European Journal of Oncology Nursing 19 (2015) 349–358

Contents lists available at ScienceDirect

European Journal of Oncology Nursing

journal homepage: www.elsevier.com/locate/ejon

The psychosocial needs of gynaecological cancer survivors: A framework for the development of a complex intervention

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Keywords:
Cancer survivorship
Rehabilitation
Gynaecological cancer
Complex interventions
Follow-up
Psychosocial support
Empowerment
Guided self-determination
Self-management
Fidelity

A B S T R A C T

Purpose: To develop and pilot test an intervention targeting the women's psychosocial needs during the follow-up period after surgical treatment for gynaecological cancer.
Methods: The project consisted of four phases. Phase 1 involved development of an intervention on the basis of meetings with key healthcare professionals, a literature review and six semi-structured interviews with women who attended the existing follow-up program. The Guided Self-Determination (GSD) method developed in diabetes care was identified as an appropriate framework for the intervention. GSD consists of reflection sheets for patients and advanced professional communication skills. The GSD method was adapted to women in a follow-up program after gynaecologic cancer treatment (GSD-GYN-C). Phase 2 involved primary pilot testing of the intervention and the findings were used to modify the intervention in phase 3. This modification involved the development of additional reflection sheets and a fidelity assessment tool. A systematic training program was arranged for the GSD-GYN-C-nurses. Phase 4 involved secondary pilot testing where nurses and women confirmed the applicability of GSD-GYN-C and final adjustments were made. Selected measurements were tested for sensitivity during pilot testing. Data from phase 2 and 4 were also used to select the primary outcome and calculate power for a future randomized clinical trial (RCT).
Results: Pilot testing supported our hypothesis that GSD-GYN-C may be transferable and useful to survivors of gynaecological cancer.
Conclusion: GSD-GYN-C was developed and validated and is now ready for evaluation in an RCT.

Introduction

Gynaecological cancer induces a major break in every-day life and a threat to existence for both the patients and their families. Many gynaecological cancer patients experience physical, psychological, social, practical and economic challenges during treatment, but may also experience difficulties as long-term survivors (Institute of Medicine and National Research Council of the National Academies, 2006). In Denmark 1838 women were diagnosed with gynaecological cancer in 2012 (Engholm et al., 2014). Those treated with surgery only continue a follow-up program in the department of gynaecological surgical oncology for three -to five years after surgery (Danish Gynaecological Cancer Group) where the main focus is physical examination for recurrence of cancer. The psychosocial effects of gynaecological cancer treatment on women may be overlooked in the existing approach to follow-up care for this group. Research has traditionally focused on active treatment using survival and complication rates as outcome measures, resulting in successful treatment, which has increased the population of gynaecological cancer survivors (Engholm et al., 2014, Klint et al., 2010; Cancer Research UK). There is limited research concerning the women's preferences and needs during follow-up (Dahl et al., 2013) leaving a gap in our knowledge of how to psychosocially support or counsel the women during the follow-up programs.

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http://dx.doi.org/10.1016/j.ejon.2015.01.007
1462-3889/

Research on women's needs during rehabilitation reports that the quality of life (QOL) is generally good, especially among early stage gynaecological cancer survivors (Dahl et al., 2013; Bradley et al., 2006; Rannestad et al., 2008; Leake et al., 2001; Frumovitz et al., 2005; Goncalves, 2010; Vistad et al., 2006; Greimel et al., 2009). Nevertheless, gynaecological cancer survivors have expressed a need for emotional support and counselling in the follow-up period (Corney et al., 1992; Miller et al., 2003; Sekse et al., 2010; Wenzel et al., 2005). There is limited research regarding interventions focussing on rehabilitation after gynaecological cancer (National Cancer Action Team NHS November, 2009, National Cancer Rehabilitation Advisory Board NHS January, 2012). Moreover, evidence regarding the effects of psychosocial interventions is inconclusive due to small sample sizes, too short follow-up periods, and insufficient reporting of trials (Hersch et al., 2009). A Cochrane review on interventions for psychosexual dysfunction in women treated for gynaecological malignancy concluded that the evidence is insufficient to support or refute any interventions due to poor methodological quality of most of the studies (Flynn et al., 2009). In a recently published Cochrane review no evidence was found that could recommend different models of follow-up care after cervical cancer (Lanceley et al., 2013). A guideline about self-management interventions targeted to cancer survivors (National Cancer Survivorship Initiative, 2010) points to the potential for tailored interventions using a validated theoretical frame of reference.

