

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

Submission date 04/06/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/06/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/04/2019	Condition category Cancer	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT02458001

Secondary identifying numbers

HTA 11/111/02; v12

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet**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 measure

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

Secondary outcome measures

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

Overall study start date

01/04/2014

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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

100

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

England

United Kingdom

Study participating centre

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Study participating centre

University Hospitals Bristol Gynaecological Oncology Centre

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University/education

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Funder(s)

Funder type

Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

The main outputs from this research will be:

1. New therapeutic materials and therapeutic intervention
2. A new format of delivery (stepped care) which will raise the issue of sexuality more widely in follow-up for all women treated for gynaecological cancer. However, we shall not be able to provide evidence of effectiveness from this pilot trial. Rather we are developing a promising and empirically based intervention whose evaluation we shall pilot. Although services may be interested in it, we shall stress that further evidence on its effectiveness will be needed before it can be recommended more generally.
3. We will publish the protocol of the study initially, together with papers describing the process of developing the 3 levels of intervention.
4. The ultimate aim of this study – and any subsequent RCT – is to evaluate the effectiveness of a stepped intervention delivery model within NHS clinics to improve sexual outcome in women treated for gynaecological cancer. We will therefore use a variety of approaches, some London and Bristol based and some national, to disseminate our findings.

5. Results will be presented to both cancer centres that participated in the research.

Participating patients will also be offered the opportunity to receive a summary of the findings or to view the results on the study web pages described above. Other forms of dissemination will include the publication of peer-reviewed articles, and presentation at conferences and seminars for practitioners, researchers, national policy makers, and users. The quantitative and qualitative study outputs will be assembled to inform the main randomised controlled trial. This will be the subject of a subsequent grant application. For example, the qualitative interviews will help to identify deficits and gaps in the treatment manuals, current practices, training and supervisory arrangements which will be revised for the main trial evaluation.

6. The patient and carer organisations who have been fully involved in the research will also assist with the wider dissemination of the results through their consumer networks. Macmillan Cancer Support are supportive of this endeavour and Julie Latimer, Education Lead of Macmillan London has engaged to roll out any findings. In addition, we will collaborate with the UCLH/UCL Patient and Public Involvement (PPI) in Research Co-ordinator and with the UCLH/UCL press offices to develop contacts with local and national media and to contribute material for the UCL /UCLH websites (including to the dedicated pages on the Research Patients Support Network and PPI in Research). Training courses in Communicating Science to the Public will be completed by the researchers.

Intention to publish date

01/01/2018

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