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CANAssess 2: managing cancer patients' needs in GP Surgeries through the use of a Needs Assessment Tool (NAT-C)

Submission date
09/03/2020

Recruitment status
No longer recruiting

Registration date
07/04/2020

Overall study status
Completed

Last Edited
23/10/2025

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-managing-the-needs-of-people-with-cancer-canassess2

Background and study aims
Many people with cancer experience a wide range of symptoms and problems across all areas of life. Studies suggest that these symptoms are common but are often not known about or managed by the doctors and nurses caring for them.
The Needs Assessment Tool-Cancer (NAT-C) has been developed for use by doctors or other clinicians in GP Surgeries to identify and address any concerning symptoms and unmet needs of their cancer patients. We will test whether regular use of this tool improves patient care.

Who can participate?
Adults with cancer registered at a GP Surgery taking part in the trial. Surgeries will identify suitable participants through medical records and send a letter/text inviting them to take part. In this letter/text, we invite patients to nominate a relative/friend who cares for them to also take part. Clinicians at intervention Surgeries and key stakeholders can take part in the sub-study (process evaluation).

What does the study involve?
Researchers will visit participants in their home or at their GP surgery and ask them to complete a questionnaire about their level of need (patient) or caring situation (carer). All participants will be asked to complete the same questionnaire one month and three months later, and some will also be asked 6 months later. All participants are offered support by a researcher in completing these. Where face-to-face visits are not possible, researchers will call patients and ask them to complete a questionnaire over the phone/via video call. Phone/video calls are not recorded.
In this study, half of the GP Surgeries taking part will use a needs assessment tool (NAT-C). If patients are registered at one of these surgeries, they will be asked to attend a NAT-C guided appointment. This appointment will be arranged remotely where face-to-face is not possible.

In the sub-study, clinicians and key stakeholders will be asked to participate in surveys and interviews about their opinions and experiences of using the NAT-C needs assessment tool (intervention).

What are the possible benefits and risks of participating?
This study could improve the quality of life of people with cancer, but the researchers cannot say that they will definitely experience an improvement. If a patient's GP Surgery is in the intervention group, they may benefit from having a guided appointment.
There are no known risks of participating in this study. Participants agreeing to complete questionnaires will be giving up some of their time to do this.

Where is the study run from?
54 GP Surgeries across Yorkshire and Tyne and Wear.

When is the study starting and how long is it expected to run for?
July 2019 to January 2024

Who is funding the study?
Yorkshire Cancer Research (UK)

Who is the main contact?
Ms Emma McNaught (public), CANASSESS@leeds.ac.uk
Prof. Miriam Johnson (scientific), miriam.johnson@hyms.ac.uk

Contact information

Type(s)
Scientific

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
270012

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 44992, IRAS 270012

Study information

Scientific Title
CANAssess 2: Cancer Patients' Needs Assessment in Primary Care – A Cluster Randomised Controlled Trial

Acronym
CANAssess 2

Study objectives
The Needs Assessment Tool-Cancer (NAT-C) used by clinicians in Surgeries with their cancer patients will address patient unmet need resulting in a better quality of life, compared to usual care

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/04/2020, London - Surrey Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 1048129; nrescommittee.secoast-surrey@nhs.net), ref: 20/LO/0312

Study design
Complex intervention cluster randomized controlled trial including sub-study

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Neoplasms of uncertain or unknown behaviour

Interventions
Current interventions as of 01/03/2022:
The CANAssess study is a cluster-randomised controlled trial, where the whole GP surgery (cluster) will be randomised to receive either the intervention or usual care. GP Surgeries will deliver either the intervention or usual care, according to their randomisation, to all patients they recruit onto the trial. The researchers cannot accurately predict what happens as part of usual care to be able to determine the effects of the intervention, which is why the researchers have a control group to also evaluate.

The researchers aim to recruit 1080 adult patients diagnosed with active cancer more than one month ago, and their friends/relatives who provide them with support. Eligible patients at 54 GP surgeries will be sent an invitation letter/text message introducing them to the study, with the Participant Information Sheet, the Carer Information Sheet, and a reply form enclosed/available to view on the CANAssess website. Patients are encouraged to return the reply form, using the pre-paid envelope provided, indicating whether they would like to take part or not, or, to express their interest on the CANAssess website. Patients who are willing to take part will then be contacted by a researcher to arrange a visit at the patient's home or at the surgery, or to arrange a phone/video call where face-to-face is not possible.

