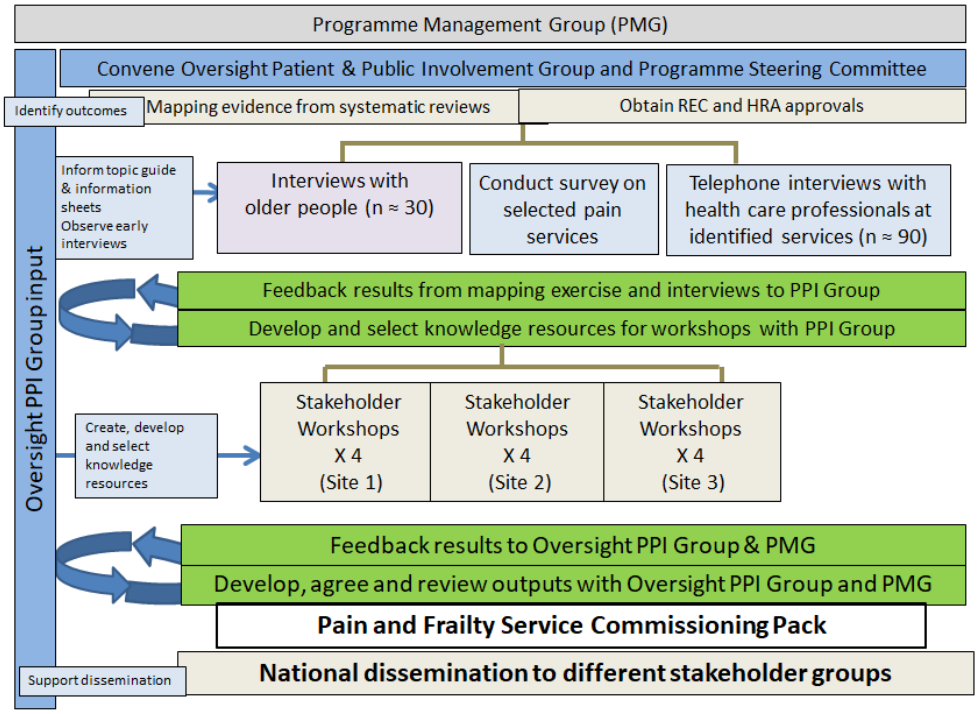

Figure 1. Study flow diagram

7. Qualitative interviews with older people and their spouse or family member

7.1 Overview

This qualitative study will be undertaken to produce a comprehensive understanding of older people's thoughts and feelings about living with pain, managing pain, the experience of engaging with health-care professionals about their pain, and what service models would better support them to manage their pain and reduce its impact on their lives.

The negative effects of pain extend beyond the patient and can impact on relationships [4]. Conversely, there is evidence of enhanced emotional wellbeing and reduced pain with spousal participation with some pain treatments [25]. Therefore, we will seek permission from some participants to approach their spouses or other family members (significant others) for proposed dyadic interviews. This will enable exploration of inter-dependent perspectives of individuals with pain and those close to them, and how individually and together they negotiate and engage in the work of pain management in their daily lives and relationships [26].

This is a prospective longitudinal qualitative study with older people living with primary or secondary chronic pain, with interviews conducted on two occasions up to 10 weeks apart. Longitudinal studies using qualitative methods prioritise exploration of phenomena over time [27] and are helpful for exploring older people's thoughts and feelings. We do not anticipate capturing change in the pain experience in the 10-week timeframe. However, initial interviews can prompt reflection on the pain experience. Between interviews we will ask interviewees to note examples of how pain impinges on decision-making and action, using their chosen method (written note, audio-recording). This will be encouraged and supported with materials to prompt note-taking. However, older people can still

participate in the research if they choose not to document their experiences of living with pain. The proposed population will be living with both frailty and pain and some may find it burdensome.

7.2 Participant sample

Participants for the qualitative interviews will be identified from the Community Ageing Research 75+ (CARE75+) Study (ISRCTN16588124) [23]. CARE75+ is a national longitudinal cohort study funded by the National Institute for Health Research, Applied Research Collaboration Yorkshire & Humber (NIHR ARC YH). CARE75+ provides observational data and a platform for research with older people. Information on pain and frailty is routinely collected as part of CARE75+.

