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The Shared Safety Net Action Plan (SSNAP): Exploring the viability of a safety-netting tool in primary care that encourages partnership between patients and staff to support earlier diagnosis of cancer

Submission date	**Recruitment status**	[X] Prospectively registered
03/11/2025	Not yet recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/11/2025	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
04/11/2025	Cancer	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

When doctors aren't sure what's causing a patient's symptoms, they often use a process called "safety-netting." This means they ask patients to keep an eye on their symptoms and come back if things don't improve. It's especially important when symptoms could be an early sign of something serious, like cancer. But sometimes patients forget what they were told or aren't sure what to look out for.

This study is testing a new tool called the Shared Safety Net Action Plan (SSNAP). SSNAP helps patients understand what symptoms to monitor, how long to monitor them, and when to return to the doctor. It also helps GP practices follow up with patients. The aim is to see if SSNAP makes safety-netting clearer and more helpful for patients and staff.

Who can participate?

Adult patients who visit their GP with vague symptoms that might be linked to cancer—such as tiredness or unexplained weight loss—may be invited to take part. Their family members and GP staff may also be involved.

What does the study involve?

Patients and families will be asked to fill in questionnaires about their experience of the GP consultation. Some patients who use SSNAP will also be invited to talk to researchers about how it worked for them. GP staff will be interviewed about their experience using SSNAP. The study will also collect data on how often SSNAP is used and what impact it has.

What are the possible benefits and risks of participating?

Taking part may help patients feel more confident about managing their symptoms and knowing when to seek help. It could also improve communication between patients and their GP. There are no known risks to taking part, and participation is voluntary.

Where is the study run from?
Bradford Teaching Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
March 2025 to April 2028

Who is funding the study?
National Institute for Health and Care Research (NIHR).

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
345898

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 63265, NIHR208819

Study information

Scientific Title

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

Acronym
SSNAP

Study objectives
To assess:
1. Whether the delivery of SSNAP is feasible in general practice;
2. Whether SSNAP is acceptable to patients, their families and staff;
3. Whether patient recruitment and follow-up is feasible in general practice;
4a. What outcomes would demonstrate whether SSNAP successfully supports communication and shared decision-making around uncertainty;
4b. What outcomes would demonstrate SSNAP improves patients' clinical outcomes;
5. How surgeries adapt SSNAP for local use.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 07/10/2025, Leeds East REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8012; leedseast.rec@hra.nhs.uk), ref: 25/YH/0163

Study design
Interventional cluster randomized

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Cancer

Interventions
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.

Intervention Type
Behavioural

Primary outcome(s)
Diagnosis of cancer at any stage is measured using anonymised electronic health record data from SystmOne at the end of WP1 (months 5-6 of the study) and in WP3 (months 16-17)

Key secondary outcome(s))
1. Time to re-attend, anonymised data will be collected twice from SystmOne: at the end of WP1 (months 5–6 of the study) and in WP3 (months 16–17)
2. Referral(s) for follow-up diagnostic tests, anonymised data will be collected twice from SystmOne: at the end of WP1 (months 5–6 of the study) and in WP3 (months 16–17)
3. Number of re-attendances & DNAs over intervention period, anonymised data will be collected twice from SystmOne: at the end of WP1 (months 5–6 of the study) and in WP3 (months 16–17)
4. Number of patients re-booking appointments, anonymised data will be collected twice from SystmOne: at the end of WP1 (months 5–6 of the study) and in WP3 (months 16–17)
5. Number of occasions intervention used (intervention surgeries) or would be used (control surgeries), anonymised data will be collected twice from SystmOne: at the end of WP1 (months 5–6 of the study) and in WP3 (months 16–17)
6. Willingness of surgeries to be randomised, data collected during interviews and focus groups with participating staff during WP3 (months 16 and 17 of the study)
7. Willingness of staff to initiate SSNAP with patients, data collected during interviews and focus groups with participating staff during WP3 (months 16 and 17 of the study)
8. Number of interviews/ focus groups/questionnaires completed, to be determined when these have taken place, around month 21
9. Intervention patients'/families' perspectives on SSNAP feasibility & acceptability, collected in patient/carer questionnaires and interviews during WP2 and WP3 (months 8–17 of the study)
10. Consultation satisfaction for intervention & control patients/families, collected in patient /carer questionnaires and interviews during WP2 and WP3 (months 8–17 of the study)
11. Number of eligible patients, anonymised data will be collected twice from SystmOne: at the end of WP1 (months 5–6 of the study) and in WP3 (months 16–17)

12. Number of patients followed-up, anonymised data will be collected twice from SystmOne: at the end of WP1 (months 5–6 of the study) and in WP3 (months 16–17)
13. Intervention staff perspectives on SSNAP feasibility & acceptability, including feasibility of data extraction and linkage, data will be collected from staff in interviews and focus groups in WP3 (months 16–21 of the study)

Completion date
30/04/2028

Eligibility

Key inclusion criteria
Patient/carer inclusion criteria for intervention:
1. Patients aged 18 and over presenting with non-specific symptoms which could indicate cancer, who have capacity to decide on their own medical treatment.
2. 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).
3. Family members or informal carers aged 18 and over who accompany SSNAP-coded patients in consultations.

Patient/carer inclusion criteria for questionnaires:
1. Patients aged 18 or over in intervention surgeries who have received SSNAP or who were recorded as eligible to receive SSNAP in control surgeries.
2. 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:
1. Patients aged 18 or over in intervention surgeries who have received SSNAP.
2. 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)
1. All staff in participating surgeries with a safety-netting role (clinical, management/ administrative).

Participant type(s)
Carer, Health professional, Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Patients/carer exclusion criteria for intervention:
1. Young people and children aged under 18 years.
2. 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.
3. Patients who have opted out of data sharing.

Patient/carer exclusion criteria for questionnaires & interviews:
1. 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).
2. Patients, family members/informal carers aged less than 18 years.
3. 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:
1. Staff not involved in safety-netting processes.

Date of first enrolment
02/03/2026

Date of final enrolment
31/07/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Yorkshire and Humber RRDN
St. James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
Bradford Teaching Hospitals NHS Foundation Trust

ROR
https://ror.org/05gekvn04

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Connected Bradford cbradford@bthft.nhs.uk; type of data are shared linked primary care and secondary care data; data will become available for 10 years or the length of the CB programme; researchers complete a data access application and this is reviewed by the programme manager and considered by Connected Bradford Board; current CB data access process, data are fully anonymised, Connected Bradford REC ref: 22/EM/0127. Qualitative datasets are available on request from Dr Lynn McVey, contact details above. Anonymised data may be shared from interviews and focus groups for qualitative analysis for a maximum of 5 years; participant consent obtained; SSNAP REC ref: 25/YH/0163.

IPD sharing plan summary
Available on request