Eligible patients can also be approached about the study by their GP/nurse in clinic. Their GP /nurse will ask the patient if a researcher can contact them with further information about the trial. If they agree, they will be given the Participant Information Sheet and Carer Information Sheet to read, and a researcher will contact them to discuss and arrange a visit or phone/video call, if happy to do so.

During the visit or phone/video call, the researcher will screen the patient/patient and their carer to confirm they are eligible to take part. If eligible, the researcher will gain informed consent and collect general demographics from the patient/patient and their carer. Consent is for data collection only. Patient consent includes access to their data through medical records. Where consent is collected over the phone the researcher will read the statements to the patient and sign on their behalf, a copy of the patient's completed consent form will then be sent to the patient. Patients will be asked to complete a questionnaire about their level of need, and carers will be asked to complete a questionnaire about their caring situation. Cancer demographics and co-morbidities will also be collected for the patient via medical records.

Patients registered at GP Surgeries allocated to the intervention will be invited to attend an appointment with their GP/nurse. The NAT-C needs assessment tool, the intervention, will guide this appointment with the patient. This will last approximately 20 minutes and can take place at the surgery or at the patient's home. Where face-to-face appointments are not possible, the appointment will take place as per practice procedures for remote consultations. Patients registered at GP surgeries allocated to usual care will receive care as normal and will not be asked to attend the appointment.

All participants, patients and carers, will be asked to complete the same questionnaire completed at the visit/phone call at 1 month and 3 months post-registration. Some participants

will also be asked to complete the questionnaire again at 6 months post-registration. This is so the researchers can determine any changes over the 6-month period. Each time a patient receives a questionnaire, a researcher will phone them to ask a few further questions about their physical ability. All participants will be given the opportunity for support by a researcher in the completion of questionnaires, either face-to-face or over the phone.

A sub-study will take place alongside the main study to determine clinician and key stakeholders' views of using the intervention in GP surgeries. Clinicians at GP surgeries randomised to the intervention will be asked to complete two surveys, one at the intervention training session and one at the end of the trial. Completion of the survey will be understood as implied consent. At the end of the training session, clinicians will be asked for permission to be contacted to participate in interviews. Informed consent will be taken prior to the interview. Key stakeholders will be approached by email to take part in the surveys and interviews, and informed consent will also be taken prior to the interview. A sample of 15-20 clinicians and 15-20 key stakeholders will be interviewed. Should the trial be positive, a plan will be developed for implementing the intervention in GP Surgeries across the UK.

Previous interventions:
The CANAssess study is a cluster-randomised controlled trial, where the whole GP surgery (cluster) will be randomised to receive either the intervention or usual care. GP Surgeries will deliver either the intervention or usual care, according to their randomisation, to all patients they recruit onto the trial. The researchers cannot accurately predict what happens as part of usual care to be able to determine the effects of the intervention, which is why the researchers have a control group to also evaluate.

The researchers aim to recruit 1080 adult patients diagnosed with active cancer more than one month ago, and their friends/relatives who provide them with support. Eligible patients at 54 GP surgeries will be sent an invitation letter introducing them to the study, with the Participant Information Sheet, the Carer Information Sheet, and a reply form enclosed. Patients are encouraged to return the reply form, using the pre-paid envelope provided, indicating whether they would like to take part or not. Patients who are willing to take part will then be contacted by a researcher to arrange a visit at the patient's home or at the surgery.

Eligible patients can also be approached about the study by their GP/nurse in clinic. Their GP /nurse will ask the patient if a researcher can contact them with further information about the trial. If they agree, they will be given the Participant Information Sheet and Carer Information Sheet to read, and a researcher will contact them to discuss and arrange a visit, if happy to do so.

At the visit, the researcher will screen the patient/patient and their carer to confirm they are eligible to take part. If eligible, the researcher will gain written informed consent and collect general demographics from the patient/patient and their carer. Consent is for data collection only. Patient consent includes access to their data through medical records. Patients will be asked to complete a questionnaire about their level of need, and carers will be asked to complete a questionnaire about their caring situation. Cancer demographics and co-morbidities will also be collected for the patient via medical records.

Patients registered at GP surgeries allocated to the intervention will be invited to attend an appointment with their GP/nurse. The NAT-C needs assessment tool, the intervention, will guide this appointment with the patient. This will last approximately 20 minutes and can take place at the Surgery or at the patient's home. Patients registered at GP surgeries allocated to usual care will receive care as normal and will not be asked to attend the appointment.

