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Cancer needs assessment in primary care

Submission date 03/07/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 05/07/2017	**Overall study status** Completed	
Last Edited 05/09/2023	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-a-new-way-to-assess-the-needs-of-people-with-cancer

Study website
http://research.hyms.ac.uk/researchcentres/chaps/seda/research-project/r

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number
221366

ClinicalTrials.gov number

Secondary identifying numbers

34461, IRAS 221366

Study information

Scientific Title
Cancer Needs Assessment in Primary Care: A cluster randomised feasibility trial (cRCT) to test the routine use of the NAT:PD-C in primary care to reduce unmet cancer patient and caregiver need and determine the feasibility of a definitive trial

Acronym
CANAssess:PC

Study objectives
The aim of this study is to investigate if a cluster randomised controlled trial (cRCT) to test the routine use of the Needs Assessment Tool Progressive Disease Cancer (NAT:PD-C) in primary care to reduce unmet patient and carer needs is feasible.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & The Humber - Leeds East Research Ethics Committee, 23/05/2017, ref: 17/YH/0141

Study design
Randomised; Both; Design type: Process of Care, Complex Intervention, Management of Care, Qualitative

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Specialty: Primary Care, Primary sub-specialty: Cancer; UKCRC code/ Disease: Cancer/ Malignant neoplasms of independent (primary) multiple sites

Interventions
Participants are asked to complete five study questionnaires about their health and wellbeing. Participants are asked to nominate a carer to join the study if they have one. Carers are requested to complete two study questionnaires on entry to the study about their experience of

caring and wellbeing. They are then requested to arrange a 20 minute appointment at their GP practice as directed by the researcher. The researcher measures how many patient appointments are conducting using the NAT:PD-C.

The most appropriate way to recruit patients for a needs assessment appointment administered by a clinician trained in the use of the NAT:PD-C is done by randomly allocating participants to one of two groups. Randomisation (1:1) takes place at the cluster level to either:

1. Promotion and use of the NAT:PD-C with directed clinical encounter with NAT:PD-C trained clinician. Participating GP practices are trained on how to use the NAT:PD-C. The main aim of this arm is to evaluate if participants are happy to attend an appointment with NAT- trained clinician with whom they do not have an existing relationship with.

2. Promotion and use of the NAT:PD-C with clinical encounter a with a clinician in line with usual practice. The main issue is how many patients will not have a NAT-guided consultation, if as many clinicians are trained as possible, but are not directed towards a specific clinician and simply asked to make an appointment.

GPs and nurses on both arms of the trial are trained in the use of the NAT:PD-C. The uncertainty here relates to the best way of ensuring that patients have a NAT:PD-C-guided consultation, to inform the primary outcome of a potential future definitive trial. For example, we do not know if patients will find it acceptable to be directed towards a NAT:PD-C trained clinician if they have not seen that person before and have a pre-existing relationship with another clinician.

Patients (and carers) are then requested to complete the study questionnaires after one, three and six months.

Intervention Type
Other

Primary outcome measure
1. Recruitment is assessed by calculating the number of GP practices recruited, number of patients screened, eligible, contacted by usual care team, agreeing to researcher contact, and registered per practice, rate of patients (and caregivers) recruited across the feasibility sites over six months
2. Uptake and delivery is assessed by calculating the uptake of the NAT:PD-C, the expected number of completed NAT:PD-C forms completed per patient vs actual will be assessed, total patients by trial arm seen by a NAT:PD-C trained clinician and had a NAT:PD-C completed for that consultation, time from baseline to needs assessment appointment, length of appointments at six months
3. Data collection and quality: Participant reported questionnaire completion rates, amount /pattern of missing data and sub-scales of the proposed primary outcome measure the SCNS, patient/carer outcomes i.e. unmet needs, ability to care, quality of life, performance at six months

Secondary outcome measures
1. Patients' supportive care needs are measured measured using the Supportive Care Needs Survey (SCNS-SF34) at baseline, one, three and six months.
2. Patients' symptom burden is measured using the Edmonton Symptom Assessment System (ESAS-R) at baseline, one, three and six months
3. Patients' health status is measured using EORTC QLQ-C15-PAL at baseline, one, three and six

4. Patients' use of health care services and personal expenses is measured using Resource Use Questionnaire (RUQ) at one, three and six
5. Patients' co-morbidities are measured using Charlson Co-morbidity Index (CCI) at baseline
6. Patients' performance status is measured using Australian Modified Karnofsky Scale (AMKS) at baseline, one, three and six
7. Patients' wellbeing is measured using ICECAP Supportive Care Measure (ICECAP-SCM) at baseline, one, three and six
8. Patients' health status is measured using EQ-5D-5L at baseline, one, three and six
9. Carers' support needs are measured using Carer Support Needs Assessment Tool (CSNAT) at baseline, one, three and six
10. Carers' experience of caring is measured using the Carer Experience Scale (CES) at baseline, one, three and six
11. Patient/carer need is measured using the Needs Assessment Tool Progressive Disease Cancer (NAT:PD-C) post-baseline

Overall study start date
01/09/2016

Completion date
30/11/2018

Eligibility

Key inclusion criteria
Patient level:
1. Adults (aged 18 and above)
2. Diagnosis of active incurable cancer
3. Willing to have a consultation with a practice clinician
4. Able to complete study measures
5. Written or observed verbal informed consent

Carers:
1. Adults (aged 18 and above)
2. Nominated by the patient
3. Able to complete study measures
4. Written or observed verbal informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

Planned Sample Size: 60; UK Sample Size: 60

Total final enrolment
64

Key exclusion criteria
Patient level:
1. Patients in complete remission
2. Patients receiving treatment with intent to cure (patients receiving anti-cancer treatments with the intention to palliate, OR receiving supportive care only will be eligible).
3. Patients living in a care home or other institutional setting
4. Patients who do not speak English well enough to provide informed consent and complete study measures.
5. Known to have a co-morbid condition which means they lack sufficient mental capacity to provide informed consent in the opinion of the clinician (e.g. dementia)
6. Have known of their diagnosis for less than one month

Carer level:
1. Carers who do not speak English well enough to provide informed consent and complete study measures.
2. Paid carers

Date of first enrolment
15/07/2017

Date of final enrolment
31/03/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
James Alexander Family Practice
Hull
United Kingdom
HU7 4DW

Study participating centre
Hedon Group Practice
Hull
United Kingdom
HU12 8JD

Sponsor information

Organisation
University of Hull

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04nkhwh30

Funder(s)

Funder type
Charity

Funder Name
Yorkshire Cancer Research

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication of the results in high quality medical journals relevant to: palliative care, cancer and primary care.

Intention to publish date
01/07/2018

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		28/01/2021	29/03/2021	Yes	No
HRA research summary			28/06/2023	No	No
Protocol file		09/05/2017	05/09/2023	No	No