Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
SSNAP: A feasibility Study

1. Is your project research?

● Yes ○ No

2. Select one category from the list below:

○ Ionising Radiation for combined review of clinical trial of an investigational medicinal product

○ Ionising Radiation and Devices form for combined review of combined trial of an investigational medicinal product and an investigational medical device

○ Clinical investigation or other study of a medical device

● Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

○ Basic science study involving procedures with human participants

○ Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology

○ Study involving qualitative methods only

○ Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)

○ Study limited to working with data (specific project only)

○ Research tissue bank

○ Research database

If your work does not fit any of these categories, select the option below:

○ Other study

2a. Will the study involve the use of any medical device without a UKCA/CE UKNI/CE Mark, or a UKCA/CE UKNI/CE marked device which has been modified or will be used outside its intended purposes?

○ Yes ● No

2b. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation?	○ Yes	● No
b) Will you be taking new human tissue samples (or other human biological samples)?	○ Yes	● No

c) Will you be using existing human tissue samples (or other human biological samples)? ○ Yes ● No

3. In which countries of the UK will the research sites be located?*(Tick all that apply)*

☑ England
☐ Scotland
☐ Wales
☐ Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

● England
○ Scotland
○ Wales
○ Northern Ireland
○ This study does not involve the NHS

4. Which applications do you require?

☑ IRAS Form
☐ Confidentiality Advisory Group (CAG)
☐ HM Prison and Probation Service (HMPPS)

5. Will any research sites in this study be NHS organisations?

● Yes ○ No

5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out the research, e.g. NHS support costs) for this study provided by an NIHR Biomedical Research Centre, NIHR Applied Research Collaboration, NIHR Patient Safety Research Collaboration, or an NIHR HealthTech Research Centre in all study sites?

Please see information button for further details.

○ Yes ● No

Please see information button for further details.

5b. Do you wish to make an application for the study to be considered for NIHR Research Delivery Network (RDN) Support and inclusion in the NIHR RDN Portfolio?

Please see information button for further details.

● Yes ○ No

The NIHR Research Delivery Network (RDN) enables the health and care system to attract, optimise and deliver research across England e.g. by supporting the successful delivery of high-quality research, as an active partner in the research system.

If you select yes to this question, information from your IRAS submission will automatically be shared with the NIHR RDN.

6. Do you plan to include any participants who are children?

○ Yes ● No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

● Yes ○ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ● No

9. Is the study or any part of it being undertaken as an educational project?

○ Yes ● No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ● No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ● No

Integrated Research Application System
Application Form for Other clinical trial or investigation

IRAS Form (project information)

Please refer to the E-Submission and Checklist tabs for instructions on submitting this application.

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
SSNAP: A feasibility Study

Please complete these details after you have booked the REC application for review.

REC Name:
Yorkshire & The Humber - Leeds East Research Ethics Committee

REC Reference Number:
25/YH/0163

Submission date:
24/07/2025

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

A feasibility study of the Shared Safety Net Action Plan (SSNAP): a safety-netting intervention that engages patients to support earlier diagnosis of cancer in general practice

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Dr	Lynn	McVey
Post	Senior Research Fellow		
Qualifications	PhD, MA		
ORCID ID	0000 0003 2009 7682		
Employer	Bradford Teaching Hospitals NHS Foundation Trust		
Work Address	Bradford Institute for Health Reserch, Temple Bank House Duckworth Lane Bradford		
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* Personal E-mail	lmcvey2@msn.com		
Work Telephone	01274382738		

* Personal Telephone/Mobile	07932856961
Fax	

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
	Ms	Jane	Dennison

Address	Bradford Institute for Health Research Duckworth Lane Bradford
Post Code	BD9 6RJ
E-mail	jane.dennison@bthft.nhs.uk
Telephone	01274382575
Fax	

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):	BTHFT 3089
Sponsor's/protocol number:	N/A
Protocol Version:	1.1
Protocol Date:	16/09/2025
Funder's reference number (enter the reference number or state not applicable):	NIHR208819
Project website:	N/A

Registry reference number(s):
The UK Policy Framework for Health and Social Care Research sets out the principle of making information about research publicly available. Furthermore: Article 19 of the World Medical Association Declaration of Helsinki adopted in 2008 states that "every clinical trial must be registered on a publicly accessible database before recruitment of the first subject"; and the International Committee of Medical Journal Editors (ICMJE) will consider a clinical trial for publication only if it has been registered in an appropriate registry. Please see guidance for more information.

International Standard Randomised Controlled Trial Number (ISRCTN):
ClinicalTrials.gov Identifier (NCT number):

Additional reference number(s):

Ref.Number Description	Reference Number

A5-2. Is this application linked to a previous study or another current application?

○ Yes ● No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments' Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.*

'Safety-netting' is used by healthcare professionals to monitor patients while they wait for diagnoses and to organise follow-up when needed. It may involve them asking patients to keep an eye on their symptoms and to come back if symptoms haven't cleared up within a certain time. This is particularly important when there is uncertainty about diagnosis and potential for serious illness like cancer. However, existing approaches do not always work well for patients. For example, patients might forget or misunderstand which symptoms they are supposed to be monitoring.

The Shared Safety Net Action Plan (SSNAP) is designed to involve patients in safety-netting who see their general practice clinician with non-specific symptoms that could be a sign of cancer, such as feeling tired or losing weight. It produces a summary of the safety-netting discussion, which can be printed or sent electronically to patients, so they understand what symptoms to monitor, for how long, and in what circumstances they should return to the practice. SSNAP also provides ways for practices to follow patients up.

This study will test if SSNAP works to support safety-netting and will run for 30 months. We will work with adult patients, their families and staff in six general practices in Northern England that serve different kinds of patients. In three practices SSNAP will be used where patients and healthcare professionals agree it is needed, while in the others SSNAP will not be used. Patients and families will complete questionnaires about how they found the consultations and those who used SSNAP will talk to researchers about it. Staff will talk to researchers about their experiences too. Statistics will be produced about SSNAP's use and effect, and user perspectives will be summarised. This information will inform the design of a larger study to test SSNAP across England.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, HRA, or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

Patient consent: We we will not consent patients individually to receive SSNAP (intervention arm) or to be coded as eligible for SSNAP (control arm), although patients will be consented to be part of the follow-up research before completing questionnaires and taking part in interviews. This decision was informed by patient consultation prior to submitting our funding application and was supported by reviewers. Reasons are as follows:

- Safety-netting is already part of routine care in general practice. SSNAP, which provides a summary of safety-netting discussions and ways to follow patients up, can support safety-netting in more consistent and patient-oriented ways and poses minimal risk (it is not a clinical decision-making tool);
- We will not randomise individual patients to intervention or control groups, but rather randomisation will be at the level of general practices (cluster-level). Intervention surgeries will deliver SSNAP as part of routine care, while control surgeries will continue to use their standard safety-netting processes;
- Consent is already in place for Connected Bradford, a data linkage service, to share patients' anonymised data with the research team after the baseline and intervention periods, through surgeries' existing data sharing agreements with Connected Bradford. Patients will be able to opt out of having their primary care data shared in this way and we will disseminate a poster in all surgeries, explaining the study to patients and how to opt out of data sharing. Where a patient opts out of data-sharing, Connected Bradford will not collect data for that patient and therefore it will not be available to the research team.

This approach is in keeping with consent arrangements within a recent cluster trial of other safety-netting software (Fleming et al., 2020, North--West, Greater Manchester West NHS REC, ref 19/NW/0692) and guidance on consent arrangements for cluster trials (Nix et al., 2021).

Fleming, S., et al., CASNET2: evaluation of an electronic safety netting cancer toolkit for the primary care electronic health record: protocol for a pragmatic stepped-wedge RCT. BMJ Open, 2020. 10(8): p. e038562

Nix, H.P., et al., Informed consent in cluster randomised trials: a guide for the perplexed. BMJ Open, 2021. 11(9): p. e054213.

Time pressures in primary care: Asking staff in primary care to take part in research can add to the time pressures they already face. Learning how to use a new system like SSNAP and embedding it within administrative processes can take more time at first (although it may save time later by reducing numbers of patients returning unnecessarily to see their clinician or returning only when their cancer is at a late stage). To address this, the tool has been co-designed and tested with staff to minimise the time it takes to learn and use it. Its format is simple and quick to use. The digital version, for example, incorporates drop-down lists and check boxes and has a 'look' that is familiar to SystmOne users. In recent evaluations clinicians were able to use SSNAP in simulated consultations within the standard 10-minute timeslot with limited preparation. In this feasibility study, we will provide training and a manual to ease staff transition to the new system. We will offer training in different formats to suit different staff needs (face-to-face, a short video).

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply*:

☐ Case series/ case note review
☐ Case control
☐ Cohort observation
☐ Controlled trial without randomisation
☐ Cross-sectional study
☐ Database analysis
☐ Epidemiology
☑ Feasibility/ pilot study
☐ Laboratory study
☐ Metanalysis
☐ Qualitative research
☐ Questionnaire, interview or observation study
☐ Randomised controlled trial
☐ Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

The principal objective of this research is to assess the feasibility and acceptability of a safety-netting intervention (SSNAP) to support earlier diagnosis of cancer in general practice, using this information to inform the design of a subsequent cluster randomised controlled trial (RCT). Thus, the principal research question is: Is the delivery of SSNAP feasible in general practice?

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

Is SSNAP acceptable to patients, their families and staff?
Is patient recruitment and follow-up for this study feasible in general practice?
What outcomes would demonstrate whether SSNAP successfully supports communication and shared decision-making around uncertainty?
What outcomes would demonstrate SSNAP improves patients' clinical outcomes?
How do surgeries adapt SSNAP for local use?

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

Delayed diagnosis of cancer – where cancer is diagnosed at stages 3 or 4 and has started to spread into surrounding tissues or body organs - is a major cause of death in the UK and worldwide (Hanna et al., 2020). Delays also contribute to health inequalities, reduce treatment options and increase costs (CRUK, 2023, Black et al., 2023, Tosetti & Cooper, 2023). The NHS aims in its Long Term Plan to increase the percentage of cancers diagnosed at stages 1 or 2 to 75% by 2028 and although there have been recent improvements, there is still some way to go to reach this target. In August 2024, for example, 58.7% of the 13 most common cancers met this target in England (National Disease Registration Service, online).

