EFFECTIVENESS OF A MULTIDIMENSIONAL MOBILE APP INTERVENTION "WOMAN-PRO III" TO REDUCE POSTSURGICAL SYMPTOM INDUCED DISTRESS IN PATIENTS WITH VULVAR NEOPLASIA: A MIXED METHODS PROJECT

Project summary

Background: Despite great advances in surgical therapy in the last decades, symptom relief for women with vulvar neoplasia (vulvar cancer and pre-stage of vulvar cancer) is still not optimal. Guidelines of the National Comprehensive Cancer Network recommend using electronic communication media, e.g. applications ("apps") to relieve symptom distress and foster self-management.

Aims: The aim of this project is to examine the effectiveness of a multidimensional mobile app intervention ("WOMAN-PRO III") to reduce postsurgical symptom induced distress in women with vulvar neoplasia as a rare and stigmatized condition with social taboos.

Design: We will use an explanatory sequential mixed-methods design in two phases (Creswell, 2011) to evaluate the effectiveness of the new mobile app intervention ("WOMAN-PRO III").

Methods: In phase 1, a randomized controlled phase III trial will be conducted with patients (n=100) from four hospitals (three Swiss hospitals, one Austrian). Patients will be randomly assigned (1:1 ratio) to control and intervention group. The standardized care group (control) will be provided with usual care and a set of brochures about supportive care options during the hospital stay and routine follow-up consultations. The mobile app intervention group ("WOMAN-PRO III") (intervention) will receive – additionally to standardized care – three counselling sessions with a gynaecologic-oncology nurse and will use an app ("Symptom diary plus") for a period of six months. The app includes the "WOMAN-PRO" symptom diary, disease and treatment-related information, evidence-based recommendations, relevant contact data including telephone numbers and a chat function with peers.

The primary outcome of the RCT will be *symptom induced distress*. Secondary outcomes will include *uncertainty* and *cost-effectiveness*. Quantitative data of the RCT will be collected at three defined points of time: diagnosis/before surgical intervention (t_0), day seven after surgery (t_1) and month six after surgery (t_2). In phase 2, qualitative interviews with women of the intervention group will be conducted to explore the mobile app intervention's ("WOMAN PRO III") acceptability, usability, strengths and weaknesses.

Project significance: This research will add new knowledge on effects of mobile app interventions in gynaecological oncology, especially with regard to reduction of symptom induced distress and improvement of uncertainty in a stigmatized disease like VIN/VC. Results will give insights if mobile app interventions are able to break anonymity and ease communication between patients and healthcare providers.