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Developing a stepped approach to improving sexual function after treatment for gynaecological cancer

Submission date
04/06/2015

Recruitment status
No longer recruiting

Registration date
04/06/2015

Overall study status
Completed

Last Edited
11/04/2019

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Women affected by gynaecological cancer (cancer that starts in the reproductive system) are often not aware of the sexual consequences of both the cancer and its treatment. Most do not receive appropriate advice or help to recover sexual function, and the impact on their sexuality may be profound, both physically and mentally. Despite this there are several potential treatments which can be effective in helping recovery of sexual activity. A major initial challenge is informing and involving the patients in an appropriate and sensitive manner, and a further issue is the delivery of such treatments in busy and often medically driven gynaecological oncology clinics. This study uses and adapts existing treatments for improving sexual function after cancer treatment and develops a model for delivering these in the NHS setting. The model of ‘stepped care’ is adapted from that used nationally and successfully in the Increasing Access to Psychological Therapies programme, where mood disorders are picked up in general practice and managed at a range of levels, from self-help through ‘low intensity’ interventions up to ‘high intensity’ interventions. Assessment at beginning and throughout all treatments allows for ‘stepping up and down’, i.e. adjusting the type of help a woman receives according to her need and her response to the treatment already given. This study will develop and test a 'stepped' system of interventions together with an algorithm for assigning treatment level. The aim of this study is to assess the feasibility of conducting a full scale study of the stepped treatment and indicate its potential benefits to patients, their partners, and to the NHS generally.

Who can participate?
Women aged over 18 (with partners at their choice) who have been treated for gynaecological cancer and have sexual function difficulties

What does the study involve?
Participants are randomly allocated to one of two groups. The control group receive treatment as usual. The intervention group receive stepped care treatment. Stepped care uses existing interventions to help women recover their sexual feelings and activity. The initial assessment determines which step is suitable initially, and women can be progressed from one treatment to another as appropriate using a newly developed algorithm. It starts with simple methods,

moving on to new talking treatments for more complex cases. Sexual function, mood, self-esteem and cost-effectiveness are measured.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
1. UCLH Gynaecological Cancer Centre (UK)
2. University Hospitals Bristol Gynaecological Oncology Centre (UK)

When is the study starting and how long is it expected to run for?
April 2014 to June 2017

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT02458001

Protocol serial number

Study information

Scientific Title
Developing a Stepped Approach to Improving Sexual Function aFteR Treatment fOr gyNaecological Cancer: a feasibility pilot study two-arm, parallel-group, randomized controlled trial

Acronym
SAFFRON

Study objectives
Feasibility pilot study with research questions as follows:
1. To establish whether women treated for gynaecological cancer with moderate to severe sexual dysfunction are willing to participate in a randomised trial model and adhere to treatment
2. To indicate likely rates of recruitment to a future evaluation of the SAFFRON intervention
3. To pilot a stepped care psychosexual intervention (SAFFRON) on the IAPT model
4. To establish whether the SAFFRON intervention is acceptable to patients
5. To establish whether SAFFRON is deliverable by a Gynae-Oncology cancer centre multi-disciplinary team
6. To indicate the most appropriate outcome measures for use in a larger trial
7. To inform estimates of the likely effect size, which will assist sample size calculations for a larger trial

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/1111102
Protocol can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0008/98765/PRO-11-111-02.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Queen Square, 12/03/2015, REC ref: 15/LO/0324, IRAS project ID: 138836

Study design
Feasibility pilot study two-arm parallel-group randomized controlled trial to gain appropriate information to inform a decision about progressing to a full randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Psycho-sexual difficulties following treatment for gynaecological cancer

Interventions

Intervention Arm: SAFFRON stepped care. Stepped care (Improving Access to Psychological Therapies, 2012) adapted for the gynaecological cancer setting to produce a 3-step model including a clinical assessment and treatment algorithm.

Assessment Algorithm FSFI Interventions

Level 1:
Best available self-help literature on psychosexual difficulties after cancer as judged by the project team and two patient advocates.