As patients are likely to report emerging symptoms in general practice, early diagnosis is particularly important here (Smith et al., 2022). Most patients with cancer first experience non-specific symptoms that, on their own, present a low risk of cancer (e.g. cough or fatigue) and many patients with non-specific symptoms seek help in primary care two or three times before being referred to see a specialist (Lyratzopoulos, 2012). This process is vulnerable to delay and misinformation, with patients feeling unclear about next steps and hesitant to reconsult. ‘Safety-netting’ – a way to manage uncertainty by involving patients in actively monitoring their symptoms - is used when undiagnosed conditions are suspected. It is particularly useful for people with undiagnosed cancer, presenting with non-specific symptoms. Safety-netting can help achieve a balance between avoiding unnecessary tests and diagnosing cancer early and, by clarifying circumstances in which re-consultation is necessary, it may also reduce numbers of patients returning unnecessarily to general practice (Black et al, 2022a, 2022b). It is encouraged by the National Institute for Health and Care Excellence for people with any symptom associated with an increased risk of cancer, who do not meet the criteria for referral or other investigative action (NICE guideline NG12). It is compatible with NHS digital pathways strategies and could be linked with patient gateways such as SystmConnect, enabling patients to submit requests directly to practices.

Recognising this, we co-designed a patient-centred safety-netting tool - the Shared Safety Net Action Plan (SSNAP) - with patients and general practice staff (https://yqsr.org/supporting-impact-tools-and-resources/, Heyhoe et al., 2022). SSNAP works in SystmOne, a widely-used electronic primary care patient record, to support active monitoring of non-specific symptoms through shared decision-making and discussion about uncertainty between patients and clinicians in consultations. It provides patients with a paper or digital summary of those discussions which clearly specifies which symptoms they are to monitor; for how long; and in what circumstances they should re-consult. SSNAP also provides ways to follow patients up, using scheduled tasks and reminders to staff and patient messaging.

Whilst other digital safety-netting interventions exist, such as the ESN toolkit and C the Signs, these tend to be clinician- rather than patient-focused. By contrast, SSNAP is, to our knowledge, unique in its focus on the joint decision-making process, a systematic review by our team having identified no tools or interventions specifically designed to promote greater patient involvement in safety-netting to achieve earlier diagnosis of cancer at the post-presentation stage (Heyhoe et al, 2018).

This study aims to assess SSNAP’s feasibility and acceptability to support earlier diagnosis of cancer in general practice, using this information to inform the design of a subsequent cluster RCT. Anticipated impacts include changing patient and staff behaviour for closer monitoring of possible non-specific cancer symptoms and increasing awareness of symptom monitoring; supporting appropriate re-attendance in general practice by clarifying criteria for re-attendance; and becoming an effective component in non-specific symptoms pathways into secondary care. Ultimately, we anticipate SSNAP will increase cancer diagnoses at earlier stages in general practice, thereby improving cancer survival rates.

References:

Black, G.B., et al., How does safety netting for lung cancer symptoms help patients to reconsult appropriately? A qualitative study. BMC primary care, 2022a. 23(1): p. 179.

Black, G., et al., Harnessing the electronic health care record to optimise patient safety in primary care: a framework for evaluating “electronic safety netting” tools. JMIR Medical Informatics, 2022b. 10(8).

Black, G.B., et al., Using an electronic safety netting tool designed to improve safety with respect to cancer referral in primary care: a qualitative service evaluation using rapid appraisal methods. BMJ Open Quality, 2023. 12(3): p. e002354.

Cancer Research UK, Longer, better lives: A manifesto for cancer research and care. 2023.

Lyratzopoulos, G., et al., Variation in number of general practitioner consultations before hospital referral for cancer: findings from the 2010 National Cancer Patient Experience Survey in England. The lancet oncology, 2012. 13(4): p. 353-365.

Hanna, T.P., et al., Mortality due to cancer treatment delay: systematic review and meta-analysis. bmj, 2020. 371.

Heyhoe, J., et al., Patient involvement in diagnosing cancer in primary care: a systematic review of current interventions. British journal of general practice, 2018. 68(668): p. e211-e224

Heyhoe, J., et al., The Shared Safety Net Action Plan (SSNAP): a co-designed intervention to promote greater involvement of patients to support the timely diagnosis of cancer in primary care. British Journal of General Practice, 2022.

National_Disease_Registration_Service, Rapid Cancer Registration Data: Incidence and treatment dashboard. Early stage proportion, 12 month rolling, England. https://nhsd-ndrs.shinyapps.io/rcrd/.

National Institute for Health and Care Excellence, NICE guideline [NG12]. Suspected cancer: Recognition and referral. . 2023: https://www.nice.org.uk/guidance/ng12

Smith, C., et al., Optimising GPs' communication of advice to facilitate patients' self-care and prompt follow-up when the diagnosis is uncertain: a realist review of 'safety-netting'in primary care. BMJ Quality and Safety, 2022. 31(7): p. 541-554.

Tosetti, I. and H. Kuper, Do people with disabilities experience disparities in cancer care? A systematic review. Plos one, 2023. 18(12): p. e0285146.
National Disease Registration Service, Rapid Cancer Registration Data: Incidence and treatment dashboard. Early stage proportion, 12 month rolling, England. phttps://nhsd-ndrs.shinyapps.io/rcrd/.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

This feasibility study takes the form of a cluster randomised controlled trial. Participants will be adult patients consulting with a primary care practitioner about non-specific symptoms that could be a sign of cancer; adult family members or informal carers who accompany eligible patients in consultations; and staff in participating surgeries with a safety-netting role (clinical, management/administrative).

Work package 1 (months 1-6): We will work with six GP surgeries in Bradford, Airedale, Wharfedale and Craven that use the primary care electronic patient record SystmOne and have data sharing agreements in place with Connected Bradford, a whole system data linkage service (https://bradfordresearch.nhs.uk/connected-bradford/). Surgeries will be randomised via block randomisation, site initiation visits will take place and surgery staff will be trained (intervention and control training will differ, with intervention surgeries being trained in how to use the SSNAP tool inclusively). SSNAP will be installed on SystmOne in intervention surgeries.

In months 5-6 clinicians in participating surgeries will identify through coding in SystmOne adult patients presenting with non-specific symptoms who are eligible for SSNAP. The research team will obtain anonymised data relating to our outcome measures (see A57, A58) for these patients (provided they have not opted out of data sharing) through Connected Bradford to establish a baseline, including anonymised demographic data. As part of a data collection feasibility exercise, staff in two surgeries will also extract the data themselves to test whether this is feasible, but these identifiable data will not be forwarded to researchers. This will inform the feasibility of data collection for a substantive trial for which we will recruit surgeries which do not have data sharing agreements with Connected Bradford.

Work package 2 (months 7-15): In intervention surgeries, digital or paper SSNAP will be used as part of routine safety-netting procedures. Using SSNAP, clinicians and patients with non-specific symptoms will agree a plan that specifies which symptoms the patient will monitor, over what time-period, and in what circumstances patients should return. Clinicians will populate the SSNAP template in SystmOne, creating a safety-netting record within patients' electronic notes. Where use of paper SSNAP is more appropriate for patients (see also A33-1), clinicians will also personalise the paper SSNAP form for patients to take away with them. Where digital SSNAP is appropriate, they will generate via SystmOne a personalised letter and a diary for the patient to monitor their symptoms, which will be sent to the patient by text or email. Clinicians can set reminders to contact patients at different priority levels, which appear on the patient home screen whenever a patient record is retrieved, and/or scheduled tasks can be set as reminders, allocating tasks such as contacting patients to specific recipients such as surgery administrators. Clinicians from control surgeries will carry out their usual safety-netting procedures and continue to code patients as eligible for SSNAP in SystmOne. Surgeries will display posters informing patients that the surgery is taking part in research about care of patients who have consulted a clinician with non-specific symptoms and they may be contacted at a future date about this, although they're free not to respond.

All patients who have received SSNAP (in intervention surgeries) or who were recorded as eligible for SSNAP (in control surgeries) will be contacted by surgery staff around four weeks after initial consultations. They will be informed that researchers are conducting a study about care of patients who have consulted a clinician with non-specific symptoms where a diagnosis has not yet been reached and invited to complete, with consent, a questionnaire measuring consultation satisfaction (online or post).

The questionnaire for people in the intervention arm will ask whether they would be willing to be contacted by the research team about a telephone/online interview (purposively sampled). Researchers will send an information sheet to those patients/carers who indicate an interest in an interview and informed consent will be taken before interviews begin. Patients and carers will be asked in the interviews about SSNAP's feasibility, acceptability, how they used and engaged with it, what they thought about it and how it might best be refined. Questions will be informed by the SSNAP logic model (appended to the protocol).

Towards the end of the intervention period, Connected Bradford will provide the same data for patients coded for SSNAP in intervention period as in the baseline period (for patients who have not opted out of data sharing) and anonymised data will be forwarded to researchers.

Work package 3 (months 16-30): Researchers will interview staff from each surgery (clinicians, managers, administrators), and will also conduct a staff focus group with staff in each surgery. Interviews and focus groups with staff from control surgeries will assess issues relating to trial design, e.g. willingness of surgeries to be randomised. Those with staff from intervention surgeries will explore SSNAP's feasibility and acceptability, how and why they used it, what factors influenced its adoption and how it might best be refined/further developed. Questions will be informed by the SSNAP logic model (appended to the protocol). Staff involved in delivering SSNAP in intervention surgeries will be asked during interviews and focus groups to complete the System Usability Scale to provide evidence of SSNAP's acceptability. Patient questionnaires and interviews will be completed.

Quantitative and qualitative data will be analysed and synthesised (see A62 for methods of analysis). In agreement with our trial steering committee, it will be determined if the intervention should progress to trial and study outputs will be prepared, namely refined paper and digital versions of SSNAP; refined logic model and programme theory; protocol for the substantive trial; and implementation guide with associated training tools. Dissemination will take place through the final trial report; at least two journal articles in international, peer-reviewed open access journals; a conference presentation and through research networks. We will explore routes to wider implementation with our patient and public involvement group, key stakeholders and the steering committee.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

☑ Design of the research
☑ Management of the research
☐ Undertaking the research
☑ Analysis of results
☑ Dissemination of findings
☐ None of the above

Give details of involvement, or if none please justify the absence of involvement.
PPIE is central to this study. Patients who had previously been diagnosed with cancer and those who had not were involved in SSNAP's co-design, as were a variety of primary care staff. PPIE representatives were also involved in the later user-needs and evaluation work we carried out when developing the tool and helped develop the funding application and trial protocol.

