Stepped approach to improving sexual function after gynaecological cancer: the SAFFRON feasibility RCT

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Scientific summary

The SAFFRON feasibility RCT

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Background

Women affected by gynaecological cancer 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. However, there are several potential therapies that can be effective in helping the recovery of at least some form of sexual activity. A major initial challenge is informing and involving the patients in an appropriate and sensitive manner, and a further issue is delivering such therapies in busy and often medically driven gynaecological oncology clinics. This study was conceived in response to a National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme call asking for proposals to improve sexual functioning in women treated for gynaecological cancer while taking into account associated issues of mood. Existing evidence-based therapies for improving sexual function after cancer treatment were adapted and placed within a 'stepped care' model for delivering these in the NHS setting. An assessment and treatment stepping algorithm was developed in parallel, both to assign women to a level at assessment and, using sessional assessment, to follow their progress closely to advise when to 'step up' to another level. The assessment tool was applied to all participants on the principle that the problem in question is sexual difficulty, not the cancer of origin.

Objectives

Aims

- To develop a stepped care psychosexual intervention [a Stepped Approach Intervention to Improve Sexual Function after Gynaecological Cancer (SAFFRON)] on the Increasing Access to Psychological Therapies (IAPT) model, together with a treatment algorithm for assigning women to levels of intervention.
- To establish whether or not women treated for gynaecological cancer with moderate to severe sexual dysfunction are willing to participate in a randomised trial model and adhere to treatment.
- To indicate likely rates of recruitment to a future evaluation of the SAFFRON intervention.
- To pilot a stepped care psychosexual intervention (SAFFRON) on the IAPT model.
- To establish whether or not the SAFFRON intervention is acceptable to patients.
- To establish whether or not SAFFRON is deliverable by a gynaelogical oncology cancer centre multidisciplinary team.
- To indicate the most appropriate outcome measures for use in a larger trial.
- To inform estimates of the likely effect size, which will assist sample size calculations for a larger trial.

Research questions

- Are women treated for gynaecological cancer who develop moderate to severe sexual dysfunction willing to participate in a randomised trial of treatment and adhere to that treatment?
- Will women agree to be randomised to an intervention to treat sexual dysfunction?
- Are different tumour sites, treatments and cancer stages at approach associated with different rates of participation in the trial and uptake of the treatment?
- Is the stepped care system operable within the NHS system as it stands?
- What is the likely effect of the three levels of intervention on sexual function, mood and self-esteem, as measured by standard measures?
- What is the rate of attrition from each treatment modality?

Purpose of research

- Is it possible to design and pilot a randomised controlled trial (RCT) that can potentially answer the question 'Is SAFFRON a clinically and cost-effective treatment for sexual dysfunction occurring after treatment for gynaecological cancer in the NHS?'?
- Can the SAFFRON intervention be evaluated in a feasibility randomised trial?
- Is a stepped treatment approach acceptable and practical to women?
- Can it be done within NHS settings?

Methods

The call from NIHR HTA programme asked for a feasibility study. The study was to take place in two phases. The first step was to be the development of a stepped intervention and a clinical algorithm to use in determining progress through the steps. This intervention was then to be evaluated in a two-arm, parallel-group, feasibility RCT. The results of this feasibility trial were to be used to inform a decision about progressing to a full RCT.

The development of the stepped intervention was carried out by a team that combined the skills of psychological therapy developers and evidence from the Cochrane review of existing interventions by Candy *et al.* (Candy B, Jones L, Vickerstaff V, Tookman A, King M. Interventions for sexual dysfunction following treatments for cancer in women. *Cochrane Database Syst Rev* 2016;**2**:CD005540), together with patient involvement from the start.

A three-level intervention was decided on, using the IAPT model for treatment access for anxiety and depression in general practice. Level 1 was simple self-help and level 2 was a taught face-to-face psychoeducation intervention that was delivered by a study-trained clinical nurse specialists (CNSs) from a gynaelogical oncology NHS team. The third level was a higher-level intervention for women with complex difficulties who had not responded to lower-level help, which was to be delivered by a study trained clinical psychologist.

The level 1 (self-help) intervention was derived from an initial wide review of publicly available English-language self-help materials on sex after cancer. All materials were reviewed by a subset of the project team and the patient advocates. Two core documents were identified as the most detailed and pertinent to patients' needs. They were rewritten to be appropriate for a UK audience, and for all sexual orientations, as well as to include specifically gynaecological cancer-related material, as our patient advocates reported finding generic information, with specific advice on other cancers, alienating. Both patient advocates contributed large amounts of material at this point. An illustrated booklet was developed for the trial.

The level 2 intervention was adapted from an evidence-based clinical psychology intervention shown to be effective in early endometrial and cervical cancer. It was rewritten to be delivered by CNSs with extra training, and all materials and worksheets were adapted to cover the full range of gynaecological cancers and their treatments, as well as the full trajectory of the cancer journey, including the palliative stage. Training materials were written, and a full day's training was delivered in Bristol to a University College London CNS and a Bristol radiotherapist to ensure identical training and to promote fidelity to the training model. Both participants reported the need for more training and a desire for close supervision, finding the areas of specific psychological therapy particularly difficult. This did not occur as the study was stopped.

The level 3 intervention for highly complex difficulties that had not responded to levels 1 and 2 was based on interpersonal therapy (IPT). A new manual was written by an IPT trainer with experience of writing therapy manuals, using input from patient advocates and a clinical psychologist experienced in gynaecological oncology. Training was written and delivered to three clinical psycho-oncologists working in embedded gynaecological cancer teams at both research sites in 1 day in London by Alessandra Lemma, a qualified IPT

trainer. All reported finding the training an augmentation of their clinical skill set and were happy to pilot the intervention with patients.

Measures were chosen for assessment that formed part of the algorithm and to answer the research questions. Time points within the study were identified for assessment on a full range of measures and the Female Sexual Function Index was chosen as the study measure to indicate response to the intervention. Health economics measures were also included. A qualitative study was also planned to augment understanding of barriers to implementation within the NHS, and interview schedules for participating staff and patients were prepared.

Results

The study was closed by the funder, NIHR, in November 2015 because of slow progression to recruitment, as well as changes to the protocol made after its original filing with NIHR that led to a substantial Research Ethics Committee amendment. These had been recommended by the Trial Steering Committee, but had not been notified to NIHR. There are therefore no results of the stepped care intervention with patients, and the questions within the objectives cannot be answered here.

The stepped interventions were completed and training took place for both level 2 and level 3 staff.

The treatment algorithm was completed and all supporting study materials and documents were completed.

Conclusions

The study interventions and treatment algorithm were completed and could be used in a future study. Patient involvement in this study made a major contribution and ideally any subsequent study would continue this involvement.

Trial registration

This trial is registered as ISRCTN12010952 and ClinicalTrials.gov NCT02458001.

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