FULL TITLE OF THE STUDY

Testing and validation of a Patient-Reported Outcome Measure for Older People with frailty and Acute Care needs (PROM-OPAC).

SHORT STUDY TITLE & ACRONYM

PROM for older people with frailty and acute care needs: validation

PROM-OPAC: validation

PROTOCOL VERSION NUMBER AND DATE

Version 1.0

01 February 2021

RESEARCH REFERENCE NUMBERS

IRAS Number:	293473
SPONSORS Number:	0815
FUNDERS Number:	NIHR300901

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

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 investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly 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.

For and on behalf of the Study Sponsor:

Signature: Date:
..../...../.....

Name (please print):

.....

Position:
.....

Chief Investigator:

Signature: Date:
..../...../.....

Name: (please print):

.....

LIST OF CONTENTS

KEY STUDY CONTACTS

Chief Investigator	Prof Simon Conroy [redacted]
Study Co-ordinator	Dr James van Oppen [redacted]
Sponsor	University of Leicester [redacted]
Joint-sponsor(s)/co-sponsor(s)	N/A
Funder(s)	National Institute for Health Research: Funding for this study is through Dr van Oppen's NIHR Doctoral Research Fellowship, NIHR300901
Key Protocol Contributors	Prof Simon Conroy [redacted] Prof Jose Maria Valderas [redacted] Dr Nicola Mackintosh [redacted] Prof Tim Coats [redacted] Leicester, Leicestershire and Rutland Patient and Public Involvement group, C/O Department of Health Sciences, University of Leicester
Committees	Leicester, Leicestershire and Rutland Patient and Public Involvement (LLR PPI) forum. PROM-OPAC expert consultation panel.

STUDY SUMMARY

Study Title	Testing and validation of a Patient-Reported Outcome Measure for Older People with frailty and Acute Care needs (PROM-OPAC).
Internal ref. no. (or short title)	PROM-OPAC: validation
Study Design	Stage 1 & 2: Multi-centre cohort validation study Stage 3: Follow-up semi-structured interviews
Study Participants	Stage 1 & 2: Older patients living with frailty, and their carers, during attendance at an Emergency Department Stage 3: As above, and Emergency Department clinicians
Planned Size of Sample (if applicable)	Stage 1: 150 Patient Participants Stage 2: 150 Patient Participants Stage 3: 30 (fifteen dyads of patients and clinicians)
Follow up duration (if applicable)	Stage 1: 1 week Stages 2 & 3: n/a
Planned Study Period	24 months
Research Question/Aim(s)	• To iteratively refine a preliminary patient-reported outcome measurement instrument. • To evaluate the instrument's completion rate, internal consistency, reproducibility, validity, and responsiveness. • To assess the pilot feasibility of PROM-OPAC implementation. • To investigate the impact of instrument use on clinical communication, shared decision-making, and patient activation.

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON-FINANCIAL SUPPORT GIVEN**
National Institute for Health Research (NIHR)	Dr van Oppen is funded by an NIHR Doctoral Research Fellowship, NIHR300901

ROLE OF STUDY SPONSOR AND FUNDER

The sponsor of this research is the University of Leicester. The University of Leicester is registered as a research sponsor with the Department of Health and routinely takes responsibility as sponsor for research activities within the NHS. Dr van Oppen is funded by an NIHR Doctoral Research Fellowship until 30 November 2023. The funder will have no role in the conduct, data analysis and interpretation, or dissemination of results.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Day-to-day co-ordination will be by Dr James van Oppen (Emergency Medicine) and Prof Simon Conroy (Geriatric Medicine), who will share responsibility for operational delivery of the over-arching programme of work. Prof Conroy will be Chief Investigator.

A Study Management Group (SMG) will be convened, comprising Dr van Oppen, Prof Conroy, Dr Nicola Mackintosh (Social Science applied to Health Research), Prof Jose Valderas (Primary Care and Health Policy), and key collaborators including Principal Investigators appointed at each recruiting site. The SMG will be responsible for overall project delivery. The SMG will have monthly meetings which will follow a structured agenda addressing progress with each work stage, collaboration with external groups (stakeholders including PPI networks), budget, risk management and outputs. The SMG meetings will be the key vehicle for synthesising the various elements of this project, SMG meetings are anticipated to take place virtually.

A stakeholder consultation panel will be formed of external lay and expert stakeholders. Lay consultees will be recruited from the Leicester, Leicestershire and Rutland Patient and Public Involvement (LLR PPI). This group has a special interest in ageing related research. Members are older people, carers of older people, or representatives of ageing related organisations. The study objectives and overview have been shared and discussed meetings of the forum. Lay collaborators from the forum, [redacted], have reviewed the study protocol and will be actively involved throughout the ongoing study. Work by lay collaborators will be reported using the GRIPP2-SF checklist. The NIHR ARC Centre for BME Health will be accessed through local Research Design Service Advisors, and approached for advice and assurance of recruitment strategies which aim to represent a diverse population.

PROTOCOL CONTRIBUTORS

We have discussed the study objectives at a meeting of the Leicester, Leicestershire and Rutland Public and Patient Involvement forum and reflected on their feedback. The ongoing study output will be communicated and discussed with interested members of the LLR PPI forum, in order to keep a patient perspective at the core of PROM development.