During the feasibility study, a core reference PPIE group will be involved in all aspects, from developing study materials and making sense of information collected, to ensuring findings are accessible to all and co-authoring publications. A lay leader co-applicant for the study will chair the group, supported by the chief investigator. Four additional PPIE colleagues have already agreed to join and we have budgeted for up to 8 members in total to allow for the group to reflect, broadly, SSNAP user demographics highlighted in previous work. The group will support further public engagement, liaising with patient groups from bodies such as cancer charities and patient participation networks in participating surgeries.

The core reference group will meet up to 10 times over the course of the study. Members will be reimbursed for their time according to NIHR guidelines and training will be provided after assessing their needs (e.g. on qualitative data analysis). In reference group meetings at the beginning, middle and end of the project, members will evaluate the study's progress towards meeting the NIHR's UK standards for public involvement for better health and social care research (https://sites.google.com/nihr.ac.uk/pi-standards/home). This will involve capturing and evaluating the impact of PPIE activities on the study, which we will report back to the funder.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A15. What is the sample group or cohort to be studied in this research?

Select all that apply:

☐ Blood
☑ Cancer
☐ Cardiovascular
☐ Congenital Disorders
☐ Dementias and Neurodegenerative Diseases
☐ Diabetes
☐ Ear
☐ Eye
☐ Generic Health Relevance
☐ Infection
☐ Inflammatory and Immune System
☐ Injuries and Accidents
☐ Mental Health
☐ Metabolic and Endocrine
☐ Musculoskeletal
☐ Neurological
☐ Oral and Gastrointestinal
☐ Paediatrics
☐ Renal and Urogenital
☐ Reproductive Health and Childbirth
☐ Respiratory
☐ Skin
☐ Stroke

Gender:	Male and female participants
Lower age limit: 18	Years
Upper age limit:	No upper age limit

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

Patient/carer inclusion criteria for intervention:
Patients aged 18 and over presenting with non-specific symptoms which could indicate cancer, who have capacity to decide on their own medical treatment.

Patients aged 18 and over presenting with non-specific symptoms which could indicate cancer, who do not have capacity to decide on their own medical treatment, but who are accompanied in the consultation by a family member or informal carer (consultee).

Family members or informal carers aged 18 and over who accompany SSNAP-coded patients in consultations.

Patient/carer inclusion criteria for questionnaires:
Patients aged 18 or over in intervention surgeries who have received SSNAP or who were recorded as eligible to receive SSNAP in control surgeries.

Family members/informal carers aged 18 and over who accompany patients in consultations where SSNAP was used in intervention surgeries or where the patient was recorded as eligible to receive SSNAP in control surgeries.

Patient/carer inclusion criteria for interviews:
Patients aged 18 or over in intervention surgeries who have received SSNAP.

Family members/informal carers aged 18 and over whose relative/significant other has received SSNAP in an intervention surgery.

Staff inclusion criteria (intervention, interviews, focus groups)
All staff in participating surgeries with a safety-netting role (clinical, management/ administrative).

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

Patients/carer exclusion criteria for intervention:
Young people and children aged under 18 years.

Patients aged 18 and over who do not have capacity to consent to their own medical treatment and who either are not accompanied by a family member or informal carer (consultee), or the consultee does not agree to receiving the SSNAP plan.

Patients who have opted out of data sharing.

Patient/carer exclusion criteria for questionnaires & interviews:
Patients who meet the inclusion criterion but for whom participation in questionnaires or interviews could cause distress or confusion, including patients without capacity to consent to the research or patients who are too ill to participate (e.g. at the end of life).

Patients, family members/informal carers aged less than 18 years.

Family members/informal carers of patients who received SSNAP (in intervention surgeries) or were recorded as eligible to receive SSNAP (in control surgeries) but passed away before the invitation to complete a questionnaire is circulated, so as not to cause unnecessary distress.

Staff exclusion criteria
Staff not involved in safety-netting processes.

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Patient or carer consultation satisfaction questionnaire	1		20 mins	Questionnaire completed online or on paper. Includes consent & demographics questions.
Intervention arm patient or carer interview	1		60 mins	Conducted by a researcher online or on telephone. Includes taking informed consent.

Staff interview	1	60 mins	Conducted by a researcher online, telephone or in surgery. Includes taking informed consent & demographics questions.
Staff focus group	1	75 mins	Conducted by a researcher online, telephone or in surgery. Includes taking informed consent, demographics questions and completing System Usability Scale.

A19. Give details of any clinical intervention(s) or procedure(s) to be received by participants as part of the research protocol. *These include uses of medicinal products or devices, other medical treatments or assessments, mental health interventions, imaging investigations and taking samples of human biological material. Include procedures which might be received as routine clinical care outside of the research.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days).
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Safety-netting a patient for non-specific symptoms using the SSNAP template in SystmOne within the standard 10 minute consultation time.	1	1	10 minutes	Primary care clinician (GP or practice nurse) at GP surgery or online/telephone if consultation conducted remotely.

A20. Will you withhold an intervention or procedure, which would normally be considered a part of routine care?

○ Yes ● No

A21. How long do you expect each participant to be in the study in total?

Patients and family members/informal carers: 12-14 weeks.

Staff: 21 months (work package 1 to around half-way through work package 3).

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

The intervention:
Risks for patients and family members/informal carers associated with receiving a SSNAP plan are minimal and no more than would be involved in standard care. The intervention is not a decision support tool and includes no clinical decision support. It only provides a visual (for the paper, icon-based tool) or written (for the digital tool) summary of what was discussed in the session and a means within SystmOne to follow-up patients via automated reminders/scheduled tasks to staff.

There is a risk that patients or carers could misplace their SSNAP plan and thus fail to follow its guidance, but this involves less risk than current practice in many surgeries, where safety-netting advice is often purely verbal. As SSNAP generates a safety-netting record in SystmOne, surgeries will be aware when patients received a SSNAP plan and can follow them up if they have concerns that they may have disregarded safety-netting advice. We have also considered whether, in summarising symptoms that might - but most likely do not – indicate cancer, SSNAP could increase patient health anxiety. Our user-needs work with people with lived experience of cancer safety-netting indicated that SSNAP would be unlikely to do so and might alleviate anxiety by supporting patients to feel heard and giving clear guidance on next steps. Nevertheless, to mitigate against this risk we will include recommendations from research and policy (Smith et al., 2022, NIHR, 2023) about how to optimise communication in safety-netting conversations in training sessions for intervention surgeries and we have budgeted for refining SSNAP during the trial if feedback from surgeries indicates that aspects of the tool trigger anxiety. For example, we could modify the wording of the patient letter. Bearing in mind the need to be sensitive to patients, patient documentation for this study focuses on the care of patients with non-specific symptoms, rather than on cancer (which, for most patients in the study, is not likely to be diagnosed).

For staff, the main burden is likely to be lack of time to undertake SSNAP training or use SSNAP in consultations, given pressures on primary care. To mitigate this risk, we will consult with participating surgeries to schedule training at suitable times (e.g. some surgeries set an afternoon aside for training at intervals) and we will also provide a manual and a training video for staff who cannot attend. In our evaluation work, surgery staff found SSNAP's format made it easy to learn and use (the digital version, for example, incorporates drop-down lists and check boxes and has a 'look' that is familiar to SystmOne users) and clinicians were able to use it in simulated consultations within the standard 10-minute timeslot with a few minutes' prior explanation.

Questionnaires, interviews and focus groups:
There is some risk that patients and their family members/informal carers could become upset when thinking or talking about their experience in consultations during questionnaires and interviews. Patients will be under the care of their GP during the trial, and will be advised to contact their surgery if, during research procedures, they appear to need further support. The research team will do all they can to respond sensitively and flexibly to patients and their carer (see section A23 below).

For staff, the main burden of participating in interviews or focus groups is likely time. In recognition of this, we will be flexible in how and where we schedule and offer interviews and focus groups, running them quickly and efficiently and at times and in places (online, participants' offices) that suit them. Researchers' post specifications make it clear that out-of-hours working may be needed to accommodate this.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

● Yes ○ No

If Yes, please give details of procedures in place to deal with these issues:

As noted in A22 above, there is a risk that patients and their family members/informal carers could become upset during questionnaires and interviews, when thinking or talking about their experience in a consultation potentially linked to cancer. This may be especially so in the rare event that patients have been diagnosed with cancer between their SSNAP consultation and being invited to complete a questionnaire or undertake an interview. On the other hand, patients and family members may not be aware that their safety-netting is potentially linked to cancer (and most patients will turn out not to have cancer). It is not for the research team to introduce this possibility to them, rather, this matter is between patients and their clinicians.

Surgeries will be asked not to send questionnaires to patients coded for SSNAP but whose records indicate that they lack the mental capacity to consent to complete a questionnaire; who are likely to be too ill to participate; or who have passed away since initial coding. Only those people who indicate on the questionnaire that they wish to be contacted by researchers will be invited to an interview, and researchers will work carefully with them (bearing in mind that some people may not feel worried by safety-netting and may be alarmed by suggestions that they might be). Patient information sheets and invitation texts/emails/letters will explain that the research is about care of patients with symptoms that could have multiple causes (rather than cancer); they will emphasise that there is no pressure to participate and patients and their family members/informal carers are free to decline; information sheets will also outline sources of support including support for cancer as well as other more general support (e.g. The Samaritans), and researchers will reiterate this before interviews, explaining too that patients and carers are free not to answer any question, to pause or end the interview when they wish, without giving a reason, and to take as much time as they wish to respond.

The questionnaire and the interview topic guides focus on understanding the consultation process (e.g. whether respondents felt listened to; whether they understood actions arising from the consultation) rather than the emotive content of the consultation, although it may not be easy for respondents to separate these. The CI has experience of interviewing participants following a potential cancer diagnosis (and was a cancer counsellor) and will mentor and support researchers in this work. We have found in other studies with people who have recently had a cancer consultation or diagnosis that they can find it helpful to talk in interviews to people who are not directly involved in their care. If patients or their families want to talk about emotive subjects, we will respect this and listen to them, signposting them to support if needed.