In conclusion there is a need to develop and test interventions tailored to gynaecological cancer survivors' individual needs in order to address their physical, psychological and social challenges. In this paper we describe the process of developing and pilot testing a supportive and patient-centred intervention within the theoretical framework of Guided Self-Determination (GSD), which was originally developed and tested effective in diabetes care (Zoffmann, 2004; Zoffmann and Kirkevold, 2005; Zoffmann and Lauritzen, 2006; Zoffmann and Kirkevold, 2007; Zoffmann et al., 2008; Zoffmann and Kirkevold, 2012).

Aim

The aim of the study was to explore gynaecological cancer survivors' need for rehabilitation during follow-up and to develop an appropriate intervention targeted at these needs.

Design & methods

Our study describes the development of a complex intervention up to the point where the intervention is ready to be tested in a randomised clinical trial (RCT), this trial is ongoing (ClinicalTrials.gov Identifier NCT01784406). The intervention was developed in four phases illustrated in Fig. 1, between September 2011 and January 2013 according to the Medical Research Council (MRC) guidance (Medical Research Council, 2008). The guidance describes a systematic process of developing, piloting, evaluating and implementing a complex intervention. According to the guidance, a complex intervention should be developed by identifying the evidence base and a relevant theoretical framework, modelling the intervention and choosing outcomes. Then the intervention must be pilot tested and recruitment and sample size must be determined. The next stage is to evaluate the effectiveness of the intervention, preferably in an RCT. Finally the guidance covers issues about implementation of interventions and long-term follow-up.

The target group was women treated surgically for gynaecological cancers: ovarian, borderline (tumours of low malignant potential), cervical, endometrial, and vulva cancers who attended follow-up visits at a gynaecological oncology outpatient clinic at a University Hospital in Copenhagen, Denmark.

Ethical considerations

Informed consent was obtained before observations, interviews and pilot conversations. According to Danish law, this study is exempt from ethical approval because human biological material is not included. This was confirmed by the Ethics Committee of the Capital Region, Denmark (H-4-2011-FSP (65)). Moreover data handling was approved by the Danish Data Protection Agency.

Phase 1 development of the intervention

The evidence base

A. Meetings with key healthcare professionals (HCPs)

Initially, a brainstorming meeting was held to discuss potential key topics for future clinical research in patients with gynaecological cancer. There was an overall interest in research that could improve and further provide an evidence base for psychosocial support in the follow-up program, as it was acknowledged that psychosocial needs were not adequately met in the existing program. Seven more meetings were held in the development of the intervention so as to receive feedback on the ongoing process from the HCPs. The meetings were further used to better understand and identify barriers and facilitators in the specific context where the intervention would be delivered. Meeting participants comprised the first author, oncologic gynaecological doctors and nurses, the departmental research manager, administrators, a sexologist, a psychologist and a nurse specialized in cancer rehabilitation.

B. Literature review

Literature on women's needs and experiences during follow-up was reviewed and relevant findings are reported in Fig. 1.

C. Observations

Observations were made by the first author during 10 follow-up visits at the out-patient gynaecological oncology clinic. These follow-up visits lasted approximately 15 min including the physical examination for recurrence and conversation. The first author obtained additional information by observing a 4-day nurse-led group rehabilitation course at the hospital for recently treated women with gynaecological cancer. Seven participants discussed their situation with staff members including doctors, nurses, a social worker, a physiotherapist, a priest and the cancer rehabilitation-nurse. This was to put focus on individual needs, combined with peer support as an integrated part of the course. Observations were made to get insight into the content of the current follow-up program and to identify the issues that are important to the women. The observer took notes about personal experiences and thoughts, which were used to develop an interview guide. Through the observations it became clear that there was very limited time to address psychosocial issues at the follow-up visits. Further, no systematic approach was used to assess potential needs for psychosocial support. In addition the observations during the rehabilitation course showed that the women experienced a need for and valued receiving individualized psychosocial support.

D. Semi-structured interviews

Six women were interviewed to explore gynaecological cancer survivors' individual needs and to what extent the women experienced that their needs were fulfilled in the current follow-up program. Women were eligible if they were aged $\geq$18 years, attended follow-up visits at the hospital after surgical treatment for gynaecological cancer, had no known recurrence and were able to