Academic supervision will be by Prof Simon Conroy and Prof Tim Coats (clinical), Prof Jose Valderas (psychometrics), and Dr Nicola Mackintosh (qualitative).

KEY WORDS

Frailty
Older age
Emergency care
Acute care
Health outcomes
Healthcare quality
Patient-reported outcomes
PROM
Patient satisfaction
Patient activation

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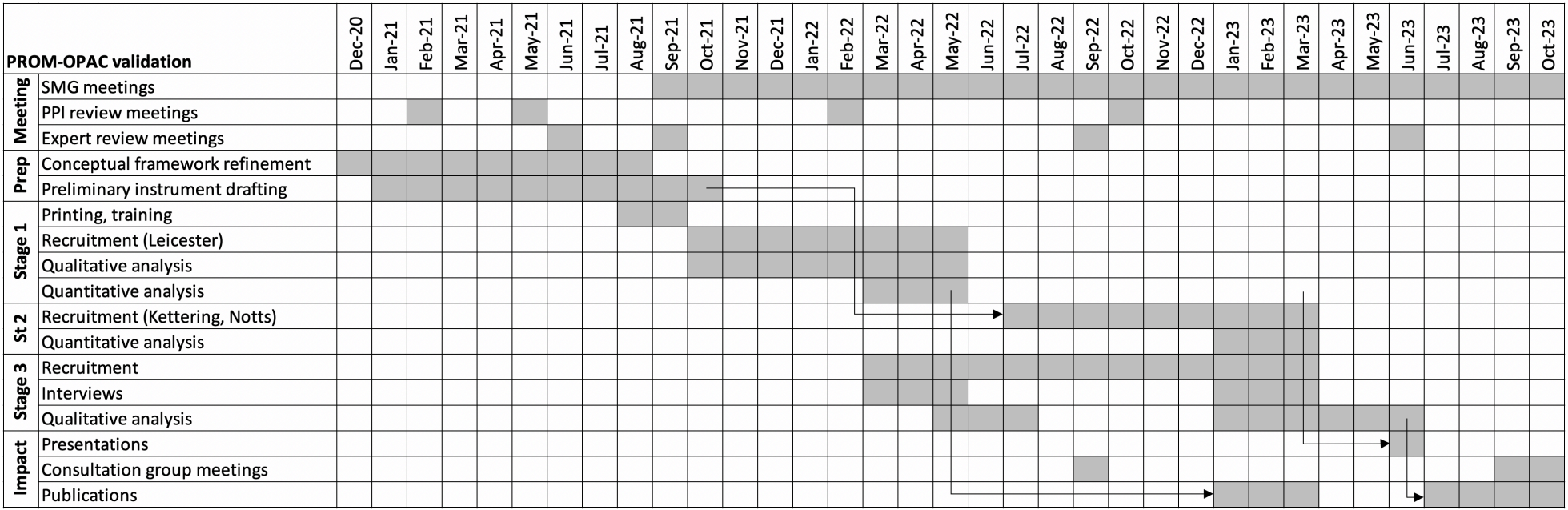
STUDY FLOW CHART



STUDY PROTOCOL

1 BACKGROUND

Frailty is a syndrome defined by the loss of physiological or metabolic reserves(1, 2) and characterised by the accumulation of comorbid illnesses or functional deficits(3), which causes increased vulnerability to adverse outcomes in response to acute stressors. While adults of all age groups consider prompt waiting time, understanding information, and getting a diagnosis to be important(4), older people with frailty have additional and perhaps unique needs and expectations when they seek attention in the Emergency Department (ED). These include greater physical care and mobility needs but also a need for holistic care, supported involvement in decision-making, reassurance, and liaison with caregivers or a wider multidisciplinary team(5-7).

Patient-reported outcome (PROM) and experience measures (PREM) stimulate healthcare improvement by affording patients the freedom to reflect on their conditions and priorities, and by facilitating communication with clinicians(8-10). PROMs can aid measurement and improvement of care effectiveness by capturing the state of a person's health from their perspective. As such, PROMs can be used to compare patients' functional, symptomatic, or quality of life outcomes before and after healthcare interventions and between different providers(11). These tools are validated to specific or generic settings. PROMs can also be used at the clinician-patient level(12) as an adjunct to identifying the domains of function or health which are most important or significant to an individual's quality of life.

The measures enable inter-provider comparison of care and are already used routinely in trial research and some clinical settings(13). For example, to achieve better care and value for money in the Welsh NHS, a "PROMs, PREMs and Effectiveness Programme" was established with the aim of completing specific or generic measurement from every patient in the secondary care system(14). There is a PROM tool for emergency care (PROM-ED) currently being developed in Canada(15). This tool was developed from qualitative enquiry among ED patients of all adult age-groups (mean 44, range 18-83)(16). None of the existing emergency care PREM tools were designed or validated specifically for older people(17-21).

A PROM for older people with frailty and emergency care needs could produce not only a numerical score quantifying the effectiveness of emergency care interventions for research and quality improvement purposes, but also produce an individualised overview of a person's healthcare priorities. Since the score is generated from instrument items specific to certain domains of care, output from a PROM could include a prioritised ranking of the aspects or themes of treatment and healthcare processes which an individual considers to be most important; previous PROM instruments (such as the Patient-Generated Index) have achieved this by allowing for free-text responses(22). This could enable identification of healthcare preferences and priorities early during an ED attendance or acute admission, and thus would support the delivery of person-centred and individualised care.