It is possible that a patient may disclose, in interviews, that they are dissatisfied with the care they are receiving. In such cases we will ask the patient to report the matter as soon as possible to a relevant healthcare professional. If the patient feels unable to report a risk, and the researcher believes this risk to be serious and immediate, the researcher will first consult with the CI and then may act on behalf of the patient to communicate the risk to the relevant, local designated health professional. It is also possible that, during discussions, participants may disclose information to the research team, or the research team may have concerns that the individual may be experiencing abuse or is at risk of abuse. In such circumstances the researcher will follow the participant's GP surgery's safeguarding adults policy (or equivalent document).

We do not believe that staff are likely to become upset in interviews or focus groups, as we will focus on issues relating to trial design and, for intervention surgeries, SSNAP's feasibility and acceptability and how it might best be refined/further developed.

A24. What is the potential for benefit to research participants?

For patients and their family members or informal carers, participating in the research may give them the satisfaction of knowing that they are helping develop systems that could help other people in similar circumstances. Patients in the intervention arm may also benefit from increased involvement in, and understanding of, the safety-netting they've received from their general practice clinician, and active follow-up. In addition, patients/carers completing a questionnaire or taking part in an interview will be offered a £20 voucher as a small token of appreciation.

Individual staff taking part in the research will not receive reimbursement but may experience satisfaction in knowing that they are helping develop systems that could help their and other surgeries to operate in more effective, patient-centred ways in the future. Surgeries will be welcome to a copy of the SSNAP tool, at no cost, after the trial ends if they wish.

A25. What arrangements are being made for continued provision of the intervention for participants, if appropriate, once the research has finished? *May apply to any clinical intervention, including a drug, medical device, mental health intervention, complementary therapy, physiotherapy, dietary manipulation, lifestyle change, etc.*

Safety-netting patients, which is a routine part of care, will continue after the research has finished in both intervention and control surgeries and will not be interrupted by the research. Intervention surgeries will be welcome to continue to retain and use the SSNAP template after the research if they wish, at no charge, or they could revert to previous safety-netting practice without use of the SSNAP template. If control surgeries express an interest in using the SSNAP tool after the trial has ended (and not before) and they have the capacity to install the tool themselves, they will also be welcome to receive and use the SSNAP template at no charge.

A26. What are the potential risks for the researchers themselves? *(if any)*

Researchers could feel upset when talking to patients or their carers about emotionally-evocative subjects such as the risk of being diagnosed with cancer and dealing with uncertainty. In response, the CI will meet regularly with the researchers and they will de-brief together following interviews, providing an opportunity to discuss any difficult feelings and to sign-post researchers to sources of support if they need it, such as counselling.

We have taken steps to reduce risks to researchers when carrying out the research, e.g. when going to research sites to carry out interviews or focus groups. Interviews with patients and their carers will take place online or via the telephone, to reduce such risks. Interviews and focus groups with staff may also take place online, but we will also offer them in surgeries, e.g. in meeting rooms or staff offices. Surgeries are busy, safe spaces, but where meetings take place at quiet times, e.g. early mornings or evenings, researchers will be able to go in pairs and/or we will arrange check-in/check-out procedures where researchers let another member of the research team know when the interview/focus group has ended and when they are safely home or back in their office. If the other member of the team does not receive this notification, we will use an escalation process, whereby they try first to contact the researchers on their mobile phone; if they don't hear from them, they will contact another person such as a partner/family member; and ultimately, if there is no contact, they will inform the local police.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used?*For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under* *arrangements with the responsible care organisation(s).*

Identifying staff to implement SSNAP in control and intervention surgeries: PIs will invite surgery staff who provide or support safety-netting in participating surgeries to take part in the study, using SSNAP safety-netting (in intervention surgeries) or coding for SSNAP eligibility (in control surgeries). A poster about the research will be displayed in staff rooms/areas.

Identifying patients at baseline: After training, in WP1 clinicians in both intervention and control surgeries will identify via coding in SystmOne adult patients presenting with non-specific symptoms that could be a sign of cancer, whom they consider to be eligible for SSNAP according to our criteria in A17-1. Clinicians will make this decision based on their clinical expertise and patients' medical background and presenting symptoms. We expect eligibility will often not be clear until clinicians have consulted with patients and discussed their symptoms with them.

Identifying patients in the intervention phase: Eligible patients will be selected for SSNAP in intervention surgeries when they (or their accompanying carer, if they do not have capacity to decide on their own medical treatment) and the clinician they consult decide, together, that they should be safety-netted using SSNAP. Patients and their carers will be free to decline to use SSNAP, i.e. the clinician will make it clear to them that they don't have to receive their SSNAP plan in paper or electronically. Whether this is the case or not, safety-netting itself will take place as part of routine care so that declining SSNAP does not affect patient care.

In control surgeries, eligible patients will continue to be recorded via a code in SystmOne. In making these decisions, clinicians will refer to the eligibility criteria in A17-1.

Identifying patients & carers to complete a consultation satisfaction questionnaire: Around four weeks after patients were initially coded in the intervention phase, their SystmOne SSNAP code will be used by surgeries to identify patients who have received SSNAP (in intervention surgeries) or were coded as eligible for SSNAP (in control surgeries). They will be informed that researchers are conducting a study about care of patients who have consulted a clinician with symptoms where a diagnosis has not yet been reached and invited to complete a questionnaire measuring consultation satisfaction (online or post, determined by the surgery, based on the information they have about patients' digital access).

To avoid unnecessary distress or confusion to patients or their families, surgeries will be asked not to send questionnaires to patients coded for SSNAP but whose records indicate that:

- they lack the mental capacity to consent to complete a questionnaire. In these cases, a family member or carer, acting as a consultee, will have accompanied them in the initial consultation and agreed to safety-netting on their behalf. Here, surgeries will be encouraged to send a questionnaire to the family member rather than the patient, if they can be identified;
- they are likely to be too ill to participate (e.g. they are at the end of life);
- the patient has passed away since initial coding.

It will be at the discretion of surgeries to decide which patients to exclude in this way.

Identifying patients and carers to participate in an interview: The consultation satisfaction questionnaire sent by intervention surgeries to patients/carers will ask them to indicate whether they would be willing to be contacted by the research team about a telephone/online interview. Because questionnaires will not be sent to those people who lack capacity or are deemed too ill to participate, they will not be included so as not to cause distress or confusion, but, as above, efforts will be made to include family members/informal carers. To avoid, where possible, causing distress when a respondent indicates that they wish to be contacted to arrange an interview, but is either diagnosed with cancer or dies before the interview can take place, we will seek to arrange interviews as quickly as possible and will do so with sensitivity and tact.

Identifying staff to take part in interviews and focus groups: Staff in participating surgeries will be informed about the SSNAP feasibility trial by PIs, following the site initiation visit. The PI will send staff an information sheet about the interviews and focus groups, and staff will be asked to contact the research team to indicate whether they wish to take part. We anticipate an average of three interviews per surgery across both arms with staff (clinicians, managers, administrators), reflecting variation in surgery size and numbers of staff involved in the study, and one staff focus group in each surgery, comprising around five staff.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

● Yes ○ No

Please give details below:
Staff in the participating surgeries will screen patients' personally identifiable data, drawing on patient records and information they provide in the consultation, at baseline when they assess their eligibility for coding; in the intervention phase when assessing their eligibility to receive SSNAP (intervention surgeries) or when coding patients as eligible for SSNAP (control surgeries); and when they invite them to complete a questionnaire.

A27-3. Describe what measures will be taken to ensure there is no breach of any duty of confidentiality owed to patients, service users or any other person in the process of identifying potential participants.*Indicate what steps have been or will be taken to inform patients and service users of the potential use of their records for this purpose. Describe the arrangements to ensure that the wishes of patients and service users regarding access to their records are respected. Please consult the guidance notes on this topic.*

In screening as set out in A27-2 above, staff will not share this personally identifiable information with the research team and thus will not breach confidentiality owed to patients, service-users or any other person in the process.

A27-4. Will researchers or individuals other than the direct care team have access to identifiable personal information of any potential participants?

○ Yes ○ No

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

● Yes ○ No

If Yes, please give details of how and where publicity will be conducted, and enclose copy of all advertising material (with version numbers and dates).

We will provide participating surgeries with posters (there are separate posters for intervention and control surgeries) that explain the research and provide information on how to opt out of data sharing if desired.

Participating surgeries will also be provided with posters for staff (separate posters will be provided for intervention and control surgeries), which explain the research and what staff will be asked to do, and, for intervention surgeries, encourages them to use SSNAP with eligible patients.

These posters are not, therefore, strictly recruitment posters but more sources of information. They are attached to this application.

A29. How and by whom will potential participants first be approached?

A poster explaining the research (see A28 above) will be displayed in patient-accessible areas in surgeries. Patients will be approached about the SSNAP plan during consultations by their clinicians.

Patients and carers will be invited to complete consultation satisfaction questionnaires by surgeries, by email, text or letter, enclosing or providing a link to a participant information sheet.

Staff in participating surgeries will be informed about the research by PIs in each surgery, following the site initiation visit. A poster about the research will be displayed in staff rooms/areas (see A28 above). PIs in each surgery will send staff an information sheet about the interviews and focus groups. Staff will be asked to contact the research team to indicate whether they wish to take part.

A30-1. Will you obtain informed consent from or on behalf of research participants?

● Yes ○ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

We will seek informed consent from patients, family members/carers and staff before they take part in questionnaires, interviews or focus groups, after having provided them with an information sheet. Consent will be taken by researchers, trained and competent to take consent according to the principles of Good Clinical Practice (GCP) and the Declaration of Helsinki.

If you are not obtaining consent, please explain why not.

Cluster randomisation will be at the level of GP surgeries rather than individual patients and SSNAP will be provided to intervention patients as part of the surgery's routine safety-netting processes. We consider SSNAP to be a low-risk intervention, as it only provides a summary of safety-netting advice and means to arrange patient follow-up and does not incorporate knowledge systems or generate diagnostic advice for clinicians. Consent is already in place for surgeries to share patients' anonymised data with the research team after the baseline and intervention periods, through surgeries' existing data sharing agreements with Connected Bradford. Patients are able to opt-out of data sharing in this way through Connected Bradford's opt-out process. No personally identifiable data about patients will be made available by Connected Bradford or surgeries themselves to researchers.