The following CARE75+ participants will be invited:

- CARE75+ participants who have provided consent to be approached about other studies
- Previous participants of the CARE75+ study who have provided post study consent to be approached about other studies
- Those undergoing routine CARE75+ assessments will be informed about the study and asked if they would like to be contacted by a researcher to find out more and assess eligibility.

7.2.1 Inclusion criteria

Participants will be over 75 years and will include those living with frailty and with chronic pain. Frailty will be based on their latest frailty assessment using either Fried frailty criteria [10] (score of 1, 2, 3, 4, 5), or alternatively an electronic frailty Index (eFI) score ≥0.13 [21]. Chronic pain is defined as pain that persists or recurs for more than 3 months, including primary chronic pain (no underlying condition adequately accounts for the pain or its impact) and chronic secondary pain (in which an underlying condition adequately accounts for the pain or its impact) [19]. See Section 7.2.3 Identification and Recruitment for details.

7.2.2 Exclusion criteria

Care home residents, people living at home who are bedbound, those with an estimated life expectancy of three months or less, or in receipt of palliative care will not be eligible. Those who have a dementia diagnosis or a current cancer diagnosis will not be eligible. However, cancer survivors (of at least 5 years cancer free and not undergoing active cancer treatment) can participate if they meet the eligibility criteria.

7.2.3 Sample identification and recruitment

Potential participants frailty level will be identified from data stored on the CARE75+ database [23]. Additionally, participants that have indicated experiencing pain or pain impact at some point during their routine CARE75+ assessments. This will be based on items collected from the Geriatric Pain Measure Short-Form [28], EQ5D [29], SF-36 [30], SF-12 [31], or have a health condition associated with pain (e.g. arthritis), or are in receipt of medication prescribed for pain. Eligibility screening, to identify those currently meeting the criteria for chronic pain [32] will be conducted during the first telephone contact.

Potential participants will be posted a brief participant information sheet which will include the names and photographs of the research team and a cover letter. Potential participants can contact the research team directly, or a researcher will telephone them within two weeks to assess their interest and eligibility for the study. For a flow chart of the recruitment process, see Figure 2.

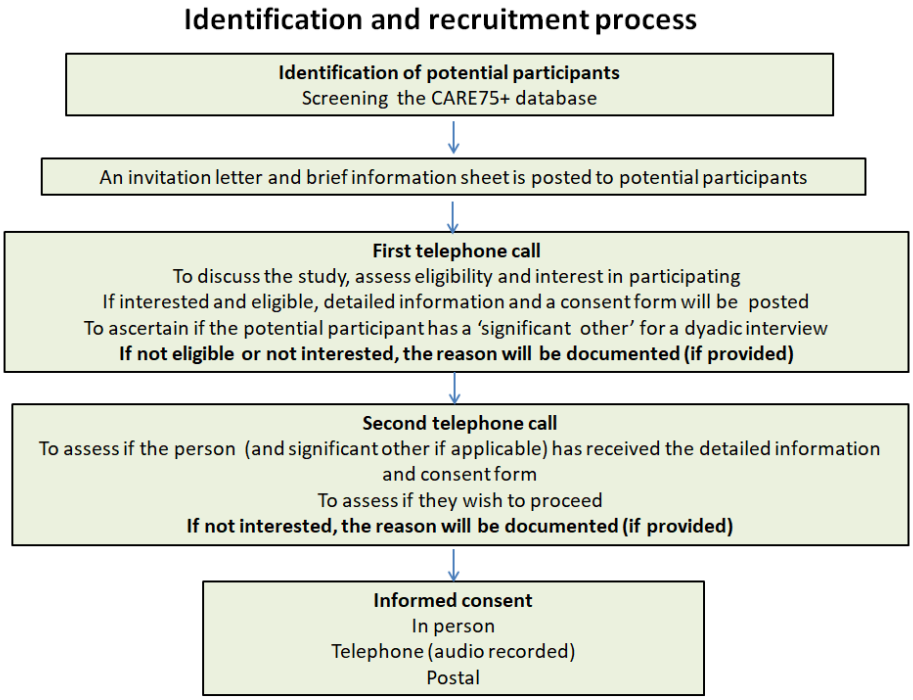

Figure 2. Identification and recruitment flow diagram

First telephone contact: The invitation pack will be followed up within two weeks with a telephone call from a researcher to assess interest and eligibility. Experience from CARE75+ [23] has demonstrated that direct telephone calls or home visits are the only reliable methods of assessing whether older people, particularly those with frailty, are interested in participating. This method is considered less burdensome than proactively initiating contact [33] and ensures that an older person receives the necessary information to make an informed decision. Potential participants will be reassured that there is no obligation to participate.

