

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

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|--|---|---|
| Submission date 28/10/2011 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 28/10/2011 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 26/10/2022 | Condition category Cancer | <input type="checkbox"/> 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

Protocol serial number

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

Study type(s)

Other

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Total final enrolment

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**

United Kingdom

England

Study participating centre

Lancashire School of Health

Preston

United Kingdom

PR1 2HE

Sponsor information**Organisation**

Lancashire Teaching Hospitals NHS Trust (UK)

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

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| Results article | results | 01/06/2018 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Plain English results | | | 26/10/2022 | No | Yes |