Each surgery will be provided with a poster for display in areas where patients and their families/carers can see it. The poster will explain that the surgery is taking part in research about care of patients who have consulted a clinician with non-specific symptoms and they may be contacted at a future date about this, although they're free not to respond. It will also include information about how to opt-out of data-sharing. This approach is in keeping with consent arrangements within a recent cluster trial of other safety-netting software (Fleming et al., 2020, North--West, Greater Manchester West NHS REC, ref 19/NW/0692) and guidance on consent arrangements for cluster trials (Nix et al., 2021).

For these reasons, patient consent will not be sought for the SSNAP intervention itself. Informed consent will be sought before participation in questionnaires and interviews, as noted above.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

● Yes ○ No

A31. How long will you allow potential participants to decide whether or not to take part?

For patient/carer consultation satisfaction questionnaires and interviews, and staff interviews and focus groups, we will allow a minimum of 24 hours for potential participants to decide whether or not to take part.

A32. Will you recruit any participants who are involved in current research or have recently been involved in any research prior to recruitment?

○ Yes

○ No

● Not Known

If Yes, please give details and justify their inclusion. If Not Known, what steps will you take to find out?

It is possible that patients in both intervention and control surgeries who receive a SSNAP plan (intervention) or are coded for SSNAP (control) may recently have been involved in other research. However, when inviting patients or their family members/carers to complete a consultation satisfaction questionnaire it will be made clear that it is up to them whether to take part, that there is no pressure to do so and it will not affect their care. If a patient, taking part in the SSNAP study, was also taking part or had recently taken part in other research, we do not consider this would raise overriding safety or design considerations.

We will check with surgeries when recruiting them that they have capacity to be involved in this study and that they are not concurrently involved in other safety-netting research.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?*(e.g. translation, use of interpreters)*

If any patients using SSNAP require language/interpretation services in a consultation, we anticipate that surgeries will access the services they normally use in such cases. We will translate patient research materials and outputs, such as infographics, into major languages spoken in participating surgeries and will use interpreters or staff with language skills in patient interviews.

A34. What arrangements will you make to ensure participants receive any information that becomes available during the course of the research that may be relevant to their continued participation?

We do not envisage information becoming available during the course of the research that may be relevant to participants' continuing participation in the study.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

● The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.

○ The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.

○ The participant would continue to be included in the study.

○ Not applicable – informed consent will not be sought from any participants in this research.

○ Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

Whilst people who do not have capacity to consent to their treatment may receive SSNAP if their consultee (family member or informal carer accompanying them in the consultation) receives the SSNAP plan on their behalf, we will ask surgeries not to send questionnaires to these patients. As a result they will also not receive invitations to interviews. It is possible, however, that someone with capacity receives a questionnaire, indicates that they want to be contacted about an interview, and then loses capacity before they are contacted (this could only apply to intervention patients or family members, as they will not be invited to interview in control surgeries). We aim to minimise the opportunity for such an event by arranging interviews promptly but if, when contacting them, it becomes clear that a patient (or family member) no longer has capacity, we will either not interview them or we will end the interview as quickly as possible, and withdraw them from the study. Any identifiable information they have provided (such as their contact details or the beginning of an interview transcript) will be withdrawn, but anonymised quantitative data will not be withdrawn retrospectively, as we will not know which patient such information is associated with.

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)?*(Tick as appropriate)*

☐ Access to medical records by those outside the direct healthcare team

☐ Access to social care records by those outside the direct social care team

☑ Electronic transfer by magnetic or optical media, email or computer networks

☐ Sharing of personal data with other organisations

☐ Export of personal data outside the EEA

☑ Use of personal addresses, postcodes, faxes, emails or telephone numbers

☑ Publication of direct quotations from respondents

☐ Publication of data that might allow identification of individuals

☑ Use of audio/visual recording devices

☑ Storage of personal data on any of the following:

- ☑ Manual files (includes paper or film)
- ☑ NHS computers
- ☐ Social Care Service computers
- ☐ Home or other personal computers
- ☑ University computers
- ☐ Private company computers
- ☑ Laptop computers

Further details:
Quantitative baseline and intervention data: Only anonymised data will be provided by Connected Bradford to the research team, in accordance with the provisions of Connected Bradford's data sharing agreements with participating surgeries.

Patient consultation satisfaction questionnaires: Surgery staff in intervention and control surgeries will be asked to invite coded patients or carers to complete a consultation satisfaction questionnaire, using contact details they already have, which will not be shared with the research team. The questionnaire, which also asks for demographic data, will be available to patients and carers online or on paper, depending on their needs. The online version will be hosted on a secure platform, with access limited to members of the research team (including administrative staff), and data will be downloaded from the questionnaire to an Excel spreadsheet, which will be stored in a secure folder on a Bradford Teaching Hospitals NHS Foundation Trust (BTHFT) server with access restricted to the research team, which is regularly backed up. Paper questionnaires will be sent to patients/carers with a stamped addressed envelope to return them to BTHFT, where they will be transcribed onto the Excel spreadsheet, after which the paper version of the form will be destroyed in confidential waste.

In the questionnaires, patients/carers will be asked if they wish: (1) to receive a £20 voucher as a thank you; (2) to take part in an interview (for intervention participants only); (3) to receive the findings of the study when available. If they indicate yes to any of these questions, they will be asked to provide the research team with a name and postal address so that vouchers or findings can be sent to them, and/or an email address or telephone number so the research team can contact them about an interview. Sending vouchers in the post in this way means that the research team will be able to check the number of vouchers allocated per household and prevent, as far as possible, bogus claims for multiple vouchers, which has unfortunately occurred in other studies where no such checks were in place. It also means that the burden of checking will not fall to hard-pressed surgeries.

Personal contact details will be deleted by researchers from the Excel spreadsheet which contains the results of the questionnaire and will be transferred to and stored in a separate Excel recruitment spreadsheet in the secure, restricted access folder on a BTHFT server, accessible only to members of the research team.

Patient, carer and staff interviews and focus groups: Consent forms, which contain participants' names, will be stored securely in the restricted access folder. Paper consent forms will be scanned and copied into the folder, after which the paper forms will be destroyed in confidential waste.

Staff will be asked to provide some demographic data in interviews and focus groups, which will be stored separately from consent forms in the restricted access folder (patients and carers will have already provided demographic data in the consultation satisfaction questionnaire). Interviews and focus groups will be recorded using encrypted recording devices or the recording function in Teams/Zoom. Interview participants will be referred to using an anonymous participant ID code.

We will ask staff during the consent process for interviews and focus groups if they would like to be kept informed of the progress of the study and of findings, and, if so, obtain permission from them to retain their contact details (in the recruitment spreadsheet) to send findings to them (patients and carers will already have been asked this in the consultation satisfaction questionnaires).

System Usability Scale: Staff involved in delivering SSNAP in intervention surgeries will be asked, following interviews and focus groups, to complete the System Usability Scale to provide evidence of SSNAP's acceptability. Where interviews and focus groups take place online, staff will be emailed a copy of the scale marked with their anonymous participant ID to complete and return to the research team, whereas a paper version marked with the participant ID will be used when in-person. In both cases, on receipt of the marked scale, research staff will transcribe the results into an Excel spreadsheet, held on the restricted access server at BTHFT. The original versions will be destroyed in confidential waste (paper forms) or deleted (electronic forms).

None of the above data will be stored on the hard drives of research team members' laptops, personal computers or devices, but will only be stored on and accessed from the secure BTHFT server. When researchers access this drive from locations other than the office, they will do so via the Trust's secure, password-protected VPN.

A37. Please describe the physical security arrangements for storage of personal data during the study?

Data will be stored on a secure folder on a BTHFT server which can only be accessed by a member of the research team (to access BTHFT servers, usernames and passwords must first be entered). Data originally provided on paper (e.g. on consent forms or paper questionnaires) will be transferred to the secure restricted access folder and the paper originals will be deleted/destroyed in confidential waste. The online versions of patient/carer consultation satisfaction questionnaires (including anonymous demographic data), patient/carer and staff consent forms and staff demographic forms will be hosted on a secure platform before being downloaded to the secure, restricted access folder. Once these data have been downloaded, questionnaire, consent and demographic data will be deleted from the online platform. Interviews and focus groups will be recorded on secure, encrypted recording devices or the recording function in Teams/Zoom. As soon as possible after the interviews and focus groups, researchers will download the recordings to the restricted access folder and delete them from the recording device or Teams/Zoom. Where recordings are sent to a transcription service, we will use a service that has secure arrangements for the transfer of recordings and transcriptions.

A38. How will you ensure the confidentiality of personal data?*Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

BTHFT will act as controller of the data which will be held in a secure environment with the highest standards of information governance and technical expertise to protect the data. Only anonymised quantitative data will be passed to the research team by Connected Bradford, part of BTHFT, and these data will only be available via a secure BTHFT server. Although several items will be extracted from individual clinical records by Connected Bradford, we have taken care to minimise the number of data items/variables that would be extracted, and we are only requesting information pertaining to age rather than date of birth. We do not believe that the data being requested would be sufficient, even in aggregate, to identify an individual. Anonymisation will ensure that it is not possible for research staff to link study data with data from other sources. All employees processing the data will be required to follow strict standard operating procedures for the secure transfer, storage, handling, backup and restore of data; complete annual mandatory training in Information Governance procedures; be made aware of their responsibilities under GDPR, and the Data Protection and Freedom of Information Acts. Breaches of confidentiality will be disciplinary matters.

Patient consultation satisfaction questionnaires and demographic information will be completed anonymously, unless patients/carers from the intervention arm indicate that they would like to receive a voucher/findings or be contacted by a member of the research team to arrange an interview, when they will be asked to provide contact details, as described above. In these cases, identifiable data will be removed from the Excel spreadsheet where questionnaire data are stored, and stored in a separate recruitment spreadsheet in a secure, restricted access folder on a BTHFT server, accessible only to members of the research team (to include administrative staff). Each questionnaire will contain an identifier for the surgery which circulated the questionnaire to facilitate allocation of recruitment data, in accordance with the NIHR RDN Recruitment Policy Document at https://www.nihr.ac.uk/nihr-crn-recruitment-policy-document, but this will not enable patient identification.

Patient and carer consent to undertake the consultation satisfaction questionnaire and associated demographic information is integrated in the questionnaires and will be provided anonymously and stored with questionnaire data.