Level 2:
A 3-5 session manualised psycho-educational intervention delivered fortnightly by study trained CNSs with taping and supervision for adherence to protocol and manual.

Level 3:
16 weekly session manualised brief psychotherapy adaptation of InterPersonal Therapy, IPT (Interpersonal Psychotherapy for Sexual Adjustment post Gynaecological Cancer, IPT-APGyC)

Control Arm: Enhanced Treatment as Usual level 1 intervention: self-help booklet. Non study trained CNS will offer assessment, advice, vaginal dilator training where appropriate, arrange topical oestrogens or other creams

Intervention Type
Behavioural

Primary outcome(s)
Primary endpoints – measures of feasibility:
1. Rate of recruitment
2. Consent rate to randomization and treatment
3. Proportion of women stepping up from level 1 to 2, and level 2 to 3
4. Proportion of women dropping out of therapy
5. Number of usable data points from all measures at all time points
6. Proportion of women lost to follow-up on trial measures

Key secondary outcome(s))
At all 5 time-points (baseline, 6 weeks, 3 months, 6 months, 12 months) the following will be recorded:
1. Change in Female Sexual Function Index (FSFI) (Rosen et al 2000), an internationally recognized rating scale which allows women to describe their sexual experience in a range of domains - desire, arousal, lubrication, orgasm, pain and satisfaction. Cut-off scores FSFI ≤ 26 signifies sexual dysfunction (lower scores signify worse sexual function (Rosen et al, 2000, Baser et al 2012)
2. Change in mood and other measures:
2.1. Economics: EQ 5D to measure cost effectiveness
2.2. Depression: Patient Health Questionnaire (PHQ-9). ≤ 20 signifies moderate to severe depression (Kroenke et al, 2001)

Preference will be given to face-to-face administration of questionnaire measures in clinic, or if necessary, at home. Data will be maximised by posting questionnaires if necessary with a telephone interview to follow up.

At 6 and 12 months:
Client Services Receipt Inventory (CSRI) short form to assess use of health and social services (Beecham and Knapp 1992)

At baseline (randomisation) the following additional demographic and clinical information will be recorded on a Case Report Form (CRF) by the RA, including:
1. Demographics: ethnicity, current relationship status, occupation, education
2. Personal history: within a relationship: gender of partner; self-rated quality of relationship measure
Disease information: cancer diagnosis (cervix, ovarian, endometrial, other), stage of disease at diagnosis, time since end of primary treatment in months, stage of disease at last appointment (relapse or first line treatment), treatment modality
3. ECOG/WHO Performance status (0-5) assessed by clinician where 0 = fully active, able to carry on all pre-disease performance without restriction, 5 = dead (Oken et al 1982)
All cancer disease information will be gathered by the RA on each site from electronic records and crosschecked against the hospital database on all Gyn-Onc patients

Process measures:
1. Qualitative feedback from patients about their experience of participating in the trial
2. Qualitative feedback from staff about implementation of study within clinics

Completion date
30/06/2017

Eligibility

Key inclusion criteria
1. Women aged over 18 (with partners at their choice) treated for any gynaecological malignancy with surgery and/or chemotherapy and/or radiation at UCLH Gynaecological Cancer Centre or University Hospitals Bristol Gynaecological Cancer Centre
2. 3 months minimum post end of treatment
3. Any sexual orientation
4. With sexual function difficulties identified by initial screen (3 clinical questions within clinical interview posed by doctor or nurse)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria

1. Poor English
2. Current drug or alcohol abuse
3. Current sexual therapy or psychotherapy

Date of first enrolment
01/07/2015

Date of final enrolment
21/03/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
UCLH Gynaecological Cancer Centre
2nd Floor North
250 Euston Road
London
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Study participating centre
University Hospitals Bristol Gynaecological Oncology Centre
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Sponsor information

Organisation
University College London (UK)

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2019	27/02/2019	Yes	No
HRA research summary			28/06/2023	No	No