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A trial of optimal personalised care after treatment for gynaecological cancer (TOPCAT-G)

Submission date 10/06/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/06/2015	**Overall study status** Completed	
Last Edited 25/10/2022	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-the-follow-up-care-after-treatment-for-cancer-of-the-cervix-womb-ovary-and-vulva

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title

A trial of optimal personalised care after treatment for gynaecological cancer (TOPCAT-G): a randomised feasibility study comparing nurse-led telephone follow-up (intervention) with standard care (control)

Acronym
TOPCAT-G

Study objectives
The primary aim of the current study is to conduct a randomised, feasibility trial comparing new nurse-led follow-up with standard, hospital-based, medical follow-up. The study will determine the feasibility and acceptability of a new nurse-led approach. Feasibility will be determined by assessing the number of patients eligible to be included in the study, monitoring recruitment and retention rates, and exploring the willingness of participants to be randomised and to complete outcome measures relating to quality of life, health economics, well-being, relapse and survival.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. NRES Committee London - South East, 22/05/2015, ref: 15/LO/0716
2. Betsi Cadwaladr University Health Board, 26/08/2015

Study design
Parallel-group single-site randomised controlled feasibility trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Gynaecological cancer

Interventions
1. Standard care:
Patients randomised to standard care will continue to have their usual hospital-based doctor-led medical reviews (at 6, and 9 months post-treatment), and will complete the Macmillan Concerns Checklist prior to their 6- and 9-month follow-up appointments at the clinic and this will inform the discussion with the clinician. Following consent, but prior to randomisation, patients will be asked to complete a set of study outcome questionnaires at baseline (at the routine 3-month follow-up appointment). Patients will also be asked to complete the study outcome questionnaires after their 6 and 9 month follow-up appointments.

2. Nurse-led intervention:
The intervention group patients will not attend the hospital for their usual follow-up appointments but will receive a nurse-led telephone follow-up intervention, known as Optimal Personalised Care After Treatment for Gynaecological cancer (OPCAT-G). After patients have been allocated to the nurse-led intervention arm of the study, patients will be introduced to the

Clinical Nurse Specialist (CNS) who will deliver the intervention. The CNS will give the patients an information booklet which will include information on patterns of relapse, possible warning symptoms, and how to respond to these. Information will also be given on possible long-term physical and psychological side-effects of treatment and how they can contact the clinical team if they have concerns or symptoms. Patients will receive treatment and diagnosis-specific supplementary leaflets attached to the booklet. The CNS will also give patients a set of needs assessment measures, including:
1. Macmillan Concerns Checklist. This checklist addresses 23 physical concerns, 9 practical concerns; 3 family/relationship concerns; 9 emotional concerns; 3 spiritual or religious concerns, and 9 lifestyle or information needs. Patients are asked to tick a box for any problems that have caused concern during the previous week.
2. CancerCAN22. This is a multi-domain needs assessment tool that measures unmet needs across 22 items (12 psycho-social needs items and 10 treatment and care items).
3. Distress Thermometer. This is a reliable measure of patients' distress and concerns.
Patients will be asked to complete the needs assessment measures prior to a scheduled telephone call from the CNS. The scheduled telephone call will take place within four weeks of randomisation and will involve a structured interview with the CNS. Patients will be asked about their general well-being and about any gynaecological symptoms experienced. Any identified needs or concerns from the three needs assessment measures will be discussed. Patients in whom problems or unmet needs are identified will be evaluated and directed to the most appropriate source of help. This could include a patient self-help group, their general practitioner, or hospital review by the gynaecology, oncology or clinical psychology team. Patients will receive additional copies of the needs assessment measures by post and will be told that if they have any problems between telephone calls, they should complete their assessments and contact the CNS. Patients will be encouraged to report problems promptly with these concerns addressed in the same structured way. Patients will then receive another scheduled telephone call at 9 months post-treatment. Patients will also receive the three needs assessment measures by post and will be asked to complete them one week prior to their 9-month scheduled telephone call from the nurse. The telephone contact will again include a structured interview and any identified needs or concerns will be discussed following the same structure as the first telephone call interview. In addition to the nurse-led intervention, patients will be asked to complete the same study outcome questionnaires as patients in the standard care arm. The outcome questionnaires will be completed at baseline (prior to randomisation) and again at 6 months post-treatment and following the 9-month telephone follow-up.

Intervention Type
Other

Primary outcome(s)
1. Patient recruitment rate. This will be calculated from the total number of patients invited to take part in the study and the number of patients giving written consent to participate in the study
2. Patient attrition rate. This will be calculated from the number of patients who gave written consent and the number of patients who have completed any measures, regardless of their completion rate

Key secondary outcome(s))
A set of study outcome questionnaires will be administered at baseline and at 6 and 9-months post-treatment:
1. EORTC QLQ-C30. This is a validated measure to assess the quality of life of cancer patients
2. EQ-5D-3L. This is a validated generic, health-related, preference-based measure comprising

five domains: mobility; self-care; usual activities; pain and discomfort; anxiety and depression
3. ICECAP-A (ICEpop CAPability measure for Adults) is a measure of capability for the general adult population
4. Client Service Receipt Inventory. This is a measure of self-report service user to evaluate and cost service use
Additional data to be captured will include:
5. Patient demographics, cancer type and stage, type of treatment received and comorbidity at baseline
6. Data on the pattern, timing and method of detection of relapse and on survival from patient records and routinely captured data sources

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Female patients who have completed treatment for cervical, endometrial, epithelial ovarian, or vulvar cancer within the last 3 months in BCUHB in North Wales
2. Patients who have completed treatment for fallopian tube and primary peritoneal carcinoma
3. Patients will be included if they are considered fit for taking part in the trial and able to give informed consent, as assessed by the multi disciplinary team
4. Patients may have received surgery, chemotherapy, radiotherapy or a combination of these but will not be receiving any continuing treatment that requires hospital care
5. At the time of entry, patients in the view of their treating consultant will not have a definite need for continued hospital care

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Patients having had treatment for sarcoma, germ cell tumour, borderline tumours or choriocarcinoma will be excluded as these women tend to require specific and/or more intense follow up often with serial imaging or tumour markers
2. Patients requiring ongoing treatment
3. The study will not include patients who do not have capacity to give informed consent or who are deemed to be unable to take part in the trial (e.g., severe learning/mental disability, severe mental health problems)
4. Patients who are not able to understand Welsh or English

Date of first enrolment

01/07/2015

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
United Kingdom

Study participating centre
Betsi Cadwaladr University Health Board
United Kingdom
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Sponsor information

Organisation
Betsi Cadwaladr University Health Board

ROR
https://ror.org/03awsb125

Funder(s)

Funder type
University/education

Funder Name
Betsi Cadwaladr University Health Board

Results and Publications

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

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	results	01/02/2018	24/01/2019	Yes	No
Protocol article	protocol	01/12/2016		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version V2		13/04/2016	No	Yes
Participant information sheet	version V1		13/04/2016	No	Yes
Plain English results			28/01/2020	No	Yes