Patient/carer interview consent forms, and staff interview/focus group consent forms and may be completed online or on paper. Online forms will be hosted on the secure platform, with access limited to members of the research team and will be downloaded into the secure recruitment folder. Once these the forms have been downloaded, the online data will be deleted from the platform. Paper consent forms will be scanned and copied into the folder, after which the paper forms will be destroyed in confidential waste.

After consenting to an interview or focus group, patients, carers or staff will be assigned a unique non-identifiable participant ID, which will be used to refer to them thereafter by the research team (e.g. in reports or publications). Staff interview and focus group transcripts, demographics forms and System Usability Scale responses will be stored under staff members' participant IDs. Transcriptions of interviews or focus groups will be reviewed carefully to remove all potentially identifiable information, such as names of people, surgeries or towns/cities. These will be replaced by non-identifiable information such as [NAME REMOVED TO PRESERVE CONFIDENTIALITY].

Names and other identifying information about patients, carers or staff will never be used in reports, articles or other outputs. The names, contact details and participant IDs of patients, carers and staff will be stored in the above-mentioned separate Excel recruitment spreadsheet in a folder on a secure BTHFT folder, with access restricted to members of the research team.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

Only members of the research team will have access to participants' personal data during the study, stored in a restricted access folder at BTHFT, with their informed consent.

Storage and use of data after the end of the study

A41. Where will the data generated by the study be analysed and by whom?

Anonymised quantitative data generated by the study from patients' primary care records via Connected Bradford will be analysed by the trial statistician via a secure BTHFT server. All other anonymised data (from questionnaires, interviews, focus groups and the System Usability Scale) will be analysed by the research team with input as needed from trial management group members. This analysis will be done on a restricted access folder on a BTHFT secure server. PPIE reference group members may also be involved in data analysis to ensure that patient and public perspectives are embedded in the analysis.

A42. Who will have control of and act as the custodian for the data generated by the study?

	Title	Forename/Initials	Surname
	Dr	Lynn	McVey

Post	Senior Research Fellow
Qualifications	MA (Hons), MA, PhD
Work Address	Bradford Institute for Health Research, Temple Bank House, BRI Duckworth Lane Bradford
Post Code	BD9 6RJ
Work Email	Lynn.McVey@bthft.nhs.uk
Work Telephone	01274382738
Fax	

A43. How long will personal data be stored or accessed after the study has ended?

○ Less than 3 months

○ 3 – 6 months

○ 6 – 12 months

○ 12 months – 3 years

● Over 3 years

If longer than 12 months, please justify:
We aim to retain personal data for a maximum of 5 years after the study has ended, to provide enough time to complete analysis/writing up the research, and then disseminating it to those participants who asked to be kept informed.

A44. For how long will you store research data generated by the study?

Years: 5
Months: 0

A45. Please give details of the long term arrangements for storage of research data after the study has ended.*Say where data will be stored, who will have access and the arrangements to ensure security.*

According to BTHFT's data governance policy, we will indicate in a data register which data we intend to store; date for deletion; and confirmation when the data have been deleted (the register does not identify individual research participants). Data will be stored on the restricted access folder until they are deleted (no paper files will be kept). The restricted access folder will be accessible only by members of the research team as well as an administrator, who will have responsibility for deleting the data on deletion date, in case research staff have moved to other posts.

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

● Yes ○ No

If Yes, please give details. For monetary payments, indicate how much and on what basis this has been determined.
Patients and family members/informal carers completing questionnaires or taking part in interviews will be offered a £20 voucher as a small token of appreciation. Participating surgeries will be reimbursed for their contribution through NHS treatment, support and research costs. Individual staff members will not receive any payments.

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

○ Yes ● No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

○ Yes ● No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

○ Yes ● No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

The UK Policy Framework for Health and Social Care Research sets out the principle of making information about research publicly available. Furthermore: Article 19 of the World Medical Association Declaration of Helsinki adopted in 2008 states that "every clinical trial must be registered on a publicly accessible database before recruitment of the first subject"; and the International Committee of Medical Journal Editors (ICMJE) will consider a clinical trial for *publication only if it has been registered in an appropriate registry. Please see guidance for more information.*

● Yes ○ No

Please give details, or justify if not registering the research.
We will register the study with the ISRCTN registry following ethical approval.

Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study?*Tick as appropriate:*

☑ Peer reviewed scientific journals

☑ Internal report

☑ Conference presentation

☑ Publication on website

☐ Other publication

☐ Submission to regulatory authorities

☐ Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators

☐ No plans to report or disseminate the results

☑ Other (please specify)

We also plan to disseminate the study in accessible ways through means such as infographics, easy-read summaries in different languages and social media posts. We will accessible dissemination methods with our PPIE group.

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

Only anonymised quantitative data from patient records will be made available to the research team and it will not be possible to report these data at an individual, identifiable level. Data from consultation satisfaction questionnaires will also be reported anonymously, whilst data from patient, carer or staff interviews and focus groups, including direct quotations, will be reported under participants' anonymous participant IDs. We will limit the specificity of details that we report about participants, to reduce the likelihood of their being identified (e.g. we will refer to surgeries in a broad geographic area rather than sharing which city or postcode they are based in; we will refer to broad categories of staff rather than individual job titles and we will report age ranges rather than specific ages.

A53. How and when will you inform participants of the study results?

If there will be no arrangements in place to inform participants please justify this.
In the patient consultation satisfaction questionnaires and during the consent process for staff interviews and focus groups, we will ask participants if they would like to be kept informed of the progress of the study and of findings, and, if so, obtain permission from them to retain their contact details to send findings to them.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed?*Tick as appropriate:*

☑ Independent external review

☐ Review within a company

☐ Review within a multi−centre research group

☐ Review within the Chief Investigator's institution or host organisation

☑ Review within the research team

☐ Review by educational supervisor

☐ Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
The study is funded by NIHR Research for Patient Benefit. The research design has been subject to the NIHR review process which involves two formal stages, each with reports from subject and methods experts together with PPI review. At the later stages we received and responded to feedback from reviewers and the funding committee. This protocol has been reviewed by the co-applicants who include academic, clinical, lived experience and statistical experts.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A56. How have the statistical aspects of the research been reviewed? *Tick as appropriate:*

☐ Review by independent statistician commissioned by funder or sponsor

☐ Other review by independent statistician

☐ Review by company statistician

☐ Review by a statistician within the Chief Investigator’s institution

☑ Review by a statistician within the research team or multi-centre group

☐ Review by educational supervisor

☐ Other review by individual with relevant statistical expertise

☐ No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

	Title	Forename/Initials	Surname
	Mr	Alex	Mitchell

Department University of York Trials Unit, Department of Health Sciences
Institution University of York
Work Address Seebohm Rowntree Building
Heslington
York
Post Code YO10 5DD
Telephone 01904 321756
Fax
Mobile
E-mail alex.mitchell@york.ac.uk

Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?

Diagnosis of cancer at all stages in primary care is our preferred primary outcome, but it may be difficult to power a later substantive trial to detect differences in this. Therefore, in the early phases of this project we will explore a range of clinical outcomes, such as primary care interval for cancer diagnoses (time between first recorded symptom of cancer and referral to secondary cancer care) and number of primary care consultations between first recorded symptoms and subsequent referral to secondary care. Having narrowed down a long set of clinical outcomes to a maximum of three, we will collect these data as part of this feasibility study.

A58. What are the secondary outcome measures?*(if any)*

Time to re-attend
Referral(s) for follow-up diagnostic tests
Number of re-attendances & DNAs over intervention period (it may be challenging to determine whether patients re-attend in relation to the index problem or other issues. We will explore whether coding can be developed that captures this information).
Number of patients re-booking appointments
Number of occasions intervention used or would be used
Willingness of surgeries to be randomised
Willingness of staff to initiate SSNAP with patients
Number of interviews/ focus groups/questionnaires completed
Intervention patients'/families' perspectives on SSNAP feasibility & acceptability
Consultation satisfaction for intervention & control patients/families
Number of eligible patients
Number of patients followed-up
Intervention staff perspectives on SSNAP feasibility & acceptability, including feasibility of data extraction and linkage

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size:	168
Total international sample size (including UK):	168
Total in European Economic Area:	168

Further details:
We anticipate 120 patients coded for SSNAP (60 per arm), giving a total of 120 patients. In addition, we plan to recruit 3 staff to interviews and 5 staff to focus groups in each of the 6 participating surgeries, giving a total of 48 staff, and a grand total of 168 participants.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

One hundred and twenty adult patients will be coded for SSNAP across the surgeries (60 per arm). Our rationale for 60 patients per arm is based on guidance on pilot studies for clinical trials, advice from GPs, who estimate they see two to four patients per week whom they might want to safety-net, and numbers of patients we require for follow-up interviews.

We anticipate a questionnaire response rate of 50% (intervention n=30; control n=30), allowing us to compare consultation satisfaction between patients in intervention and control arms. We anticipate half of intervention patients/carers who complete the questionnaire may agree to be interviewed (n=15).

We will conduct an average of three interviews per surgery across both arms with staff (clinicians, managers, administrators), reflecting variation in surgery size and numbers of staff involved in the study. We will also conduct a staff focus group in each surgery, comprising around five staff.

A61. Will participants be allocated to groups at random?

● Yes ○ No

If yes, please give details of the intended method of randomisation:
General practices will be randomised using block randomisation. This will ensure three practices each are allocated to intervention and control.

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

Analyses will be conducted on an intention-to-treat basis following a pre-specified statistical analysis plan. Participant flow will be presented using a CONSORT diagram. Numbers of sites recruited and reasons for sites declining to take part will be reported. The average number of patients recruited per site per month will be calculated. The proportion of participants for whom data was obtained during the data collection feasibility exercise will be presented. Numbers of patients eligible and numbers of times SSNAP was used will be summarised descriptively. In addition, outcome data on re-booking appointments; attending appointments; time to re-attend; number of re-attendances; number of referrals for diagnostic tests; variables relating to diagnosis of cancer; and patient consultation satisfaction will be summarised descriptively by randomised group. The number and proportion of patients for whom outcome data could be obtained will be summarised by randomised group. The intra-cluster correlation coefficient for each outcome will be estimated alongside a 95% confidence interval. Patient questionnaire data will be summarised descriptively by randomised group.