The researcher will conduct eligibility screening. We will classify chronic pain using ICD-11 criteria (pain of at least 3 months duration) [32]. If interested and eligible, a detailed information sheet and a consent form will be posted to the participant. A consent form will be posted even if consent will be undertaken by telephone or in-person, so that the person has an opportunity to read it, discuss with trusted others, and ask questions at the next contact.

Second telephone contact: The second telephone call will establish if the person has received the detailed information and consent form, if they wish to proceed into the study, and their preference for consent and interview format. Interview options will include: telephone; in-person in the person's home; or video-conference (Zoom etc.). A time will be agreed for the interview.

7.2.4 Informed consent

If the potential participant wishes, family members and trusted others can speak to the researcher to ensure that study information has been understood, considered and retained. A period of 48

hours will be offered to potential participants for reflection and discussion with trusted others regarding participation.

Consent can be provided via a written consent form (in person or posted) or audio recorded. A transcript of the recording will be sent to the participant if requested.

There is an association between frailty, cognitive impairment and dementia [8]. We will complete an assessment of capacity to consent to participation during the recruitment process. The Mental Capacity Act 2005 (MCA) provides a framework for the assessment of the capacity of an individual to make informed decisions [34]. It will be assumed that all individuals have capacity in the first instance. The researchers will undertake training in the MCA and its application in the research setting.

Consent will be gained from those who have capacity to make a decision regarding participation. Those who lack capacity will not be included in this research. Consent to participate is ongoing and will be assessed prior to both first and second interviews.

The consent form will include optional items: to use collected data in the event of the participant's death; to use data collected from the first interview if they are unable/unwilling to participate in the second interview; to allow access to data previously collected through CARE75+ to provide a contextual picture; to provide a designated contact person in the event of deteriorating health during the course of the study; and permission to approach their 'significant others' for the proposed dyadic interviews. A separate consent form and information sheet will be provided to the significant other for inclusion in the dyadic interviews.

Those who decline participation will be asked to provide demographic information and reasons for declining to compare with those who take part.

7.3 Sampling frame

We will interview up to 30 older people and aim for up to half of these interviews to be dyadic interviews which will include a spouse or family member (significant other), or the participant's carer. We will purposively sample to include people from different geographical locations, from a mixture of urban and rural locations and spanning the least deprived and most deprived locations (identified from Index of Multiple Deprivation deciles). We aim to include people from different living circumstances (living alone/with spouse) and with different levels of frailty, determined by their electronic Frailty Index (eFI) score [21] or Fried phenotype score [10].We aim to include people from different ethno-cultural backgrounds where feasible to do so mindful of language constraints.

7.4 Topic guides, piloting and interviews

Topic guides will be informed from the mapping exercise (objective 1), current guidelines on pain management (e.g. NICE chronic pain guideline), and with input from the Oversight PPI group. Topic guides will be piloted with 1-2 older people in the PPI Oversight Group to ensure questions are understandable, relevant and prompt meaningful discussion. Questions will be modified as required.

Depending on the participant's preference, interviews will take place in the person's home by telephone or by teleconference (e.g. Zoom). Researchers will accommodate different formats for the first and second interview.

7.5 Data analysis

Audio-recordings will be transcribed verbatim. We will employ grounded theory analytic techniques: simultaneous data collection and analysis, constant comparison and search for negative cases; and use the conditional matrix as a sensitising framework to elucidate meaning, processes and action relating to managing pain and frailty [35] and to engage with research findings from the literature review mapping exercise (objective 1).

Anonymous findings will be shared with the Oversight PPI group to identify case study examples that can be developed into vignettes and shared in the subsequent interviews with health-care professionals and in the workshops.

