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LETTER TO THE EDITOR

SystematiC nurse-led cONsultations based oN Electronic patient-reported outcome among women with ovarian- or endometrial Cancer during chemoTherapy – protocol for the CONNECT study

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Introduction

In 2018, nearly 680,000 women were diagnosed globally with endometrial-, and ovarian cancer [1]. The standard of care for women with early-stage ovarian cancer (Stage IA–IIIB) is primary debulking surgery followed by three-weekly chemotherapy with carboplatin plus paclitaxel [2]. In some cases, patients with advanced ovarian cancer (Stage IIIC–IV) are considered for neoadjuvant chemotherapy [3]. Among women with endometrial cancer, staging and treatment are mainly surgical, and in some cases followed by adjuvant radiation and chemotherapy [4,5]. However, new treatment options are rapidly evolving [6,7].

During chemotherapy, the women experience multiple diseases- and treatment-related symptoms [8–10] resulting in decreased levels of health-related quality of life (HRQoL) and causing an increased psychological burden [11,12]. Chemotherapy is often administered in an outpatient setting, resulting in patients managing their disease, symptoms, and side effects at home between treatment cycles while being at a physical distance from healthcare professionals [13]. Meanwhile, between the three-weekly scheduled appointments at the hospital, patients may have difficulties in recalling the symptoms [14,15]. Further, it is well-known that health care professionals tend to underestimate patients' symptomatic adverse events, causing symptoms unidentified [16,17].

In clinical practice, a profound symptom assessment and evidence-based management often require well-planned multidisciplinary collaboration, and specialised oncology nurses play a significant role in the management of chemotherapy-related side effects and symptoms [18–20]. Nurse-led consultations in cancer care are feasible [21] and nurses may even report treatment-related toxicities more accurately than physician-led consultations ensuring optimal patient care and safety [22]. Patient-reported outcome (PRO) has been introduced as a tool that can provide a systematic and direct measurement of the patients' symptoms and contributes with a systematic method increasing patient involvement and quality of cancer care [23]. The use of PRO in clinical oncological practice can improve patient-clinician communication, clinicians' alertness to symptoms, symptom management, patient satisfaction, HRQoL, and overall survival [24–27]. A recent study [28] shows that the combination of patient self-reported electronic PRO (ePRO) during chemotherapy in combination with guidance on self-management strategies and the use of clinical algorithms for management can improve physical wellbeing and self-efficacy. Further, ePRO tools have also proven feasible among fragile and comorbid cancer patients [29]. Finally, ePRO can deliver cost-effectively appropriate and continuous symptom monitoring and empowers clinicians to identify unmet needs, thus guiding optimal symptom interventions [30].

Within gynaecological cancer a PRO measure: measure of ovarian symptoms and treatment (MOST) has been developed and validated to assess patient-reported benefits and burden in clinical trials of palliative chemotherapy for women with recurrent ovarian cancer [31,32]. Furthermore, the use of PRO in follow-up care has been tested among women with ovarian cancer [33] and ePRO is currently being tested during follow-up in Australia [34]. To the best of our knowledge, this study protocol is the first to investigate ePRO among women with ovarian and endometrial cancer in combination with serial and systematic nurse-led consultations during active treatment. We hypothesise that ePRO-based nurse-led consultations will be feasible, safe and improve symptom identification and self-efficacy, reduce anxiety and depressive symptoms and maintain HRQoL among women with ovarian and endometrial cancer receiving chemotherapy. Therefore, this study aims to develop a model for systematic nurse-led consultations based on ePRO facilitating symptom management and to examine whether