Qualitative data will be analysed thematically, paying attention to acceptability and feasibility components of the work. We will consider how SSNAP worked (including how it affected patients' understanding of safety-netting advice), under which circumstances and how it was adapted locally, with reference to the SSNAP logic model, programme theory and COM-B Framework. This will enable us to refine the SSNAP logic model and programme theory and determine if the intervention should progress to trial, in agreement with our trial steering committee.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co-applicants, protocol co-authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title	Forename/Initials	Surname
	Professor	Rebecca	Lawton

Post	Professor, Psychology of Healthcare (co-Chief Investigator)
Qualifications	PhD
Employer	Institute of Psychological Sciences, University of Leeds
Work Address	Bradford Institute for Health Research, Temple Bank House, BRI Duckworth Lane Bradford
Post Code	BD9 6RJ
Telephone	
Fax	
Mobile	
Work Email	R.J.Lawton@leeds.ac.uk

	Title	Forename/Initials	Surname
	Ms	Stella	Johnson

Post	Research Manager, West Yorkshire Research and Development
Qualifications	
Employer	NHS West Yorkshire Integrated Care Board
Work Address	Scorex House West 1 Bolton Road Bradford
Post Code	BD1 4AS
Telephone	
Fax	
Mobile	07980 905888
Work Email	stella.johnson@bradford.nhs.uk

	Title	Forename/Initials	Surname
	Dr	Claire	Friedemann-Smith

Post	Senior Researcher, Nuffield Department of Primary Care
Qualifications	
Employer	University of Oxford
Work Address	Radcliffe Primary Care Building, Radcliffe Observatory Quarter Woodstock Road Oxford
Post Code	OX2 6GG
Telephone	01865 289297
Fax	
Mobile	
Work Email	claire.friedemann@phc.ox.ac.uk

Title	Forename/Initials	Surname
Mr	Alex	Mitchell

Post	Research Fellow & Statistician, University of York Trials Unit, Department of Health Sciences
Qualifications	
Employer	University of York
Work Address	Seebohm Rowntree Building Heslington York
Post Code	YO10 5DD
Telephone	01904 321756
Fax	
Mobile	
Work Email	alex.mitchell@york.ac.uk

Title	Forename/Initials	Surname
Dr	Gemma	Louch

Post	Associate Professor in Applied Health and Care Research, School of Healthcare
Qualifications	
Employer	University of Leeds
Work Address	Worsley Building Leeds
Post Code	LS2 9JT
Telephone	0113 343 7173
Fax	
Mobile	
Work Email	G.E.Louch@leeds.ac.uk

Title	Forename/Initials	Surname
Dr	Elizabeth	Sweeting

Post	Clinical Leadership Fellow, Improvement Academy, Bradford Institute for Health Research (and General Practitioner)
Qualifications	
Employer	Bradford Teaching Hospitals NHS Foundation Trust
Work Address	Bradford Institute for Health Research Duckworth Lane Bradford
Post Code	BD9 6RJ

Telephone	
Fax	
Mobile	
Work Email	Elizabeth.Sweeting@yhia.nhs.uk

Title	Forename/Initials	Surname
Ms	Pam	Essler

Post	Lay Leader, Yorkshire Quality and Safety Research Group, Bradford Teaching Hospitals NHS Foundation Trust
Qualifications	
Employer	N/A (PPIE lead and co-applicant)
Work Address	Bradford Institute for Health Research Duckworth Lane Bradford
Post Code	BD9 6RJ
Telephone	
Fax	
Mobile	07787 552711
Work Email	essler.pam@gmail.com

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
● NHS or HSC care organisation
○ Academic
○ Pharmaceutical industry
○ Medical device industry
○ Local Authority
○ Other social care provider (including voluntary sector or private organisation)
○ Other

Commercial status: Non-Commercial

If Other, please specify:

Contact person

Name of organisation	Bradford Teaching Hospitals NHS Foundation Trust
Given name	Jane
Family name	Dennison
Address	Bradford Institute for Health Research
Town/city	Duckworth Lane
Post code	BD9 6RJ
Country	United Kingdom
Telephone	01274382575

Fax	
E-mail	jane.dennison@bthft.nhs.uk

Legal representative for clinical investigation of medical device (studies involving Northern Ireland only)
Clinical Investigations of Medical Devices that take place in Northern Ireland must have a legal representative of the sponsor that is based in Northern Ireland or the EU

Contact person

Name of organisation
Given name
Family name
Address
Town/city
Post code
Country
Telephone
Fax
E-mail

A65. Has external funding for the research been secured?

Please tick at least one check box.

☑ Funding secured from one or more funders
☐ External funding application to one or more funders in progress
☐ No application for external funding will be made

What type of research project is this?

● Standalone project
○ Project that is part of a programme grant
○ Project that is part of a Centre grant
○ Project that is part of a fellowship/ personal award/ research training award
○ Other

Other – please state:

Please give details of funding applications.

Organisation	National Institute for Health and Care Research
Address	NIHRCC, Grange House 15 Church Street Twickenham
Post Code	TW1 3NL
Telephone	020 8843 8000

Fax
Mobile
Email rfpb@nihr.ac.uk

Funding Application Status: ● Secured ○ In progress

Amount: £299,337.00

Duration
Years: 2
Months: 6

If applicable, please specify the programme/ funding stream:

What is the funding stream/ programme for this research project?
Research for Patient Benefit

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? *Please give details of subcontractors if applicable.*

○ Yes ● No

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

○ Yes ● No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

	Title	Forename/Initials	Surname
	Ms	Jane	Dennison

Organisation Bradford Teaching Hospitals NHS Foundation Trust
Address Bradford Institute for Health Research
Duckworth Lane
Bradford
Post Code BD9 6RJ
Work Email jane.dennison@bthft.nhs.uk
Telephone 01274382575
Fax
Mobile

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A68-2. Select the Regional Research Delivery Network for the NHS Organisation identified in A68-1:

Yorkshire and Humber

For more information, please refer to the question specific guidance.

A69-1. How long do you expect the study to last in the UK?

Planned start date: 03/11/2025
Planned end date: 30/04/2028
Total duration:
Years: 2 Months: 5 Days: 28

A71-1. Is this study?

○ Single centre
● Multicentre

A71-2. Where will the research take place? *(Tick as appropriate)*

☑ England
☐ Scotland
☐ Wales
☐ Northern Ireland
☐ Other countries in European Economic Area

Total UK sites in study 6

Does this trial involve countries outside the EU?
○ Yes ● No

A72. Which organisations in the UK will host the research?*Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

☐ NHS organisations in England	
☐ NHS organisations in Wales	
☐ NHS organisations in Scotland	
☐ HSC organisations in Northern Ireland	
☑ GP practices in England	6
☐ GP practices in Wales	
☐ GP practices in Scotland	
☐ GP practices in Northern Ireland	
☐ Joint health and social care agencies (eg community mental health teams)	
☐ Local authorities	
☐ Phase 1 trial units	
☐ Prison establishments	
☐ Probation areas	
☐ Independent (private or voluntary sector) organisations	
☐ Educational establishments	

☐ Independent research units

☐ Other (give details)

Total UK sites in study: 6

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

○ Yes ● No

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

The study may be monitored or audited in accordance with the approved protocol, GCP, relevant regulations and standard operating procedures.

A75-1. What arrangements will be made to review interim safety and efficacy data from the trial? Will a formal data monitoring committee or equivalent body be convened?

The Trial Steering Committee will review interim safety data about related and unexpected serious adverse events to determine patterns and trends of events, or to identify safety issues which would not be apparent on an individual case basis, consider trial continuation in light of safety concerns and take appropriate action to escalate issues of concern. It will feed back progress to the Sponsor. Owing to the low-risk nature of this feasibility trial, a Data Monitoring and Ethics Committee will not be convened.

If a formal DMC is to be convened, please forward details of the membership and standard operating procedures to the Research Ethics Committee when available. The REC should also be notified of DMC recommendations and receive summary reports of interim analyses.

A75-2. What are the criteria for electively stopping the trial or other research prematurely?

The criteria for stopping the trial prematurely will be judged by the Trial Steering Committee and could include a public health crisis such as a pandemic or an unacceptable level of related and unexpected serious adverse events. In such a case, the CI would notify the REC within 15 days and an end of study declaration form would be submitted. The CI would also inform the Sponsor.

A76. Insurance/ indemnity to meet potential legal liabilities

***Note:** in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland*

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

☑ NHS indemnity scheme will apply (NHS sponsors only)

☐ Other insurance or indemnity arrangements will apply (give details below)

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as* *applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

☑ NHS indemnity scheme will apply (protocol authors with NHS contracts only)

☑ Other insurance or indemnity arrangements will apply (give details below)

The study was designed by Dr Lynn McVey, a NHS member of staff covered by NHS indemnity, in collaboration with co-applicants from the universities of Leeds, York and Oxford. Thus, whilst NHS indemnity applies to the design of the study from the NHS sponsor perspective, the collaborating universities' indemnity schemes would also cover their employees who are protocol authors in the event of harm to participants from the design of the research. The universities' indemnity information is attached. (Ms Stella Johnson from the West Yorkshire ICB, Dr Elizabeth Sweeting, a NHS member of staff, and Ms Pam Essler, a lay leader associated with Bradford Teaching Hospitals NHS Foundation Trust have also advised on the design of the research, with NHS indemnity).

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

☑ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)

☐ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Participants will be recruited at NHS sites only.

Please enclose a copy of relevant documents.

A77. Has the sponsor(s) made arrangements for payment of compensation in the event of harm to the research participants where no legal liability arises?

○ Yes ● No

Please enclose a copy of relevant documents.

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

● Yes ○ No ○ Not sure

B. All research other than CTIMPs

In this sub-section, an adult means a person aged 16 or over.

B1. What impairing condition(s) will the participants have?

The study must be connected to this condition or its treatment.

Patients in this study will be experiencing non-specific symptoms which could be a sign of cancer (or not).

B2. Justify the inclusion of adults unable to consent for themselves. It should be clear why the research could not be carried out as effectively if confined to adults capable of giving consent.

In previous patient and public consultation and user needs work, it was made clear that safety-netting can present particular challenges for people living with dementia and other conditions that make them unable to consent for themselves. Such people and their family members/carers may struggle to remember or to follow clinicians' safety-netting advice and may find it difficult to ask questions/seek clarification about their care. The paper, icon-based version of SSNAP was co-designed with their needs in mind, with a view to supporting their engagement in safety-netting.