All participants, patients and carers, will be asked to complete the same questionnaire completed at the visit at 1 month and 3 months post-registration. Some participants will also be asked to complete the questionnaire again at 6 months post-registration. This is so the researchers can determine any changes over the 6-month period. Each time a patient receives a questionnaire, a researcher will phone them to ask a few further questions about their physical ability. All participants will be given the opportunity for support by a researcher in the completion of questionnaires, either face-to-face or over the phone.

A sub-study will take place alongside the main study to determine clinician and key stakeholders' views of using the intervention in GP surgeries. Clinicians at GP Surgeries randomised to the intervention will be asked to complete two surveys, one at the intervention training session and one at the end of the trial. Completion of the survey will be understood as implied consent. At the end of the training session, clinicians will be asked for permission to be contacted to participate in interviews. Informed consent will be taken prior to the interview. Key stakeholders will be approached by letter to take part in the surveys and interviews, and informed consent will also be taken prior to the interview. A sample of 15-20 clinicians and 15-20 key stakeholders will be interviewed. Should the trial be positive, a plan will be developed for implementing the intervention in GP surgeries across the UK.

Intervention Type
Other

Primary outcome(s)
Unmet need identified in any domain in the Supportive Care Needs Survey Short Form 34 (SCNS-SF34) at 3 months post-registration

Key secondary outcome(s))
Assessed at 1, 3 and 6 months post-registration, except for intervention uptake which is assessed at 3 months.
Effectiveness of the NAT-C compared to usual care with regard to:
1. The individual components of the primary endpoint, namely the proportion of patients with unmet need, and level of unmet need, on psychological, health system information, physical and daily activity, patient care and support, and sexuality domains, and overall on the SCNS-SF34 at 1, 3 and 6 months
2. Patient performance status, measured using the Australian-modified Karnofsky Performance Status (AKPS)
3. Patient severity of symptoms, measured using the Edmonton Symptom Assessment System (ESAS-r)
4. Patient mood and quality of life as measured by the EORTC QLQ-C15-PAL
5. Service utilisation and cost-effectiveness assessed using a bespoke Resource Use Questionnaire, the EQ-5D-5L and ICECAP-SCM
6. Caregivers' ability to care and caregiver wellbeing as measured using the Carer Experience Survey (CES) and Zarit Burden Interview (ZBI-12).
7. Evaluate intervention delivery, uptake and fidelity of the NAT-C as measured by:
7.1. NAT-C training of GPs and nurses in each GP Surgery
7.2. Completed NAT-C consultations by patient and GP Surgery
7.3. Length of NAT-C consultations; and actions taken to meet identified unmet need (including referrals to health professionals and/or services) from the completed NAT-C

Completion date
19/01/2024

Eligibility

Key inclusion criteria
GENERAL PRACTICES:
1. Willing to be trained and to offer and use the NAT-C, if so allocated, for all recruited patients
2. Willing to commit to trial procedures:
2.1. Supporting screening and inviting patients to participate
2.2. Allowing researchers access to the GP surgery to support the study
3. Capacity to recruit approximately 20 patients
4. Written informed consent provided by practice manager or deputy

PATIENTS:
1. Adults (aged 18 years and above)
2. Diagnosis of active cancer (receiving anti-cancer treatment both with curative or palliative intent; managed with “watch and wait”; recurrent or metastatic; or inoperable) Note: anti-cancer treatment includes any treatment designed to modify the growth of the cancer, such as chemotherapy, immunotherapy, hormone therapy, radiotherapy, or surgery
3. Willing and able to complete questionnaires at the trial follow-up schedule (able to complete trial measures
4. Provision of written or observed verbal informed consent.
5. Sufficient knowledge of the English language to provide informed consent and complete trial questionnaires. The use of an appropriate translator/interpreter is allowed

CARERS:
1. Adults (aged 18 years and above)
2. Nominated by the patient
3. Able to complete trial measures
4. Written or observed verbal informed consent
5. Sufficient knowledge of the English language to provide informed consent and complete trial questionnaires. The use of an appropriate translator/interpreter is allowed

PROCESS EVALUATION - CLINICIANS:
1. Any clinician who has received NAT-C training (survey 1)
2. Any clinician who has delivered the NAT-C intervention (survey 2)
3. Any clinician who has received NAT-C training and/or delivered the NAT-C intervention (interview)