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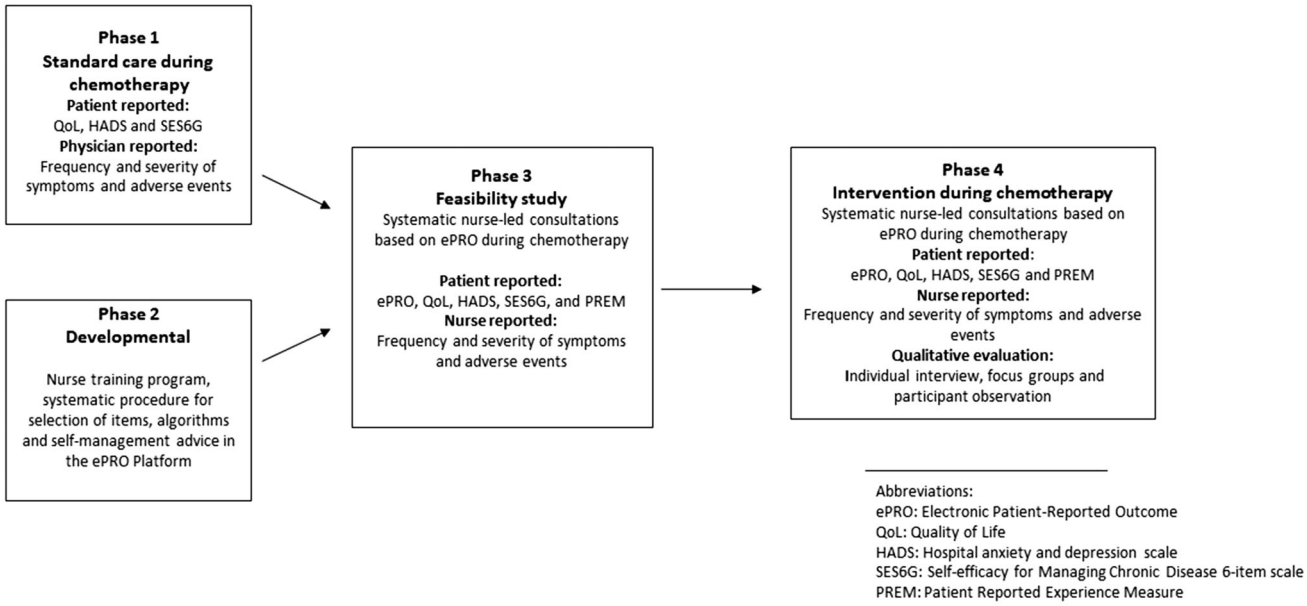

Figure 1. Study design.

nurse-led consultations can be integrated into a multidisciplinary treatment regimen for women with ovarian and endometrial cancer receiving chemotherapy.

Material and methods

Design

This study is a prospective quasi-experimental, four-phase sequential cohort research design with comparisons between non-equivalent groups (Figure 1), an underutilised design within gynaecologic oncology research [35]. This study will be carried out as a single-centre study at the Department of Oncology, Copenhagen University Hospital, Denmark. This protocol is prepared following the SPIRIT-PRO guidelines [36,37].

Patients

Women $\geq$18 years with a diagnosis of the ovarian, fallopian tube, peritoneal, and endometrial cancer, scheduled to receive chemotherapy (Docetaxel/Paclitaxel, Carboplatin ± Bevacizumab) and able to understand, read, and speak Danish are eligible to participate. Women with a severe cognitive deficit or psychiatric disease are considered ineligible.

Recruitment procedure

The patients will be informed about the aim of this study by their treating physician or nurse. The primary researcher will then provide the patient with verbal and written information and patients must give written informed consent by which they can withdraw at any time. The recruitment will take place from May 2021 to November 2023 and a screening log will be held [38].

Study phases

The patients recruited in Phase 1 receive standard care including clinical assessment of the patient's side effects and symptoms, physician grading of adverse events as described by Common Terminology Criteria for Adverse Events symptomatic adverse events (CTCAE) [39] every three weeks before chemotherapy. The CTCAE toxicity score is an objective grading of oncological adverse events conducted by the physician in standard care or the specialised nurses in the intervention group [40]. During the treatment course, the patients have scheduled outpatient visits every three weeks before chemotherapy resulting in a total of approximately six months of active treatment followed by the individual follow-up [41,42].