7.6 Assessment and management of risk

Risks to participants

Older people's health may fluctuate during the course of the study. We will ensure, where possible, the same interviewer conducts the telephone calls, consent and interviews so a trusting relationship is developed. If a participant becomes unwell or their health deteriorates, we will liaise with the person directly or with the designated contact person (if one has been identified) about ongoing study participation and if they should be contacted at a later date.

The researcher will monitor for fatigue during interviews. Should a participant show signs of tiredness, the interviewer will pause the interview and arrange to return or reconvene later the same day, or in the following days.

Risk to researcher

The interviewer will be an experienced qualitative researcher and will ensure the research is conducted within the conditions approved by the Research Ethics Committee and in accordance with the principles of Good Clinical Practice (GCP) and within the UK Policy Framework for Health and Social Care Research [36].

Some interviews may be conducted in the participants' homes and the researcher will notify another staff member prior to the visit so they are aware of where the researcher will be and an approximate time for completion when the research will call to say they have finished. Researchers will comply with Bradford Teaching Hospitals NHS Foundation Trust policies on safe working practices.

7.7 Safeguarding issues

Consent will be obtained on the understanding that all information will be kept confidential unless the researcher witnesses or receives information that cause them to be concerned for a participant's safety. If the researcher witnesses something which they feel presents a potential or actual harm to the participant or others, or if a participant discloses information which the researcher feels has, or may result in harm, the researcher will encourage the participant to raise this with a relevant professional, or seek their consent to raise it on their behalf.

If the researcher feels that the participant is at risk, then the researcher will disclose the issue without consent but in the interest of the participant using the following process. Details will be discussed with the Principal Investigator (PI). All details discussed will be kept strictly confidential. The PI will then agree a strategy to minimise harm whilst maintaining privacy. This is likely to involve

discussing the anonymised details of the disclosure with a local clinician and/or the Designated Safeguarding Supervisor.

8. SURVEY OF SELECTED PAIN MANAGEMENT SERVICES AND INTERVIEWS WITH HEALTH-CARE PROFESSIONALS

8.1 OVERVIEW

A survey of selected pain services and interviews with health-care professionals and service providers will be undertaken to provide a comprehensive understanding of the perceptions, attitudes and barriers to engagement in PMPs and pain services for older people, those with comorbidities and with frailty. Data on what support health-care professionals consider necessary to better support older people living with pain and what resources might be most useful will be gathered. The survey of specific services will provide context to the interview findings.

8.2 IDENTIFICATION OF SERVICES

We will review the Clinical Commissioning Groups (CCGs) across England and purposively select three from varied localities (metropolitan, urban/rural) with a mix of ethnic and socio-economic population characteristics. We will contact CCGs directly, utilise our own extensive contacts, review data from previous audits of pain services, and via online NHS directories to identify what pain services have been commissioned in those areas in terms of organisational location (specialist or primary/community care-based), and provider type (NHS, third sector, private) and whether specific pain services have been commissioned or are under consideration for people with frailty. From the identified services we will purposively select a spread of pain service types, organisational locations and providers (3 to 4 within each CCG). Local contacts (for example, senior clinicians, service managers) will be identified at each service department to provide more detailed service information. See 8.3 for survey content.

8.3 SURVEY CONTENT

A brief survey will be administered online to obtain information about the structure and organisation of identified pain services. This will include questions on the size of service, referral source, eligibility criteria and any service exclusions, mode of delivery, staff numbers and disciplines and the characteristics of those typically using the service (e.g. age, ethnicity, and inclusivity of non-English speakers). The survey will contain open and closed questions and will be tested with Bury Integrated Pain Service, The Northern Care Alliance NHS Foundation trust Group, prior to implementation.

8.4 ADMINISTRATION AND ANALYSIS

A named person in each service will be approached to complete the survey. This may be a senior clinician, service manager or delegated colleague. The survey will be sent by email, with a link to the survey. A survey tool will be used, for example Survey Monkey or Redcap. There will be a time-frame for completion and prompts will be sent if not returned by the designated time. On submission of the survey, data will be uploaded onto a secure server at BTHFT and data will be extracted on to an Excel spread sheet. Quantitative data from the demographic and closed-ended

survey questions will provide descriptive statistics. Qualitative data from the open-ended questions will be organized using analysed thematic analysis [37].