This study will comprise three stages. In Stage 1, we will iteratively refine the preliminary domains and items of a draft instrument (Patient-Reported Outcome Measure for Older People with frailty and Acute Care needs – PROM-OPAC). These domains and items are specific to the preferred outcomes of older people with frailty and emergency care needs, and are currently being developed through our qualitative work. Stage 1 will 'field test' our preliminary instrument for user experience including appearance and difficulty among patients (and/or their carers) who are receiving emergency care.

These patients will be aged over 65 and will have frailty. Frailty will be indicated by the rapid and reliable Clinical Frailty Score(23) which is used routinely in many urgent care settings. Scores of 5-9 out of 9 during a bedside assessment suggest frailty. Stage 2 will then validate the PROM-OPAC instrument during disseminated testing for attributes including completion rate, internal consistency, construct validity, sensitivity and acceptability. We will explore whether reproducibility can be evaluated in the acute care context of dynamic health states. Finally, in Stage 3 we will investigate the experiences of early users of PROM-OPAC. We will explore the impact on clinical encounters of PROM-ECOP's use as a communication tool. We will reflect on and report how early use of the instrument impacted on person-centredness in clinical practice.

2 RATIONALE

There is a lack of evidence that describes expectations for care as reported by older patients and their carers(24). Healthcare outcomes are predominantly reported using service metrics rather than person-centred measures. Older patients with frailty form a unique subgroup of the Emergency Department population; having frequent atypical presentations and complex comorbid states, their clinical needs may be poorly served by traditional fast-flowing, protocol-driven ED systems(25, 26). Our systematic review(27) and initial Patient and Public Involvement feedback exercise yielded similar outcomes to other recent review work(7), suggesting that older people with frailty have unique preferred healthcare outcomes and priorities for their ED attendances including greater emphasis on communication and shared-decision making with patients and their relatives, and requirements for functional assessment and support. Service metrics such as mortality and readmissions cannot capture these perceptions, and may well not be meaningful as measures of 'what matters' to patients.

A Patient-Reported Outcome Measure could be used not only to compare outcomes between care providers and thus inform service delivery, but also to support elicitation of individual perspectives to inform person-centred care(28). Indeed, NICE advocate an individualised approach to care through acknowledgement of differences in perspectives(29). There is no existing PROM instrument validated for older people with frailty and emergency care needs, and there has been little investigation into the use of PROMs as communication support tools.

3 THEORETICAL FRAMEWORK

Expert consensus places the patient-based conceptual framework at the core of development of PROM instruments(30-33). We have developed an early population-specific framework of emergency healthcare outcome goals for older people. The literature to-date has often dichotomised people as 'younger' or 'older'(27); our current qualitative work is expanding the framework to account for any effect of frailty. We are developing draft instrument items, assimilating questions from existing validated instruments, and iteratively writing and scaling new items where framework domains lack coverage.

We are currently evaluating the 'internal reliability' and 'content validity' of preliminary versions of the instrument in a study using patient interviews and feedback. Internal reliability is the coherence and consistency of items within each instrument domain, and content validity is the relevance of those domains(34, 35) to older people with frailty. The final instrument will include individualised elements so that people's priorities for their care episode can be ascertained concurrently with reporting of outcomes.

In this next phase of development, we will evaluate the draft instrument's acceptability and 'precision' (the extent to which PROM-OPAC captures people's actual patient experiences), using qualitative methods and analysis of administration time, response rates and extent of missing data. We will collect quantitative and qualitative data to analyse 'feasibility' (the ease of instrument administration) and 'interpretability' (the meaning of an expressed score or change in score). Measurement errors will be appraised through analysis of 'internal consistency' (the correlation between items within each instrument domain). We will explore whether 'reproducibility' (test-retest reliability when a second, identical, instrument is administered) can be evaluated in the acute care context of a dynamic health state. 'Construct validity' will be evaluated: PROM-OPAC scores in domains relating to physical and emotional health and function will be correlated to participants' degree of frailty (clinical frailty score), EQ-5D-5L scores (an existing generic PROM for global health and functionality), and Duke score (a shorted PROM for older people with particular validity for mental health). Here, we hypothesise that our instrument developed for an older population with frailty will assess health and function concordantly with existing validated methods and will overcome the limiting ceiling-effect of frailty on EQ-5D measurements.

4 RESEARCH AIM

To refine, validate, and evaluate the early impact of a novel PROM instrument, the Patient-Reported Outcome Measure for Older People with frailty and Acute Care Needs (PROM-OPAC).

