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Comparing hospital and telephone follow up for women treated for endometrial cancer (ENDCAT): ENDometrial CAncer Telephone follow up trial)

Submission date
28/10/2011

Recruitment status
No longer recruiting

Registration date
28/10/2011

Overall study status
Completed

Last Edited
26/10/2022

Condition category
Cancer

[X] Prospectively registered
[_] 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-comparing-hospital-and-telephone-follow-up-after-treatment-for-womb-cancer-endcat

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11016

Study information

Scientific Title
Comparing hospital and telephone follow up for women treated for endometrial cancer (ENDCAT): ENDometrial CAncer Telephone follow up trial): a randomised controlled trial

Acronym
ENDCAT

Study objectives
This study aims to demonstrate that specialist nurses have the skills and expertise to meet the information needs and concerns of women treated for endometrial cancer, with no physical or psychological detriment, by carrying out a randomised controlled trial comparing traditional hospital follow-up with telephone follow-up by specialist gynaecology oncology nurses. In addition, we aim to explore patient views and experiences of receiving telephone follow-up.

This study is a randomised controlled trial (RCT) comparing two forms of service provision: standard hospital outpatient follow-up (control arm) and a telephone intervention administered by specialist gynaecology oncology nurses (intervention arm). Primary outcomes are psychological morbidity and patient satisfaction with information; secondary outcomes are quality of life, patient satisfaction with service, number of referrals, time to detection of recurrent disease and cost effectiveness (efficiency). In addition we will also conduct a qualitative study, using semi-structured interviews, to obtain more in-depth information on patients experiences of telephone follow-up and nurse specialist views on positive and negative aspects of delivering the telephone intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service (NRES) Committee North West Preston, 03/10/2011, REC ref: 11/NW/0648

Study design
Randomised; Interventional; Design type: Process of Care

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please contact Kinta Beaver (KBeaver@uclan.ac.uk) to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Gynaecological Cancer; Disease: Endometrium

Interventions
The total sample size of 256 includes equal distribution between those randomised to the intervention group (telephone follow-up) and those randomised to the control arm (standard care)

Telephone follow-up by specialist gynaecology oncology nurses at specified time points using a structured telephone intervention designed to meet information and support needs and promote self management.; Follow Up Length: 24 month(s); Study Entry : Registration and One or More Randomisations

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Psychological Morbidity; Timepoint(s): Baseline (pre-randomisation), 1st scheduled clinic appointment post randomisation

Secondary outcome measures
1. Clinical outcomes (time to detection of recurrence); Timepoint(s): At each telephone/hospital appointment that takes place during study period
2. Efficiency; Timepoint(s): 6 and 12 months post randomisation
3. Patient satisfaction with information; Timepoint(s): Baseline (pre-randomisation), 1st scheduled clinic appointment post randomisation
4. Patient satisfaction with service; Timepoint(s): Baseline (pre-randomisation), 1st scheduled clinic appointment post randomisation
5. Quality of Life; Timepoint(s): Baseline (pre-randomisation), 1st scheduled clinic appointment post randomisation

Overall study start date
23/03/2012

Completion date
30/06/2014

Eligibility

Key inclusion criteria
1. Known diagnosis of Stage I endometrial cancer
2. Completed primary treatment (e.g. surgery, radiotherapy, chemotherapy)

3. Attending outpatient clinics for the purposes of routine monitoring and surveillance
4. Access to a telephone
5. No age limitations
Gender = female; Target Gender: Female

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Planned Sample Size: 256; UK Sample Size: 256

Total final enrolment
259

Key exclusion criteria
1. Known diagnosis of stage II, III or IV endometrial cancer
2. Currently receiving active treatment
3. Taking part in clinical trials that have pre-defined follow-up regimes
4. Auditory problems that inhibit the use of the telephone
5. Cannot speak or understand English where no interpreter services are available

Date of first enrolment
23/03/2012

Date of final enrolment
30/06/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Lancashire School of Health
Preston
United Kingdom
PR1 2HE

Sponsor information

Organisation
Lancashire Teaching Hospitals NHS Trust (UK)

Sponsor details
School of Health
University of Central Lancashire
Brook Building 4th Floor (Room BB 440)
Preston
England
United Kingdom
PR1 2HE

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02j7n9748

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2018		Yes	No
Plain English results			26/10/2022	No	Yes