Therefore, we aim to offer the SSNAP intervention to such people, and, where possible, to ask any family members or informal carers who accompanied them in safety-netting consultations to take part in consultation satisfaction questionnaires and, in the intervention arm only, in interviews. We will provide such family members/carers with participant information sheets beforehand and will take their informed consent. We are NOT proposing to ask eligible adults unable to consent for themselves to take part in the consultation satisfaction questionnaires or the interviews. We propose to involve them only by receiving the SSNAP intervention in intervention surgeries or by being coded for SSNAP in control surgeries. As explained in A30-1, we do not propose to seek patient consent for either receiving the intervention or SSNAP coding, given that this feasibility study is a cluster RCT and SSNAP's low-risk nature. Extraction of anonymised patient data by Connected Bradford will be undertaken only for patients who have not opted-out of data sharing, according to the terms of surgeries' existing data sharing agreements with Connected Bradford.

B3. Who in the research team will decide whether or not the participants have the capacity to give consent? What training/experience will they have to enable them to reach this decision?

Surgery staff (rather than researchers) will invite patients to undertake consultation satisfaction questionnaires and will not send the invitation to any SSNAP-coded patients who, according to their patient records, do not have capacity. As noted in B11 below, it is possible – though unlikely- that a patient or family member/carer with capacity to give consent loses that capacity between agreeing to undertake an interview and being interviewed. In this case, the researcher offering the interview and taking consent would decide whether or not the patient continued to have capacity to give consent. Researchers will be trained and competent to take consent according to the principles of Good Clinical Practice (GCP) and the Declaration of Helsinki and will undertake Informed Consent: Including Adults Lacking Capacity NIHR e-learning.

B4. Does the research have the potential to benefit participants who are unable to consent for themselves?

● Yes ○ No

If Yes, please indicate the nature of this benefit. You may refer back to your answer to Question A24.

As noted in A24, patients in the intervention arm may benefit from increased involvement in, and understanding of, the safety-netting they've received from their general practice clinician, and active follow-up. Indeed, the paper, icon-based version of SSNAP was co-designed to be accessible for seldom-heard groups such as people with learning difficulties and cognitive impairments and to help them understand and engage with safety-netting advice.

B5. Will the research contribute to knowledge of the causes or the treatment or care of persons with the same impairing condition (or a similar condition)?

● Yes ○ No

If Yes, please explain how the research will achieve this:

The research is intended to contribute to the care of people with the impairing condition (non-specific symptoms which could be a sign of cancer), including people who are unable to consent for themselves. Our logic model (appended to the protocol) hypothesises how this will be done. For example, by providing a summary of the safety-netting discussions which specifies which symptoms to monitor, for how long, and in what circumstances patients should re-consult, SSNAP should: (1) reduce opportunities for misinterpretation (e.g. forgetting which symptoms to monitor or for how long) and (2) false reassurance (e.g. feeling that because the patient has seen a doctor, any further symptoms can be ignored); and (3) promote patient self-advocacy and empowerment (e.g. by encouraging patients to keep an eye on their own symptoms with reference to the SSNAP plan, and giving them psychological 'permission' to reconsult if symptoms do not resolve).

B6. Will the research involve any foreseeable risk or burden for these participants, or interfere in any way with their freedom of action or privacy?

○ Yes ● No

Questions B7 and B8 apply to any participants recruited in England and Wales.

B7. What arrangements will be made to identify and consult persons able to advise on the presumed wishes and feelings of participants unable to consent for themselves and on their inclusion in the research?

Adult patients who do not have capacity to decide on their own medical treatment will receive the SSNAP intervention as part of their routine care in intervention surgeries if a family member or informal carer accompanying them in the consultation agrees to receiving the SSNAP plan (as noted above, consent will not be sought for the SSNAP intervention itself in this cluster RCT). Patients who are unable to consent for themselves will not be involved in any other aspects of the research.

Please enclose a copy of the written information to be provided to consultees. This should describe their role under section 32 of the Mental Capacity Act and provide information about the research similar to that which might be given to participants able to consent for themselves.

B8. Is it possible that a participant requiring urgent treatment might need to be recruited into research before it is possible to identify and consult a person under B7?

○ Yes ● No

If Yes, say whether arrangements will be made instead to seek agreement from a registered medical practitioner and outline these arrangements. Or, if this is also not feasible, outline how decisions will be made on the inclusion of participants and what arrangements will be made to seek consent from the participant (if capacity has been recovered) or advice from a consultee as soon as practicable thereafter.

B9. What arrangements will be made to continue to consult such persons during the course of the research where necessary?

As consent is not being sought for the SSNAP intervention, there will be no need to continue to consult such persons during the course of the research, but where possible we will invite such persons to complete a consultation satisfaction questionnaire and, in the intervention arm, to attend an interview to share their perspectives on the SSNAP tool.

B10. What steps will you take, if appropriate, to provide participants who are unable to consent for themselves with information about the research, and to consider their wishes and feelings?

Where a family member or informal carer accompanies an adult patient who is unable to decide on their own medical treatment in a consultation and agrees to receiving the SSNAP plan, such agreement would take place following discussion between the family member or informal carer and the clinician, in the consultation, about safety-netting. Families/carers will consider the patient's wishes and feelings in so doing. We will not involve patients without capacity in any other aspect of the research.

B11. Is it possible that the capacity of participants could fluctuate during the research? How would this be handled?

Given the patient population, which is likely to include older people, is possible that patients (or their family members/carers) who initially have capacity to decide to complete a questionnaire lose that capacity before being invited to interview. We aim to minimise the opportunity for such an event by arranging interviews promptly but if, when contacting them, it becomes clear to the researcher that a the participant no longer has capacity, we will either not interview them or we will end the interview as quickly and sensitively as possible and withdraw them from the study. Any identifiable information they have provided (such as their contact details) will be withdrawn, but anonymised quantitative data will not be withdrawn, as we will not know which patient such information is associated with. See also A35.

B12-1. What will be the criteria for withdrawal of participants?

Patients will not be eligible to take part in questionnaires and interviews when such participation could cause distress or confusion, including patients without capacity to consent to the research (see A17-1). As stated in B11, patients who initially met these criteria but whose capacity fluctuates such that researchers become aware that they no longer have capacity will be withdrawn from the study.

B13. Describe what steps will be taken to ensure that nothing is done to which participants appear to object (unless it is to protect them from harm or minimise pain or discomfort).

The SSNAP plan documents safety-netting advice that would be given in the consultation verbally in any case, and provides a way for surgeries to follow-up patients after this advice has been received. As such, it is part of routine care, and surgeries' usual processes will be used to ensure that nothing is done to which patients appear to object, unless to protect them from harm or to minimise pain or discomfort. For example, clinicians will observe patients' responses to the discussion and check their understanding – indeed, SSNAP is specifically intended to promote patient-centred practice, encouraging patients and their family members to be involved in safety-netting discussions, ask questions if they don't understand and speak up if they disagree with anything. Importantly, the paper, icon-based version of SSNAP was co-designed to be accessible to people with different needs, such as people living with cognitive impairments or learning disabilities. We hypothesise that this version of the SSNAP plan will help patients who otherwise might struggle to understand safety-netting advice and, therefore, to express concerns to clinicians. We will explore whether this is indeed the case in the feasibility study. The need to engage patients and offer SSNAP accessibly will be emphasised in intervention staff training.

B14. Describe what steps will be taken to ensure that nothing is done which is contrary to any advance decision or statement by the participant?

Only the data of patients who have not opted out of data sharing will be made available to the research team by Connected Bradford. A SSNAP plan will only be provided for patients in intervention surgeries who do not have capacity to decide on their own treatment if they are accompanied in the consultation by an adult family member or informal caregiver who agrees on their behalf with the clinician that they should receive a plan as part of safety-netting. If they do not agree, the patient will not be included in the study but this will not affect their care, which will continue as normal. Family members/carers will know whether, by agreeing, they are doing anything contrary to any advance decision or statement by the participant. Patients without capacity to consent to treatment or research will not be involved in questionnaires or interviews.

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For further information please refer to guidance.*

Investigator identifier	Research site		Investigator Name
IN1	● NHS/HSC Site ○ Non-NHS/HSC Site		Forename Middle name Family name Email Qualification (MD...) Country
	Organisation name	Yorkshire and Humber RRDN	
	Address	ST. JAMES'S UNIVERSITY HOSPITAL BECKETT STREET LEEDS	
	Post Code	LS9 7TF	
	Country	ENGLAND	

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

2. I undertake to fulfil the responsibilities of the chief investigator for this study as set out in the UK Policy Framework for Health and Social Care Research.

3. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.

4. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.

5. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.

6. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.

7. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.

8. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.

9. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 2018.

10. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:

    - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
    - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
    - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
    - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
    - May be sent by email to REC members.

11. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 2018.

12. I understand that the main REC or its operational managers may share information in this application or supporting documentation with the Medicines and Healthcare products Regulatory Agency (MHRA) where it is relevant to the Agency’s statutory responsibilities.

13. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the Health Research Authority (HRA) together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after the issue of the ethics committee’s final opinion or the withdrawal of the application.

Contact point for publication*(Not applicable for R&D Forms)*

HRA would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

○ Chief Investigator

○ Sponsor

○ Study co-ordinator

○ Student

○ Other – please give details

○ None

Access to application for training purposes *(Not applicable for R&D Forms)*

Optional – please tick as appropriate:

☐ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by Dr Lynn McVey on 30/09/2025 14:36.

Job Title/Post:	Senior Research Fellow
Organisation:	Bradford Teaching Hospitals NHS Foundation Trust
Email:	lynn.mcvey@bthft.nhs.uk

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co−sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.
2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.
3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.
4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.
5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.
6. The responsibilities of sponsors set out in the UK Policy Framework for Health and Social Care Research will be fulfilled in relation to this research.

   Please note: *The declarations below do not form part of the application for approval above. They will not be considered by the Research Ethics Committee.*
7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.
8. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publically accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

This section was signed electronically by Jane Dennison on 30/09/2025 15:58.

Job Title/Post: Research Support & Governance Manager

Organisation: Bradford Teaching Hospitals NHS Foundation Trust

Email: jane.dennison@bthft.nhs.uk