5 STUDY DESIGN, SETTING, AND METHODS

5.1 Stage 1: Field-testing.

We will recruit 150 participants for this stage. The sample size is based on the number of instrument items anticipated to be developed during qualitative ground work, with expert consensus advocating samples of ten subjects per instrument items. Research subjects will be older patients with frailty (*Section 6*) who are receiving emergency care at University Hospitals Leicester NHS Trust's Emergency Department. Leicester's ED is one of the busiest in Europe, and is located centrally in one of the UK's most culturally diverse cities(36). Eligible patients will be identified by the clinical care team (researchers and trained research nurses are part of the clinical care team) using ED 'dashboard' software systems which are already in place and used routinely for clinical and research applications. Having explained the objectives and overview of the study and provided written information for later reference, we will invite consent for potential participants to complete a preliminary version of the PROM-OPAC instrument. This will be a questionnaire enquiring about baseline health, participants' reasons for attending the ED, and their preferred outcomes from the current care episode. The instrument will take approximately 10-30 minutes to complete, depending on whether participants wish to provide additional comments. Consent for participation will be taken by one of the researchers or by a trained research nurse; the self-administered electronic questionnaire will include a tick box consent declaration.

Patients attending the ED inevitably spend time waiting for assessments, investigations, or transfers. We will approach potential participants during these waiting periods both in order to avoid inconveniencing them and their care processes, and also to allow attention on deciding whether they wish to take part and on completing the instrument. Some participants will be triaged as 'ambulatory' and may feel comfortable completing the tool in the waiting room (and may welcome the distraction),

whereas others will prefer us to return when they are in the relative privacy of a cubicle space. We will accommodate their preference. Some participants will prefer to complete the instrument with the assistance or input of a relative or familiar caregiver. This will be the case especially for those participants with cognitive impairment, who may need support to reflect on their reasons for seeking care and whose perspectives are equally requiring representation within a measure for older peoples' care. Some participants may ask the researcher to help them completing the instrument; we will note any assistance required by participants, in order to inform iteration of the tool. The time taken for staff administration and patients' completion of the instrument will be recorded.

The instrument is anticipated to be collected using an electronic questionnaire on a tablet device which will be provided. The tablet device will have accessibility options including zoom, colour, and read-aloud functions and will be thoroughly piloted with lay collaborators. An identical version, printed in large font on paper, will be available to help overcome accessibility barriers. The questionnaire instruments will be formed mainly of scale questions (for example, Likert scales or visual analogue scales) where participants would indicate their agreement with a statement or the extent of their symptoms. These values will be incorporated into the final PROM 'score'. The paper and electronic formats will both have sufficient blank space or text boxes provided for comments on the design of usability of the PROM, to enable additional qualitative outputs to be captured. The questionnaire will have a final open-ended box inviting the participant to give a single-sentence summary of "what matters most to me today," which eventually could be used to build the agenda and focus for clinical encounters.

After participants have completed the instrument, a member of the research team will invite feedback on the tool's appearance and use, using a standardised question framework with additional blank space. We will collect participants' contact details in the form of a self-addressed envelope or email, so that a second, identical, copy of the preliminary PROM can be posted or emailed (according to their preference) to them after 24 hours. We will invite participants to complete and return this second copy within one week of their ED attendance. This step enables calculation of test-retest reliability and evaluation of instrument responsiveness to change.

Quantitative analytical outcomes for Stage 1 are the preliminary instrument's feasibility, internal consistency, response rates and reproducibility. Data for these outcomes will be analysed and reviewed with psychometric expert collaborators.

Qualitative data will be analysed in two rounds; firstly, we will use NVivo software to organise data entered by participants into the PROM and analyse using a discordant approach, seeking divergent themes which contradict our underpinning framework. This will inform iterative improvement of the tool. Secondly, we will use a constant comparative process to categorise and reflect on feedback gathered from participants who have completed the tool, in particular seeking to inform iterations based on the difficulty of completion, appearance, and textual content. We will involve our PPI collaborators in reviewing the output of this second step and in refining the appearance of our tool, in order to keep a lay person-centred focus to emerging output.

Output 1: a re-drafted and refined PROM instrument.

5.2 Stage 2: Disseminated testing and validation.

The second stage of this project will seek to validate the refined PROM instrument with a disseminated sample of Emergency Department patients. We will recruit 150 older patients to complete the PROM-OPAC instrument during their attendance at Emergency Departments outside of Leicester. These are anticipated to be at Nottingham University Hospitals NHS Trust and Kettering General Hospital NHS Foundation Trust. People attending these hospitals will experience a range of models of care, as Nottingham is a very large Major Trauma Centre while Kettering is a small District General Hospital. Again, we will include older people with frailty (*Section 6)* who have emergency care needs. We will again invite participants to complete the instrument during natural waiting periods of their care episode. This is again anticipated to take 10-30 minutes.

Eligible patients will be identified from ED 'dashboard' software by the clinical care team. Trained research nurses or assistants at the hosting sites will approach and seek consent from potential participants in the same manner as during Stage 1. A site file will be maintained at each hosting hospital, in which the details of recruited patients (enrolment log) will be stored for local audit purposes. During Stage 2, individuals' total time in ED and decision-to-admit time where applicable will be recorded.

Administration of the PROM-OPAC instrument will be in the same manner as Stage 1; as an electronic questionnaire with a large font paper 'back-up'. In this stage we will also ask patients to complete additional research instruments as able, including the widely-utilised EQ-5D-5L(37), which is a measure of people's baseline function and requires little time to complete, the McGill Quality of Life questionnaire, and the Palliative care Outcome Scale. These are quality of life measurement tools used widely in research and which are optimised for older people. Collection of these additional instruments will provide person-centred data to compare and validate the preliminary PROM-OPAC against. We will again seek participant feedback regarding use and experience of the instrument and analyse this qualitatively. Paper-based completions will be collected by assistants at each hosting site and forwarded to the researchers. Electronic completions will be forwarded automatically.