8.5 Identification of health-care professionals, service managers and those involved in commissioning of services for telephone interviews

In order to gain an in-depth understanding of provision and professional perceptions of services for support with pain within a local health system, we will seek to conduct interviews with approximately 5-8 staff members in each service depending on their size. This will include psychologists, nurses, physiotherapists, occupational therapists and doctors. The service manager will be asked to approach staff within the service to participate in the interviews. Interviews will be conducted by telephone/teleconference (Zoom etc.) at a convenient time. The cost of staff time will be reimbursed.

Additionally, we will include professionals within community therapy services who may, within their work remit, offer advice and support about pain and pain management within their broader scope, for example community nurses, physiotherapists and occupational therapists. Insight from commissioners will be sought.

8.6 Informed consent for interviews

The researcher will provide an information sheet and explain the purpose of the study. Staff will provide fully informed consent before they participate. Consent will be audio-recorded. The information sheet will contain contact details of the research team and it will be made clear that they may stop the interview/withdraw from the study at any time.

8.7 Topic guide for telephone interviews with health-care professionals

Interviews will cover participants' perceptions, attitudes and barriers to engagement in PMPs and pain services for older people, those with comorbidities and with frailty. This will include whether they think that older people could use their service more, and their understanding of the findings of pain management programmes for older people. We will gather data on what support health-care professionals consider necessary to better support older people living with pain and what resources might be useful.

The topic guide will be developed from findings from the literature review, on-going findings from the interviews with older people and with input from the Oversight PPI group. The topic guide will be refined and revised according to on-going analysis through discussion with the research team. We will use vignettes developed from the older peoples' interviews to encourage discussion and reflection which will be shared prior to the telephone interview. We will work with the Oversight PPI group to construct vignettes to understand how the health-care professional might handle a particular situation with an older person presenting with pain and frailty.

8.8 Analysis of health-care professional interviews

Interviews will be recorded and transcribed verbatim. We will employ an interpretive descriptive approach to analysis relevant to applied practice problems to construct a summary of professionals' accounts of their work in pain management. This approach is an Interpretative Phenomenological Analysis, a form of thematic analysis [37]. Data will be organised using NVivo.

9. CO-DESIGN WORKSHOPS TO INFORM TARGETED SUPPORTIVE PAIN INTERVENTIONS

We will use a co-design approach [38] with multiple stakeholders to inform supportive interventions that are workable in different service contexts and that meet the specific needs of people with frailty.

9.1 IDENTIFICATION OF WORK-SHOP PARTICIPANTS

We will establish stakeholder groups in the three different CCG locations. Participants will include older people recruited from the CARE75+ study, or through contacts with PPI group members, their significant other or their caregivers (experiential 'experts'), multidisciplinary professionals involved in pain management services (physiotherapists, nurses, psychologists, GPs, geriatricians, third sector staff), service managers, and commissioners. Some stakeholders will have participated in the earlier individual interviews and some will have not. Lay participants will be reimbursed for travelling expenses (based on INVOLVE guidance for reimbursement of service users).

9.2 RESOURCES FOR WORKSHOPS

Outputs from each of the empirical studies (objectives 1, 2 and 3) will provide the vignettes or 'knowledge resources' to facilitate engagement within and between stakeholder groups. This will iteratively inform the co-design work in sequential steps. The Oversight PPI Group will contribute towards the creation and selection of the 'knowledge resource' vignettes for the co-design workshops. This will include selecting key themes/topics from the interviews with older people and healthcare professional interviews that they consider most impactful and are pertinent to include in the workshops.

Vignettes will be written, illustrated, or audio-visual podcasts. They will highlight and exemplify critical events in an older person's life that mark a change in either the pain experience, its impact and consequences on peoples' lives, and points of heightened emotion; and patterns of pain work in the context of frailty and encounters with health services and health-care professionals. PPI members will be asked to provide 'voices' for the audio-visual vignettes. We will include examples of how health-care professionals currently work successfully with older people living with frailty, or what successful working might look like. The vignettes will provide examples of people and behaviours in certain situations that can help formulate opinions and generate discussion. Vignettes have been used previously in health service research to explore various topics [39].

