

**Research Information Sheet for Practices**

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| **Study Title:** | Cancer Patients Needs Assessment in Primary Care funded by Yorkshire Cancer Research (CANAssess) |
| **NIHR Portfolio Ref:**  **IRAS ID:** | 44992  270012 |
| **Sponsor:** | University of Hull |
| **Funder:** | Yorkshire Cancer Research |
| **Chief Investigator:** | Prof Miriam Johnson  Wolfson Palliative Care Centre  University of Hull  Email: [miriam.johnson@hyms.ac.uk](mailto:miriam.johnson@hyms.ac.uk) |
| **Research Team Contact:** | Emma McNaught  Study Coordinator  Email: [CANASSESS@leeds.ac.uk](mailto:CANASSESS@leeds.ac.uk) |
| **Study Design:** | Two-Armed Cluster Randomised Controlled Trial (cRCT) with embedded process evaluation and cost effectiveness evaluation |
| **Study Aim and Objectives (refer to protocol for full details):** | To test the effectiveness of the Needs Assessment Tool: Cancer (NAT-C) in primary care for people with active cancer with regard to unmet patient and caregiver need.  We aim to improve the lives of people with cancer living in Yorkshire and Tyne and Wear by using the NAT-C in primary care. If effective, the NAT-C will help primary care clinicians identify the needs of people with cancer, allowing referral to the appropriate specialist to reduce the unmet needs. |
| **Practice Recruitment:** | CANAssess will recruit from 4 regional hubs: Hull and East/North Yorkshire (Hull); Leeds and West Yorkshire (Leeds); Sheffield and South Yorkshire (Sheffield); Tyne and Wear.  54 General Practices will be recruited across the four recruitment hubs. |
| **Practice Eligibility:** | Inclusion:   * Willing to be trained and to offer and use the NAT-C, if so allocated, for all recruited patients * Willing to commit to trial procedures   + Supporting screening and inviting patients to participate   + Allowing researchers access to the GP Surgery to support the study * Capacity to recruit approximately 20 patients * Written informed consent provided by practice manager or deputy   Exclusion:   * GP Surgeries who routinely repeat cancer care reviews/holistic needs assessments using a structured template (as determined by the CI & GP hub leads). |
| **Practice Randomisation:** | Practices are randomised on a 1:1 basis to either NAT-C intervention or control.  **Intervention:**  Clinicians and other practice staff will receive training in the Needs Assessment Tool: Cancer (NAT-C). NAT-C is a generic one-page tool to assess palliative care needs across a broad range of domains and comprehensive framework in order to identify and address unmet patient need. The NAT-C can be delivered in a 20 minute consultation and can help reduce late referrals for palliative care for people with cancer, and improve referrals where there are physical, psychological, social and spiritual problems.  Templates can be embedded into electronic systems, or used as a paper copy then scanned into the patient record. Registered patients will be invited to attend a NAT-C guided consultation with a trained clinician/nurse. Action as a result of the consultation will be according to the individual clinician’s or nurse judgement and patient/caregiver’s agreement.  **Control:**  Usual care is defined as the management normally provided for patients with cancer registered at the GP Surgery concerned in accordance with the General Medical Services contract. Management includes: i) consultation with or without physical examination to identify “the need for treatment or further investigation”, ii) making available such treatment or further investigation, including the referral of the patient to other services, iii) liaison with other health care professionals involved in the patient’s treatment and care, and iv) enacting usual end-of-life care protocols. |
| **Participant Recruitment:** | Each General Practice will aim to recruit around 20 patients over a period of up to 12 months. Each patient will be followed up for a period of 6 months, with the primary endpoint at 3 months.  The trial will include a total of 1080 patients, and their carers. Participant recruitment at all practices will take place between October 2020 and June 2022, with the follow-up period complete at the end of September 2022. |
| **Practice Activities:** | * Complete training in study procedures. * Run searches on the cancer registry for adults aged 18 and over diagnosed with cancer within the last 5 years. * Review clinical eligibility of patients. *Clinician only* * Mail out to potential patients. This mail out includes an invitation letter, PIS, Carer Information Sheet, reply slip, and pre-paid envelope. Chase patients who do not respond a maximum of 2 times within a pre-specified timeframe. * Allow research nurse\*/researcher to access your practice to support the study.   *If allocated to the intervention*:   * Provide at least 2 clinicians (if the practice has medical practitioners, at least one clinician should be a doctor) involved in the care of cancer patients who will be expected to complete intervention training. Face-to-face or remote interactive intervention training will last approx. 1 hour 30 minutes; the online version of the training will last 45 minutes. * Arrange 20-minute NAT-C appointment with each study-registered patient, or a home visit if clinically necessary. * Conduct NAT-C–guided assessment with each registered patient. *Trained clinician only* * Clinicians who perform the intervention may be invited to take part in surveys and interviews to discuss their experiences of using the intervention. |
| **Per-Participant Research Activities:** | Individual patient research activity support in practices from the Leeds, Sheffield and Tyne and Wear regions will be provided by a CANAssess trial research nurse\*. |
| **Costs:** | The research nurse\* will receive travel costs to the patient’s home, or the patient’s practice (if they choose to travel to meet the nurse at the practice). This will come out of the budget managed by the hub.  All other tasks related to specific participants will be paid for on a per participant recruited basis recognising that the levels of patient contact are unpredictable. Some participants will need more contact, and others will need none, therefore an average payment has been estimated.  Practices will receive:  **Service Support Costs (paid via the Clinical Research Network):** £460.80 single payment for database search, screening and clinical eligibility check, plus £9 per patient for consent.  **Research Costs (paid via the research grant):**  £116.10 single practice payment for attending training in trial procedures and chasing response to mail outs, plus £70 per participant payment for room space.  ***All Intervention practices:*** additional £212.40 single payment for training in the research methods.  **Excess Treatment Costs:**  ***All intervention practices:*** £58.55 per participant for intervention-related activities (training, set-up of infrastructure, arranging the intervention and delivering the intervention).  Please refer to Table 1 for a detailed breakdown of payments. |
| **Patient Eligibility Criteria:** | Inclusion:   * Adults (aged 18 years and above); * 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; * Willing and able to complete questionnaires at the trial follow-up schedule (able to complete trial measures); * Provision of written or observed verbal informed consent; and * Sufficient knowledge of the English language to provide informed consent and complete trial questionnaires. The use of an appropriate translator/interpreter is allowed.   Exclusion:   * Patients in complete remission (no clinical or radiological evidence of cancer, and at least one month post anti-cancer treatments); * Patients with basal cell carcinoma only; * Patients living in a care home or other institutional setting; * Within one month of receiving their initial cancer diagnosis. |
| **Practice Steps for Opening to Recruitment** | Review of Documents and Confirmation of Capacity and Capability  **+**  Signing of Contracts + Consent  **+**  Number of patients returned on search given to CTRU  Cluster Randomisation to Usual Care or Intervention  Training and Essential Documents  Eligibility Questionnaire Completion  EOI Returned  Open to Recruitment |
| **COVID-19 Impact** | This study can be fully delivered in a remote environment following the COVID-19 pandemic. Practices may send an SMS text message to invite patients to participate; the patient baseline discussion, including consent and data collection, may be performed over the phone/via video chat; and, the intervention appointment can be delivered with participants over the phone/via video chat. |