Phase 2 is the developmental phase and an educational programme and the concept of the systematic nurse-led consultations inspired by the evidence-based PEPPA framework will be developed [43]. In the ePRO platform powered by Kaiku Health Ltd. (Helsinki, Finland) [44], self-management advice and algorithms will be developed based on existing experience [45]. Further, the selection of the cancer-specific ovarian and endometrial items to be represented in the ePRO platform will be selected following a literature search, involvement of patients, and focus group interviews with healthcare experts, and with inspiration from similar research [46,47]. The items will be selected from the Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) which is patient-centred complementation to CTCAE already translated and validated into Danish [48,49].

Phase 3 will be a feasibility study testing the systematic nurse-led consultations based on ePRO. The patients will respond to the ePRO at baseline, weekly during chemotherapy until treatment completion at six months and it will be mandatory that the nurses review and include the ePRO response in the consultation. Patient care will be facilitated

by specialised nurses who will grade adverse events according to CTCAE [39].

In Phase 4, we will estimate the effect of systematic nurse-led consultations based on ePRO during chemotherapy compared to the results from standard care compiled in Phase 1.

Primary objective and endpoints

The primary outcome is the difference in overall global HRQOL measured by EORTC QLQ C-30 from baseline to 9 months. Secondary and explorative outcomes are frequency and severity of the physician/nurse CTCAE toxicity score [39], frequency of patients' symptoms of anxiety and depression, and self-efficacy.

Measurements

The patients in Phase 1, 3, and 4 will complete questionnaires at baseline, 3, 6, and 9 months (Table 1). The patients can respond to the questionnaires either via a secure encrypted database REDCap [50] or paper-based, according to the patients' preferences. The patients will complete demographic data at baseline and data on tumour type, histology, stage, and treatment will be collected from the medical journals and will be stored in REDCap [50].

The following questionnaires will be collected for research purposes and the answers are not available for other than the researchers [33]. HRQoL is measured by the generic European Organization for Research and Treatment of Cancer (EORTC QLQ C- 30) [51]. EORTC QLQ-C30 is validated and consists of five functional scales (physical, role, cognitive, emotional, and social functioning); nine symptom scales (fatigue, nausea/vomiting, pain, dyspnoea, sleeping disturbances, appetite-loss, constipation, diarrhoea, and financial impact) and a global scale [51]. The scoring system is according to the EORTC guidelines and comprises a score range from 0 to 100 points [51]. The ovarian-specific supplement EORTC QLQ OV28 consists of 28 items and measures abdominal/gastrointestinal symptoms, peripheral neuropathy, other chemotherapy side-effects, hormonal/menopausal symptoms, body image, attitude to disease/treatment, and sexual functioning [52]. The endometrial-specific supplement EORTC QLQ-EN24 consists of 24 items and measures lymphoedema, urological symptoms, gastrointestinal symptoms, body image, sexual/vaginal problems and functioning, back/pelvic pain, tingling/numbness, muscular/joint pain, hair loss, taste change, sexual interest, sexual activity, and sexual enjoyment [53].

Anxiety and depressive symptoms will be measured by the Hospital Anxiety and Depression scale (HADS) [54]. HADS is a validated screening tool and includes 14 questions regarding anxiety and depressive symptoms with seven items each in the previous seven days [54]. Self-efficacy is measured by the Self-Efficacy for Managing Chronic Disease 6-Item Scale (SES6G) on a 10-point Likert Scale [55]. Additionally, the patients in Phases 3 and 4 will complete The Patient Feedback Form (PREM) consisting of 13 items to measure the level of patient satisfaction with the ePRO [56].

Experiences will be explored within a subgroup of patients in Phases 3 or 4 with individual interviews regarding the use of ePRO, evaluation of nurse-led consultations, symptom-management strategies, needs, and satisfaction. Furthermore, we will conduct two focus group interviews with physicians and nurses exploring the changing roles and workflows, the use of ePRO, and implications for future practice. The interview guide for both individual and focus group interviews will be based on inspiration from the existing literature. Lastly, the primary researcher will conduct participant observation where the nurse-led consultations will be observed to investigate the cultural context, interactions, and behaviours. The interviews and observational data will be analysed based on the six steps in the reflexive thematic analysis as outlined by Braun and Clarke [57,58].