Outcomes from quantitative analysis will be the interpretability and construct validity of PROM-OPAC. Here, construct validity is the quantitative relationship between clinical impression, existing measures, and PROM-OPAC domains for health-related quality of life. Scores for instrument items relating to baseline emotional and physical health and function will be analysed for correlation with the EQ-5D-5L, McGill QOL, and Duke instrument data using linear regression. Scores overall and for each domain will be analysed for correlation with to participants' clinical frailty score collected by a trained Emergency Department clinician. We hypothesise there to be a correlation with people having greater degree of frailty reporting poorer health and function. Overall PROM-OPAC scores will be compared with total time in ED and decision-to-admit times using logistic regression with thresholds set at current waiting targets. Data will be analysed using Stata. Interpretability, or the meaningfulness of PROM scores, will be evaluated with PPI collaborators and clinical and psychometric experts.

Output 2: a PROM instrument for older people with frailty and emergency care needs, with proven or disproven validity.

5.3 Stage 3: Evaluation of early implementation.

This Stage will investigate people's experiences using the PROM-OPAC instrument. We will recruit patient participants who completed the instrument and also clinicians who cared for people who had

used the tool. We will explore the effects of instrument use on communication and decision-making, and attitudes towards PROM collection among each group.

Participants recruited to Stage 1 and Stage 2 cohorts will be informed of this programme of follow-up interviews, and having completed the PROM instruments will be asked to indicate their interest. Contact details will be collected from those people interested in further research, for the purpose of arranging an interview. We will recruit treating clinicians through internal email advertisements and through opportunistic workplace encounters at each host site. A purposive strategy will include a mixture of consultants, junior doctors, nursing and allied health professionals, and advanced clinical practitioners.

We will provide participant information leaflets adapted for the patient and clinician groups. Having explained our aims, we will invite written consent for short interviews lasting approximately thirty minutes with one of the study researchers. We will include consent for audio-recording using an encrypted device.

Interviews for patients will be conducted at a location of their choosing, either over telephone or videocall, or, subject to Covid-19 restrictions lifting, in their homes or local communities. Interviews with clinicians will be conducted at their convenience away from department ‘shop floors’ over telephone or in person. We will use a topic guide to structure our interviews, which will explore participants’ experiences of using the PROM-OPAC tool. The interviewer will support participants to reflect and share on how the instrument use affected communication of healthcare priorities, whether clinical encounters were experienced differently, and whether management approaches were altered. We will include unstructured time for participants to share their reflections on the tool and its potential.

Audio-recordings will be transferred to a professional transcription service (Clayton Research Services, who hold a confidentiality agreement with the University) using secure electronic means. Recordings will be stored on a University network drive and deleted once transcripts have been checked for accuracy. We will analyse the transcripts by coding data occurrences, inductively observing the themes of participants’ perceptions and attitudes towards the tool. We will organise data using NVivo software, grouping and merging codes using a constant comparative approach. We will share and discuss the thematic outcomes and key illustrative (anonymous) transcript quotes with our PPI collaborators to help us reflect on the implications for PROM-OPAC’s impact.

Output 3: feedback on implementing and early impact of PROM-OPAC on person-centred care, to guide future deployment and evaluation.

6 SAMPLE AND RECRUITMENT

6.1 Eligibility Criteria

We will recruit older patients with frailty and acute care needs during attendance at one of several Emergency Departments. We will include people who have cognitive impairment and are able to express their preferences; we will invite familiar caregivers to be consultees where this would help to overcome a person’s communication barriers. We will exclude patients who, in the opinion of their treating clinician, are too unwell to communicate their preferences.

6.1.1 Inclusion criteria

Participants:

Age: patients aged over 65 years.

Frailty: patients with “Clinical Frailty Score”(23) >4.

Acute care needs: current attendance at a hosting Emergency Department.

Capacity: patients who are able to consent to recruitment and communicate their preferences. Also, those patients unable to consent but able to express their preferences, who attend with a caregiver or relative who is able and willing to act as consultee and support the participant in overcoming communication barriers. We will seek to evaluate the preferred outcomes of all older patients irrespective of communication or cognitive impairment, wherever possible.

Ethnicity, gender, and socioeconomic status: any patients. We will seek the input of the LLR PPI forum, Emergency Department volunteers, and the NIHR Centre for BME Health in order to obtain a representative sample of the regional diverse population, by seeking their feedback on non-identifying participant demographics such as age and cultural background.

Relatives or familiar caregivers:

Capacity: able to consent to recruitment. Able to support the patient participant as consultee.

Healthcare professionals

Role: professionally qualified staff (allied health professionals, advanced practitioners, nurses, doctors) working in acute and emergency care at a hosting site.

Capacity: able to consent to recruitment.

6.1.2 Exclusion criteria

Participants:

Age: patients younger than 65 years.

Frailty: older patients with CFS scores ≤4.

Consent: patients who decline participation, those patients who attend alone and are unable to consent to recruitment or communicate their preferences, and those patients for whom a potential supporting consultee declines to participate.

