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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
28/10/2011		☐ Protocol		
Registration date 28/10/2011	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
26/10/2022	Cancer			

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

Contact name

Prof Kinta Beaver

Contact details

Lancashire School of Health Preston United Kingdom PR1 2HE +44 (0)1772 89 3715 kbeaver@uclan.ac.uk

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, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), 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

Study outputs

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