Sample size calculation

The primary outcome is the difference in global HRQOL (QLQ C-30) from baseline to 9 months. Based on a similar group of patients we estimate that the standard deviation (SD) for

Table 1. Study assessment times and measures.

	Data collection	Baseline	3 months	6 months	9 months
All patients (usual care and ePRO group)	Informed consent	◯			
	Demographic data[a]	◯			
	EORTC QLQ-C30[b]	◯	◯	◯	◯
	EORTC QLQ-OV28[c]/EORTC QLQ-EN24[d]	◯	◯	◯	◯
	HADS[e]	◯	◯	◯	◯
	SES6G[f]	◯	◯	◯	◯
Physicians (usual care)	CTCAE[g] (every three weeks before chemotherapy)	◯	◯	◯	◯
Patients in the ePRO group	ePRO[h] (weekly)	◯	◯	◯	
Patients in the ePRO group	PREMi[i]			◯	
Nurses (ePRO group)	CTCAE[g] (every three weeks before chemotherapy)	◯	◯	◯	

[a]Demographic data (marital and family status, educational level, and occupation);
[b]EORTC QLQ-C30: European Organization for Research and Treatment of Quality of life;
[c]EORTC QLQ-COV28: European Organization for Research and Treatment of Quality of life- Ovarian module;
[d]EORTC QLQ-EN24: European Organization for Research and Treatment of Quality of life- Endometrial module;
[e]HADS: Hospital anxiety and depression scale;
[f]SES6G: Self-efficacy for Managing Chronic Disease 6-item scale;
[g]CTCAE: The Common Terminology Criteria of Adverse Events;
[h]ePRO: Electronic Patient-Reported Outcome;
[i]PREM: Patient-Reported Experience Measure.

changes of HRQoL is approximately 15 [59]. Based on a two-sample t-test at level 0.05, patients in each group are required to obtain a power of 0.8 for detecting a difference of 10 between changes of HRQoL in the two groups. To account for an estimated drop-out rate of 10% we aim at including ($n = 41$) patients in each group.

Statistical analysis

Statistical analyses will include multiple linear regression analysis, t-test, analysis of covariance, and descriptive of the QLQ C-30 domains. In the ePRO module correlations of diverse patient-reported symptoms will be analysed using heat maps, as inspired by Iivanainen et al. [45]. Paired t-tests will be used to compare the means for the two groups and p values $< .05$ are considered statistically significant. Endpoints in the feasibility study in Phase 3 will be recruitment rate, attrition, safety, and response rate.

Patient involvement in the research process

Patient involvement is essential to ensure patient-centeredness [60]. A patient advisory board consisting of women with a history of ovarian- or endometrial cancer ($n = 9$) has been recruited through a closed online network group under auspices of the Danish patient association for women with gynaecological cancer (Kraeft I Underlivet). The patient advisory board is based on volunteering and the board is engaged in the entire research process from preparation to dissemination and application of the findings. The patient board contributes with feedback on written materials, development of the research, and capturing the patients' voices and perspectives.

Ethical approval

The study follows the Declaration of Helsinki and is registered at the Danish Data Protection Agency (Jr. nr. P-2021-179) and the Danish Research Ethics Committee (jr. nr. H-20075652).

Conclusion

This study will contribute with new knowledge as it tests ePRO based nurse-led consultations for women with ovarian- or endometrial cancer during chemotherapy. This study will deliver important information on the patients' quality of life, levels of anxiety and depressive symptoms, and self-efficacy. We assume that the use of proactive ePRO in the nurse-led consultations will contribute to better symptom management, enhanced self-management, and an improved CONNECTion between patients and healthcare professionals.

Study registration

ClinicalTrials.gov Identifier: NCT04945187.

Disclosure statement

The authors report there are no competing interests to declare.

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