Additionally we will exclude those patients who are considered by their treating clinicians to be too unwell to participate.

Relatives or familiar caregivers:

Consent: caregivers who decline participation.

6.2 Sampling

6.2.1 Size of sample

The combined sample size for Stages 1 and 2 is based on the COSMIN methodological recommendations(38) which advocate 10 subjects per questionnaire item. The PROM-OPAC instrument is being drafted in current work and is anticipated to contain up to 30 items. Therefore, 150

participants will be recruited for the Stage 1 field-testing and 150 further participants, at separate centres, for the Stage 2 validation. This is a similar sample size to previous validation studies for existing PROMs(39-41). Stage 3 will recruit fifteen instrument users and fifteen treating clinicians in order to enable us to review a broad range of experiences.

6.2.2 Sampling technique

Eligible patients attending the hosting Emergency Departments will be sampled purposively; recruitment will be discussed with collaborators from the Leicester, Leicestershire and Rutland Patient and Public Involvement (LLR PPI) forum and the NIHR Centre for BME Health in order to ensure that the study population is representative and broad. In particular, we will ensure the inclusion of people across the range of older age including those who have conditions impairing their ability to communicate, see, hear, or mobilise, in order to ensure that a wide range of individuals' perceptions are represented. We will recruit participants with similar gender and cultural demographics to each sites' local populations.

6.3 Recruitment

Recruitment will take place from October 2021 to May 2022 (Stage 1 – field testing) and from July 2022 to March 2023 (Stage 2 – validation). We will recruit users of the PROM-ECOP instrument for Stage 3 interviews between March 2022 and March 2023 (Figure 1).

6.3.1 Sample identification

Use of the Clinical Frailty Score(23) for adults aged over 65 is routine department practice in Leicester and Nottingham, will soon be routinely collected across UK ambulance services, and is easily scalable for research use elsewhere. This scoring tool is a rapidly applied screening device for frailty, with a score of 5 or more indicating that the patient may be frail. Patients who are eligible for research will be identified by treating clinicians and hosting sites' research departments (where already in place), who will pass details to the researchers or a trained research nurse, if the patient agrees. These details will include the patient's age and clinical frailty score (so that eligibility can be checked), and their name and current location (so that they can be approached to discuss the research). The research team will explain the study objectives and the PROM-OPAC instrument overview to potential participants. Potential participants will be invited to reflect on the study. If they feel that they have had sufficient time for consideration, then we will take consent from patients and provide the PROM questionnaire for completion during their ED attendance. Patients who complete the instrument will be asked whether they would be happy to be approached for involvement in further research in the form of a short interview.

6.3.2 Consent

We will explain the purpose and format of the study, and give an information sheet to identified eligible patients. We will answer questions that potential participants may have, and allow time for them to consider their involvement in the study. The PROM-OPAC instrument will collect data pertinent to people's reasons for seeking emergency care and is intended to be completed during an ED attendance. Some patients will feel that this time period is too short to duly consider their involvement

in research, whereas others will feel able to adequately reflect on their potential participation. We will invite interested participants to complete a consent form before collecting data. We envisage consent being recorded on an electronic form as part of the tablet-based instrument collection. Participants will receive contact details for the research team in case they later choose to withdraw their data from analysis; this will be possible during the two-week period following collection.

In this study, we aim to include the perspectives of people who have cognitive impairment, which is common among those living with frailty. We will assess patients' capacity to consent to participation at the time of the interview. This will necessarily include assessment of ability to understand the nature of the study and the questionnaire process, and to be able to make a free choice. When patients do not have capacity to consent to research, or where capacity is unclear, but are able to express their opinions regarding health outcome goals, we will seek to involve their relatives or caregivers. We will provide the same explanations as to the nature of the study and processes, and invite consultee consent. Some people may wish to complete the PROM instrument with the assistance of a relative or caregiver. This may help to overcome communication barriers and ensure that perspectives are shared and considered as far as possible.

Patients who complete the instrument will be asked whether they would be happy to be approached for involvement in further research (Stage 3) in the form of a short interview. We will ask interested participants for permission to retain their contact details until an interview has been arranged.

We will seek additional and separate consent from patients and clinicians who indicate their interest in participating in Stage 3 interviews about their experiences of using the PROM tool. We will provide an information sheet about the interview format, duration, and anticipated content. We will invite potential participants to reflect on their involvement in research for a period of at least 24 hours before recording written consent from those who are interested. If consented in advance, we will confirm consent at the time of the follow-up interview. Participants will be reminded that they can cease their interview and withdraw their consent at any time and without reason, and may contact us within two weeks of the interview to withdraw their data from analysis.

7 ETHICAL AND REGULATORY CONSIDERATIONS

Personal identifying data will be collected in this study, including names on consent forms and contact details for the purpose of forwarding the second identical questionnaire (Stage 1) and arranging interviews (Stage 3). Participants' identifying data (including names and hospital numbers) will be stored for audit and regulatory purposes in a site file by the hosting hospitals (anticipated as being University Hospitals of Leicester NHS Trust, Nottingham University Hospitals NHS Trust, and Kettering General Hospital NHS Foundation Trust) during this study, in accordance with a sponsorship agreement. Site files will be stored in locked settings within hospital research departments. Host site research teams will store these data for five years after the study has finished, and then it will be destroyed.