We may present some findings from earlier phases, to particular groups, for example, dementia groups, or Black, Asian and Minority Ethnic (BAME) groups. This will enable us to receive comments and feedback which can be shared at the co-production workshops.

9.3 WORKSHOP PLAN

We will plan four workshops in the three participating sites. Workshops will be located to minimise travel burden for participants. We envisage workshops lasting approximately two hours with a refreshment break in the middle. Previous workshops undertaken as part of research within the Academic Unit for Ageing and Stroke Research https://www.bradfordresearch.nhs.uk/our-research-teams/academic-unit-for-ageing-and-stroke-research/ have found this an appropriate time duration.

However, we are mindful that the workshops include older people, some living with pain and frailty who might tire easily and will modify workshops accordingly if necessary (for example, due to COVID-19 restrictions). Workshops will depend on findings from the literature review and the interviews. However, they are likely to include some of the following components:

Workshop 1. Participants will receive a participant information sheet prior to the workshops which will provide background information, study aims, and outline the workshop process. Comprehensive details will be provided at the introductory workshop. The initial meeting will provide an opportunity to explore and develop an understanding of the co-design process that participants have been invited to engage with, and to start to think about ways of working collaboratively as opposed to staff or expert-led approaches to patient and public involvement, which they may be more familiar with. The workshops will begin with a short presentation to introduce the purpose of the workshop and convey relevant information in preparation for facilitated discussion/tasks.

Workshops 2 and 3. Participants will be asked to reflect on the 'knowledge resources' generated from the previous study components (objectives 1, 2 and 3). These could include narratives, illustrations or audio-visual podcasts. These resources will enable each stakeholder group to 'listen' and 'see' other perspectives in framing problems, challenges and solutions, and engage in dialogue with them. This recognises that individuals and groups will be most familiar with those aspects of health and health systems with which they interact directly and which exert greatest influence on their perceptions and action. Tasks and worksheets will be pre-prepared. The facilitated discussion/tasks will draw upon the knowledge resources and the knowledge and experience of the group supported/facilitated by a researcher.

Workshop 4. Participants will consider ideas about what changes in services and what support might be required to enable access to, and provide appropriate assistance with pain management to older people with frailty, identifying barriers that would need to be overcome in each local setting to make it happen.

We plan for a flexible, inclusive approach to the workshops and will support people to join 'remotely' via telephone/video conference if they prefer. Whilst we recognise that many people prefer to meet face-to-face, the on-going COVID-19 concerns may preclude this, or result in some anxiety about group meetings. Our recent experience of conducting a survey during COVID-19, (https://www.bradfordresearch.nhs.uk/care75/care75-covid-19/) found that older people are increasingly using technology to keep in touch with family and friends and will be supported to join the workshops remotely if they prefer.

The co-design groups at each of the three sites will operate independently of each other. However, the session objectives may evolve as the consultations progress, for example based on locally relevant information that is provided by workshop attendees or on local working practices/staffing structure. Researchers will observe proceedings, recording impressions in field notes. Discussions will be audio-recorded and transcribed for comparative analysis, drawing out shared and divergent perspectives as well as sites of tension and conflict.

9.4 Outputs

The outputs of the three co-design groups will be summarised and presented to the Oversight PPI Group and the PMG. The agreed final outputs will draw on all layers of stakeholder work. Outputs will be a synthesis of sets of interventions, processes and guidance for designing, commissioning and implementing pain management services for older people with frailty. The primary outputs will include a Pain and Frailty Service Commissioning Pack.

Learning will be captured in action-oriented guidance, providing specific practical examples, tailored to different stakeholder groups (health-care professionals, commissioners and older people's organisations) in different formats for dissemination across pain management services at primary and secondary care levels. Oversight PPI members will contribute to developing and reviewing guidance and outputs, particularly patient stories and examples of living with pain and frailty.