**Table 1: Payments**

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|  |  |  | **Person Responsible** | | | | | **Payment** | | |
| Task | Trial Arm | Time (Mins) | GP | Practice Nurse | Practice Manager | Admin | Research Nurse\* | Type | Amount | Single Payment/ Per Participant |
| ***General Activities*** | | | | | | | | | | |
| Study Training in Trial Procedures | Both | 30 | X | X | X |  |  | Research | £80.10 | Single Payment |
| NPT Study (\*Part of 1 hour intervention training) | NAT-C | 60 | Min. 2 | X |  |  |  | Research | £212.40 | Single Payment |
| Performing the search on the cancer registry (database search) | Both | 180 |  | X |  | \* |  | Service | £108 | Single Payment |
| Clinical eligibility check | Both | 60 | X |  |  |  |  | Service | £88.20 | Single Payment |
| Opportunistic Screening | Both | 180 | X | X |  |  |  | Service | £264.60 | Single Payment |
| Mail out to potential participants and chasing responses | Both | 180 |  |  | X | X |  | Research | £36 | Single Payment |
| ***Per Participant Activities*** | | | | | | | | | | |
| Informed consent | Both | 15 |  |  |  |  | X | Service | £9 | Per Participant |
| ***Other*** | | | | | | | | | | |
| Room space for research nurse\*/ trial activity | Both | - |  |  |  |  | X | Research | £70 | Per Participant |