Electronic instrument data collected in Stages 1 and 2 will be anonymous, and are anticipated as being collected using the GDPR-compliant onlinesurveys.ac.uk platform to which the University of Leicester subscribes. Each entry will be assigned an automated ID number, against which researchers will record participants' age and clinical frailty score. It will not be possible to link the electronic PROM data back to individual participants without access to the research team's site file. The completed PROMs will be stored, processed, and analysed on the University of Leicester secure Research (R:)

Drive, to which only the research team will have access. The raw data (questionnaire scores anonymised by removal of study ID numbers) will be retained in a database and may be made available to other researchers. Where participants complete the consent and PROM instrument using paper format, completed consent forms will be stored in the local site file, and paper PROM questionnaires will be stored in a locked cabinet in a locked University office and managed in accordance with University of Leicester best practice procedures. Paper instruments will be securely destroyed following transfer to the electronic database.

Written consent forms for Stage 3 interviews will be stored in local site files. Encrypted audio-recordings of patient and clinician interviews will be transferred by secure electronic means to a professional service [redacted] who have a confidentiality agreement in place with the sponsor. Anonymised verbatim interview transcripts will again be stored on the University's secure R: Drive, to which only approved researchers will have access. We do not anticipate a requirement for data transfer to other parties. No personal identifying data will be shared outside of the research team.

7.1 Assessment and management of risk

The process of approaching eligible patients and providing the PROM tool for completion will be scheduled to minimise inconvenience and disruption during their ED visit. We will be sensitive to the health and wellbeing of participants, who will be unwell and may feel vulnerable or anxious. We will check with their treating clinician that they are well enough to participate in the research and can communicate their preferences through a questionnaire instrument, and that the research would not cause disturbance to treatment schedules. Participants will be reminded that they can pause or withdraw from the research at any time before they have completed the PROM, and may contact us to withdraw their data from analysis within two weeks of participating. The research team have completed the Good Clinical Practice training, are familiar with research ethical principles and relevant legislation, and are experienced in working with older people including assessing capacity.

During qualitative analysis of 'free text' responses, there is a chance that we may discover causes for concern regarding participants' welfare. These could include safeguarding concerns relating to the home or hospital environment, or health problems which the person did not wish to raise with their clinician. The researcher will discuss any concerns with the Chief Investigator (Prof S Conroy, a Consultant Geriatrician), and where necessary alert the treating clinical team, social services, or the person's GP. We will inform potential participants in the study information sheet and consent form that we will follow these actions if we are concerned for their welfare.

In Stage 3 of the study, we will be interviewing older people with frailty, or their carers, about their experience of using the PROM instrument and whether it impacted on their emergency care. The interviews will encourage patient participants to reflect on events, and may well lead to discussion about what was an emotional and frightening experience. We need to do this in order to understand and ultimately measure the patient perspective during an emergency care episode, so that the experience and outcomes for future patients can be improved. Clinician participants may also feel uncomfortable during the interview process, for example if discussion is prompted around issues regarding quality or failings in care. The welfare of interview participants is our paramount concern and we will change topic or stop the interview if the content appears to be causing distress.

Interviews will be carried out by Dr van Oppen over telephone, in the hospital, or in participants' homes or communities. The University has a lone worker policy. Dr van Oppen will manage locations and times for interviews with University IT calendar systems, and will share the data with Prof Conroy by secure calendar access coupled with telephone messages before and after each interview. Should concerns for patient participants' welfare become apparent during the interviews then Dr van Oppen will act promptly in order to mitigate the risk of harm. Concerns might include symptoms or signs of an ongoing or acute physical illness, inadequate social care support in the home, symptoms of poor mental health such as depression, or signs of elder abuse such as neglect. Dr van Oppen is an Emergency Medicine doctor and is experienced in recognising such concerns. Appropriate responses could include instigating a new emergency care episode through the 999 or 111 systems, in which case Dr van Oppen would stay with the participant until care responsibility was handed over to another professional or carer. We will be equally alert for welfare concerns or disclosures of witnessed malpractice among the clinical staff we interview. Appropriate responses might include signposting staff to occupational counselling services or to clinical supervisors, or discussing issues with clinical leads via site Principal Investigators.

7.2 Research Ethics Committee (REC) and other Regulatory review & reports

Prior to recruiting for the study, we will seek a favourable opinion from an NHS Research Ethics Committee approved for research involving vulnerable adults.

Once the initial sponsor review process is complete and a sponsor reference number has been allocated, and all requested documentation has been received and checked, authorisation from the University of Leicester's Research Governance Office will be received to book further review of the proposed research. The NHS Research Ethics Committee and the Health Research Authority will then review the proposal. Agreement in principle is subject to the research receiving all relevant regulatory permissions. Submission for regulatory approvals will be submitted via Integrated Research Application System (IRAS). The Chief Investigator will ensure that all regulatory approvals, confirmation of capacity and capability from NHS sites and Sponsor 'green light' are in place before participants are approached.

For any required amendment to the study, the Chief Investigator, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. Amendments will be implemented upon receiving Sponsor Green Light.

The Research Governance Office's standard operational procedures will be followed for the duration of the trial.