9.5 Pain and Frailty Service Commissioning Pack

The Pain and Frailty Service Commissioning Pack will provide practical guidance for healthcare commissioners to facilitate and improve services for older people living with frailty and pain. The content will depend on the research findings. However, we envisage inclusion of the following:

- The case for change including the evidence and background to pain and frailty
- Case study examples of living with frailty and pain
- Case study examples of current services successfully meeting the needs of older people living with pain and frailty
- Case study examples of health-care professionals currently working successfully with older people with frailty and pain
- How older people should be identified and referred for support for their pain, including different routes into services to optimise take-up
- Examples of how services might be located within current services, or aligned to existing services
- Recommendations for the components of a good frailty and pain service:
    - The format (group, individual, web-access)
    - Duration of participation in the service
    - What components the service should offer (e.g., peer support, education, exercise, coping strategies, psychological therapies)
    - Which health-care professionals should be involved in delivering the service
    - How services might better support older people from BAME communities (if differences emerge from the interviews and the workshops)
    - How services might support people with different levels of frailty (if differences emerge from the interviews and the workshops).
- Case examples of local implementation guidance and how good practice might be adopted and customised for local needs
- An outline of the potential costings of a new pain and frailty service or service components.

9.6 Costing of a pain and frailty service

A health economist will undertake a costing analysis of Pain and Frailty Service. This will consider costs of resource inputs associated with delivering the Pain and Frailty Service. Key inputs include staffing and training, service delivery and associated technology among other components of a good

pain and frailty service as identified in objective 4. We expect that a range of costing scenarios will be considered depending on whether a completely new service or service components would be required, or if an established service could be extended.

For the budget impact analysis, the health economist will compare the costs of the new service (or service components) with costs associated with current pain management services. They will abstract information on mean change in healthcare costs from objective 1. Uncertainties in model parameters will be explored in deterministic and probabilistic sensitivity analysis (PSA). Deterministic analysis will consider the impact of different discount rates, different time horizons and different parameter sets (e.g. different assumptions about the service components being used). In the PSA, suitable distributions will be assigned to each model parameter (the choice of these distributions will be guided by parameter type and standard statistical methods of their estimation for example, gamma or log normal distributions for cost parameters, gamma distribution for frailty) and Monte-Carlo simulation with independent sampling will be performed to generate the estimates of costs accounting for any parameter uncertainties.

10. DISSEMINATION

The research will generate new knowledge and associated guidance for interventions, implementation strategies and services to improve access and deliver targeted support to reduce the pain burden of older people living with frailty. See table 1.

Table 1. Provisional dissemination targets

Target group	Engagement activity
Policy makers, commissioners, managers, clinicians, patients and public	• Existing links with NHS England through co-investigator AC's representation on the NHS England Ageing Well Programme Clinical Reference Group • Established links with NHS Right Care • Disseminate findings through the Future NHS Collaboration Frailty in Primary Care Network, CCGs, Local Authorities, Age UK and the British Geriatrics Society. • ARC Yorkshire & Humber (ARC YH) (https://www.arc-yh.nihr.ac.uk/) and cross ARC networks • The ARC YH Older People's programme (https://www.arc-yh.nihr.ac.uk/what-we-do/older-people established a Research Implementation Advisory Group, with regional representation across NHS commissioner and provider organisations, adult social care, public health, voluntary sector, and national policy representation • Target clinicians in the pain field: clinics, clinicians, the British Pain Society, the Royal College of Anaesthetists Faculty of Pain Medicine and charities including Versus Arthritis. This will be via conferences, newsletters and journal papers • Planners, practitioners and policy makers will be identified through the National Frailty Collaborative that has been established by co-investigator AC Yorkshire & Humber AHSN Improvement Academy Healthy Ageing theme. Members of the collaborative include GPs and primary care practitioners, secondary care clinicians, CCG leads, local authority representatives, public health clinicians, lay members and voluntary sector staff.
Researchers and academics	• High impact journals and presentations at national and international conferences • Networks including the NIHR ARC links and infrastructure to accelerate spread and adoption of the new evidence • A range of media: tailored and targeted summary briefings; engagement events; online communications (e.g. ARC websites); and mainstream and social media (e.g. Twitter).
Patient and public involvement groups:	• PPI Oversight group members and FOG members will be supported to share study findings with their relevant organisations (e.g., Primary Care Patient Participant groups), or voluntary

Oversight PPI Group Frailty Oversight Group	organisations and supported to attend a relevant conference. • Findings will be shared in the CARE75+ [23] twice yearly newsletter.
Engagement of patients, NHS, social care and the wider population	• Links with older people living with frailty, carers, health and care • Links with NHS England through AC's collaborative work to develop the infrastructure and supporting guidance for the 2017/18 GP contract to enable national frailty identification and management.