PROCESS EVALUATION - OTHER GP STAFF:
1. Practice management and administrative staff in participating intervention practices

PROCESS EVALUATION - KEY STAKEHOLDERS:
1. Identified by the research team or clinical experts as having a key role in health policy and commissioning, relevant to cancer care in primary care

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Sex
All

Total final enrolment
788

Key exclusion criteria
Current exclusion criteria as of 01/03/2022:
GP surgeries that do not meet the inclusion criteria will be excluded

PATIENTS:
1. In complete remission (no clinical or radiological evidence of cancer, and at least one-month post anti-cancer treatments)
2. With basal cell carcinoma only
3. Living in a care home or other institutional setting
4. Within 1 month of receiving their initial cancer diagnosis

CARERS:
1. Employed to look after the patient

PROCESS EVALUATION - CLINICIANS:
1. Clinicians on the Usual Care arm of the study

PROCESS EVALUATION - OTHER GP STAFF:
1. Practice management and administrative staff on the Usual Care arm of the study

Previous exclusion criteria:
GENERAL PRACTICES:
1. Locum GPs who work across general practices and registrars due to leave the practice before the end of the trial will be excluded to avoid potential contamination
2. GP surgeries with existing or planned (within the recruitment period of the trial) systematic implementation of cancer care review services/holistic needs assessments, which have the potential to significantly overlap with the NAT-C (as determined by the CI & GP hub leads), will be excluded.

PATIENTS:
1. In complete remission (no clinical or radiological evidence of cancer, and at least 1-month post anti-cancer treatments)
2. With basal cell carcinoma
3. Living in a care home or other institutional setting
4. Within 1 month of receiving their initial cancer diagnosis

CARERS:
1. Paid carers

PROCESS EVALUATION - CLINICIANS:
1. Clinicians on the Usual Care arm of the study

PROCESS EVALUATION - OTHER GP STAFF:
1. Practice management and administrative staff on the Usual Care arm of the study

Date of first enrolment
21/10/2020

Date of final enrolment
31/08/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Leeds
Clinical Trials Research Unit
Leeds Institute of Clinical Trials Research
Woodhouse Lane
Leeds
United Kingdom
LS2 9JT

Sponsor information

Organisation
University of Hull

ROR
https://ror.org/04nkhwh30

Funder(s)

Funder type
Charity

Funder Name

Yorkshire Cancer Research; Grant Codes: H423

Alternative Name(s)
YCR

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Current individual participant data (IPD) sharing statement as of 01/07/2022:
De-identified individual participant data datasets generated and/or analysed during the current study will be available upon request from the Clinical Trials Research Unit, University of Leeds (contact CTRU-DataAccess@leeds.ac.uk in the first instance). Data will be made available at the end of the trial, i.e. usually when all primary and secondary endpoints have been met and all key analyses are complete. Data will remain available from then on for as long as CTRU retains the data.
CTRU makes data available by a 'controlled access' approach. Data will only be released for legitimate secondary research purposes, where the Chief Investigator, Sponsor and CTRU agree that the proposed use has scientific value and will be carried out to a high standard (in terms of scientific rigour and information governance and security), and that there are resources available to satisfy the request. Data will only be released in line with participants' consent, all applicable laws relating to data protection and confidentiality, and any contractual obligations to which the CTRU is subject. No individual participant data will be released before an appropriate agreement is in place setting out the conditions of release. The agreement will govern data retention, usually stipulating that data recipients must delete their copy of the released data at the end of the planned project.
The CTRU encourages a collaborative approach to data sharing, and believe it is best practice for researchers who generated datasets to be involved in subsequent uses of those datasets. Recipients of trial data for secondary research will also receive data dictionaries, copies of key trial documents and any other information required to understand and reuse the released datasets.
The conditions of release for aggregate data may differ from those applying to individual participant data. Requests for aggregate data should also be sent to the above email address to discuss and agree suitable requirements for release.

Previous individual participant data (IPD) sharing statement:
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. CTRU-DataAccess@leeds.ac.uk. Data will be shared according to a controlled-access approach. Data will only be shared for participants who

have given consent to use of their data for secondary research. Requests will be reviewed by relevant stakeholders. No data will be released before an appropriate agreement is in place setting out the conditions of release.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/10/2025	23/10/2025	Yes	No
Protocol article		04/05/2022	05/05/2022	Yes	No
Basic results		16/01/2025	16/01/2025	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			22/10/2025	No	Yes