Annual progress reports will be submitted by the Chief Investigator to the Ethics Committee on the anniversary date of favourable opinion being given. The Chief Investigator will notify the REC when the study has ended by completing the end of study notification form and will submit a final report of the results within one year after notifying REC.

A trial master file will be maintained for the duration of the study and will be stored for 5 years after the study has ended.

7.3 Peer review

We reflected on and incorporated feedback following peer review of the protocol by [redacted]

The research protocol was also reviewed by Dr van Oppen's academic supervisors (Prof Conroy, Dr Mackintosh, Prof Valderas, and Prof Coats), and was scrutinised during the competition process for Dr van Oppen's NIHR Doctoral Research Fellowship.

7.4 Patient & Public Involvement

We have presented and discussed the study overview and process with the Leicester, Leicestershire and Rutland Public and Patient Involvement (LLR PPI) forum. This forum has a focus on ageing-related research. Lay members are connected to ageing-related charities and organisations, or are themselves older people. Many have personal experience of being patients or carers. The forum has membership from diverse cultural and professional backgrounds and together the members have strong experience in advising research development. We have reflected on their feedback and incorporated this into the study protocol. We will provide regular reports on study progress for future forum meetings.

Two volunteers from the LLR PPI forum, [redacted], are lay collaborators with this research. We will engage them with the research from start to finish. In regular meetings, we will share the emerging output and seek their feedback to ensure the communicability of our work to a lay patient audience. We will report on PPI work with reference to the GRIPP2-SF checklist(42) and will formally acknowledge the significance of PPI collaborators' work in publications.

7.5 Protocol compliance

Accidental deviation from the protocol could occur at any time. When recognised, any deviation will be documented and logged promptly, and reported to the Chief Investigator and Sponsor. Should deviations become recurrent then we will investigate the cause and take appropriate action.

7.6 Data protection and patient confidentiality

The study researchers have completed training in Good Clinical Practice and Protecting Information in order to comply with the requirements of the Data Protection Act 1998 and General Data Protection Regulation with regards to the collection, storage, processing and disclosure of personal information.

Personal identifying information will be obtained for a number of purposes. A site file at each hosting hospital will record demographic data (including name, date of birth, and hospital number) for audit purposes. Those consent forms completed on paper will also be stored in site files. These files will be kept in locked offices in respective research departments, and destroyed after five years. We will collect participants' contact details to forward a second PROM questionnaire and arrange interviews for those interested in participating in a follow-up feedback study. This data will be stored in a locked cabinet in a locked University office and destroyed once participants have been contacted.

At the University of Leicester, we will retain completed electronic PROMs on a secure University server (R: Drive) for five years before deletion. We will retain completed paper PROMs in a locked cabinet in a locked office until transfer to the electronic database, and will then destroy them. Finally,

we will retain contact details of participants who wish to receive a copy of a final report. We will destroy these details once a report has been disseminated, which we anticipate being within one year of the end of study recruitment.

7.7 Indemnity

The University of Leicester insurance applies for this study.

7.8 Access to the final study dataset

The Chief Investigator and other researchers at the University of Leicester who may be appointed will have access to the full dataset. Appointments will be recorded in the trial master file.

Direct access will be granted to authorised representatives from the Sponsor and host institutions for monitoring and/or audit of the study to ensure compliance with regulations.

8 DISSEMINATION POLICY

8.1 Dissemination policy

This study outline has been discussed locally with Geriatrician colleagues and nationally at a Royal College of Emergency Medicine academic forum and a conference of the Acute Frailty Network. If practical, the final protocol will be made available online.

A final study report will be prepared and shared with the sponsor and research ethics committee within one year of completion of study recruitment. A specially drafted public newsletter will be prepared with input from lay collaborators, which we will share with the study participants and the LLR PPI forum.

The primary output will be to validate the PROM instrument in broadly representative older populations. This instrument for ascertaining and measuring older people's preferred outcomes for emergency care will be of interest to researchers and healthcare professionals, and we will disseminate this through conference presentations and journal publications. If a beneficial impact on clinical encounters is identified, then we will conduct future work to implement the instrument into emergency care practice.

This study will form the basis of Dr van Oppen's Doctoral Research Fellowship. Research output including publications will acknowledge the funder, NIHR. The funder will not have review rights for the study data or report.

8.2 Authorship eligibility guidelines and any intended use of professional writers

Publication authors will be those contributors who have participated in either conception and design, or acquisition of data, or analysis and interpretation of data and who then either participate in drafting or reviewing the manuscript, and who approve the final draft. We will not use a professional writing service.

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10 APPENDICES

10.1 Appendix 1 – Schedule of Procedures

Study stage	Procedures	Visits (insert visit numbers as appropriate)			
		Screening	Day 1	Week 1	Month 1
All	Eligibility check	X			
All	Informed consent		X		
Stage 1 (UHL)	Complete PROM 1		X		
	Complete feedback		X		
	Complete retest PROM			X	
	Completion of CRF (age & clinical frailty score)		X		
Stage 2 (Kettering and Nottingham)	Complete PROM 2		X		
	Complete feedback		X		
	Complete comparison research instruments		X		
	Completion of CRF (age, clinical frailty score and time spent in Emergency Department)		X		
Stage 3 (participants from Stage 1 and 2) and Healthcare Professionals	Follow-up interview				X

10.2 Appendix 2 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made