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**Dear Colleagues,**

**We would like to invite you to participate in this Clinical Research Study.**

**Study Title:**

CANAssess: CAncer Patients’ Needs ASSESSment in Primary Care, a cluster randomised controlled trial funded by Yorkshire Cancer Research

For more information **see attached information sheet and PIS.**

**Study Number**

CPMS: 44992

IRAS: 270012

**Commercial/ Non-Commercial**

Non-Commercial

**Expected Start Date & Closure Date**

Start Date: October 2020

Expected Closing Date: September 2022

**Study Target**

National Target: 1080

Site Target: capacity to recruit around 20 patients

**Funder, Sponsor and Chief Investigator**

Funder: Yorkshire Cancer Research

Sponsor: University of Hull

Chief Investigator: Professor Miriam Johnson, Professor of Palliative Medicine, Wolfson Palliative Care Centre, University of Hull

*Please note: Research Nurse\* could be a CANAssess Research Nurse, Research Assistant, or Clinical Studies Officer*

**Benefits of Taking Part**

* 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 6 months of diagnosis, but a NAT-C assessment of a patient within 6 months of cancer diagnosis will count for the Quality Outcomes Framework cancer review target;
* 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.

**Practice Involvement**

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.

**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\*. Practices in the Hull regions will receive payment for research activity which may be provided by research nurses\* already in post or practice nurses identified and trained for this purpose.** Practices are randomised on a 1:1 basis to either NAT-C intervention or usual care.

All Practices:

* 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 participants. *Clinician only*
* Mail out to potential participants. 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 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.

**What patients need to do:**

* Complete a questionnaire at the baseline visit with the research nurse\*.
* Complete the same questionnaire a further 3 times at 1, 3 and 6 months post-registration. These will be mainly through the post however patients will be offered support in completing these over the phone or face-to-face with a research nurse\*.
* If registered with an intervention-allocated practice, attend a 20-minute NAT-C appointment with a trained clinician.

**Practice Payment**

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 the attached RISP for a detailed breakdown of payments.

**FURTHER INFORMATION**

Trial Coordinator: Emma McNaught

Tel: 0113 343 1978

Email: CANASSESS@leeds.ac.uk

**General Practice Details**

Please answer the questions below for us to determine your eligibility for this trial.

|  |  |
| --- | --- |
| Practice name/stamp: |  |
| Research lead/key contact for this study | Name | Click or tap here to enter text. |
| Role | Click or tap here to enter text. |
| Email | Click or tap here to enter text. |
| Tel. | Click or tap here to enter text. |
| Electronic Health Record system: | SystmOne[ ]  | EMIS[ ]  | Vision[ ]  | Other[ ] Please specify: Click or tap here to enter text. |
| Is your general practice a training practice? | Yes [ ]  / No [ ]  |
| Do you have a cancer/palliative care lead? | Yes [ ]  / No [ ]  |
| *If yes, please provide their name* | Click or tap here to enter text. |

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| --- |
| Please indicate any practices that share clinical responsibilities with your general practice (**where patients from another practice may be clinically assessed and managed by a clinician from your practice**), and provide contact details for the lead manager/clinician: |
| General Practice Name | Lead contact (*if different to above*) |
| Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. |
| *Please add additional rows as required* |  |
| **Use of other systems for managing cancer patient needs.**This is important for us to know as it may mean that your practice would not be eligible to participate depending on your responses. |
| Do your practice clinicians use any cancer needs assessment tools? For example, the Macmillan recovery package (holistic needs assessment or completion of cancer care review template) | Yes [ ] / No [ ] If yes, please specify:Click or tap here to enter text. |
| *If yes, how often do they use this tool?* | [ ] Rarely[ ] Sometimes[ ] All of the time |
| *If yes, have your practice clinicians received training, support or other resources in its use?* | Yes [ ] / No [ ] If yes, please state the training/support/resources: Click or tap here to enter text. |
| *If no, do you plan to use any cancer needs assessment tools routinely within the duration of the trial?* | Yes [ ] / No [ ] Click or tap here to enter text. |
| This is important for us to know but does not determine if your practice can take part |
| Do your practice clinicians use Electronic Palliative Care Co-ordination systems (EPaCCS)? | Yes [ ] / No [ ]  |
| 1. If yes, how often do they use the EPaCCS model?
 | [ ] Rarely[ ] Sometimes[ ] All of the time |

**Deadline Date for Returning EOI**

**3rd December 2020**

To submit an EOI, please respond by email to:

studysupport.crnyorkshumber@nihr.ac.uk **and** CANASSESS@leeds.ac.uk

You do not need to complete the questions above straight away if you do not want to. Please feel free to get in touch with us with any questions or to request further details prior to completion.

*Please note: Expressing interest does not commit the practice to participate. Equally it does not guarantee involvement in the study. In most cases sites are selected on a first come basis.*

**CRN Website**

NIHR CRN Y&H Homepage: [www.crn.nihr.ac.uk/yorkshumber](http://www.crn.nihr.ac.uk/yorkshumber)

General Enquiries Email: crnyorkshumber@nihr.ac.uk

Patient/Carer enquiries email: patient.crnprimarycare.nihr.ac.uk

Twitter: @NIHRCRN\_yorks or @NIHRCRNpcare

**Patient Confidentiality**

All patient information collected during the course of the research will be kept strictly confidential.

All information will be stored and used according to the guidelines on data protection and confidentiality as outlined in the Data Protection Act 1998.

Your details will be passed to the National Institute for Health Research Clinical Research Network Coordinating Centre (NIHR CRN CC) to inform funding flows.

Clinical Research Network: Yorkshire and Humber is part of the National Institute for Health Research and forms part of the UK Clinical Research Network. The Networks support and delivery high quality research studies.