**Excess Treatment Cost: intervention activity (training, arranging and performing intervention) - £58.55**

\*Some tasks listed above may also be completed by another staff member, as indicated by the asterisks (\*).

Please note: postal costs incurred by the study will be covered by the hub budget and will be reimbursed to the practice.

**Further Details on Costs:**

A new system to access Excess Treatment Costs (ETCs) was implemented in October 2018. Although the NHS treatment costs are paid by NHS England, the Clinical Research Network (CRN) facilitate payments of ETCs direct to the general practice. Payments no longer go through CCGs.

NHS Service Support Costs will be paid directly from the Clinical Research Network, quarterly in arrears, based on the activity (accrual of participant or database search/mail out). The Clinical Trials Research Unit (CTRU) at the University of Leeds will be the key contact with the Study Support Service at the CRN, to ensure activity is accurately recorded.

Research costs will be paid direct from the sponsor, via the CTRU, quarterly in arears, based on activity.

**Frequently Asked Questions**

**Why have we been invited to participate?**

This research study is taking place in Yorkshire and Tyne and Wear. We want to ensure that each practice is offered equal opportunity to take part in this trial.

**Do we have to take part?**

No. You do not have to take part in this study and you do not have to provide us with a reason for non-participation if you do not wish to do so. If you do agree to take part, you can withdraw at any time.

**If I want to, will I definitely be able to take part?**

Unfortunately, no. If, upon review of your EOI form, we decide that you use a needs assessment template above what we define to be usual care, you would be ineligible to take part. This is also the case if you are taking part in any initiatives which have similar components to our intervention. This is because we would not be able to accurately determine the effects of our intervention if you were to take part.

**What are the possible benefits and risks of taking part?**

We do not foresee any risks to taking part in this trial. Benefits of taking part include:

* Research Nurse\* support;
* Practice Nurse can act as Principal Investigator;
* CANAssess can be delivered alongside other current cancer trials;
* The study is not limited to patients within 12 months of diagnosis, but a NAT-C assessment of a patient within 12 months of cancer diagnosis will count for the Quality Outcomes Framework cancer review target (CAN004);
* Q1003 compliance;
* Practices will be trained in the intervention, and control practices will receive priority training in the intervention if the trial results show to be effective;
* GPs and nurses trained in the intervention will be given a certificate for use in their revalidation appraisal;and
* The intervention is easily uploaded onto EMIS and SystmOne.

**Will the information be confidential?**

Yes, all information will be stored at the University of Leeds and the University of Hull and will be kept confidential.

**What will happen to the results of this research?**

We will distribute the results of the research study to all general practices who take part. You will not be able to identify individual practices from the results. We will also present at clinical and research conferences, publish findings in peer reviewed journals, and disseminate executive summaries to policy and public influencers.

**Who is organising the research?**

Our team includes experienced researchers from the University of Leeds and the University of Hull, GPs, health economists, and patient representatives, who all contribute to the research. The chief investigator is Prof. Miriam Johnson, Professor of Palliative Medicine at the University of Hull.

**How much could our practice receive for taking part?**

**Trial Set-up and screening:**

*Control Practices:* £576.90

*Intervention Practices:* £789.30

**Per-patient recruited:**

*All practices:*

*Control Practice: £79.00*

*Intervention Practice: £137.55*

**What if we need further information?**

Please contact Emma McNaught, CANAssess Senior Trial Coordinator on:

Email: CANASSESS@Leeds.ac.uk, Tel. 0113 343 1978