11. ETHICAL AND REGULATORY CONSIDERATIONS

11.1 DATA PROTECTION AND CONFIDENTIALITY

A data protection impact assessment (DPIA) has been completed with assistance from the information governance manager at Bradford Teaching Hospitals NHS Foundation Trust, to identify risks and ensure data is being stored appropriately. A DPIA is necessary as new information about individuals is being collected and the project will compare and match data from multiple sources.

Qualitative study with older people:

- The study will use a password protected excel file to store contact details. Once the target sample has been attained, the details of those un-recruited will be deleted.
- Consent can be conducted by telephone and audio-recorded, or conducted in person, providing a written hard copy of the consent form. Audio recordings or scanned hard copy form will be stored on the BTHFT server in a secure folder with controlled access.
- Interviews will be conducted with consented older people, in their home, by telephone or by video-conference formats (e.g. Zoom, Teams etc.). Interviews will be audio-recorded and stored securely in password protected zip file or in a secure area.
- Participants will be ascribed a participant identification number (ID) so only the participant ID is named on the audio-recording. A password protected excel file will link the participants name and ID.
- Once the audio-recordings have been transcribed (and any identifiable information removed), the transcript will be stored with their ID number.
- Only the lead investigators and the immediate research team will have access to personal data.
- Telephone contact will be conducted privately and access to information will be limited to the Chief Investigators and members of the study research team.

Survey of specific pain management services and interviews with health-care professionals:

- Managers of specific pain services (outside of BTHFT) will be approached and asked to complete a survey about their service. The survey will be completed using a tool such as redcap or survey monkey. The managers will be provided with an email link to access the survey. The results will be stored at BTHFT in a restricted access folder.
- The manager of the services will asked to provide names, emails, and telephone numbers of staff members to participate in interviews. This information will be stored at BTHFT in a password protected file.
- Consent will be conducted by telephone and audio-recorded and the audios stored in a secure folder on the BTHFT server.

- Interviews will be audio recorded and stored in a secure folder. Participants will be ascribed a participant ID so only their ID is named on the recording.
- Once the audio-recordings have been transcribed (and any identifiable information removed), they will be stored with their ID number.
- Only the lead investigator and the immediate research team will have access to personal data.

Co-design workshops:

- These will take place in different locations (outside of the trust) and will involve different stakeholders including older people, health-care professionals and those involved in commissioning services.
- Consent will be taken prior to the workshops commencing and will be audio recorded or written. Audio-recordings or scanned hard copy consent forms will be stored at BTHFT in a secure folder.
- The workshops will be filmed (video-recorded) and stored in a secure folder for no longer than 5 years.

Applicable to all of the above:

- Staff members outside of the immediate research team but based at the Academic Unit of Ageing and Research (BTHFT) may have limited access to personal data. For example, the office manager will need to reimburse travel expenses to workshop attendees and will need access to personal data to undertake this process.
- Audio files will be deleted as soon as a transcript is produced; transcripts and other research data will be kept for up to 20 years in line with Record Management Code of Practice (research data), in compliance with Bradford Teaching Hospital NHS Foundation Trust (BTHFT) before being destroyed.
- Consent forms received by email will be saved in a password protected folders or in a secure place on a BTHFT computer. Hard copy consent forms will be kept in a locked filing cabinet.

11.2 Review by a Research Ethics Committee

Before the study starts, ethics approval will be sought from an NHS Research Ethics Committee. Ethical review will be booked with a recognised REC once the IRAS application form is submitted and HRA approval validation is received.

12. Access to the final study dataset

We will also make the anonymised qualitative data freely available to other research teams on reasonable request to optimise its use, following completion of the project.

13. Authorship eligibility guidelines and any intended use of professional writers

Decisions about authorship on any journal publication arising from this work will be based on International Journal of Medical Journal Editors conditions (ICMJE, 2020), which recommends the following four criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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