Items from the World Health Organization Trial Registration Data Set

Data category	Information
Primary registry and trial identifying number	ClinicalTrials.gov NCT04122235
Date of registration in primary registry	09.02.2019
Secondary identifying numbers	REC 2019/11093
Source(s) of monetary or material support	The Norwegian Cancer Association The UNI foundation The South-Eastern Norway Regional Health Authorities The funding sources had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results
Primary sponsor	Hospital of Southern Norway The sponsor had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results
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Contact for scientific queries	Ingvild Vistad MD, Hospital of Southern Norway
Public title	The LETSGO study
Scientific title	Lifestyle and Empowerment Techniques in Survivorship of Gynecologic Oncology (LETSGO study). A multicenter longitudinal intervention study using mobile health technology and biobanking.
Countries of recruitment	Norway
Health condition(s) or problem(s) studied	Follow-up of gynecological cancer patients
Intervention(s)	Partly nurse-led follow up with an emphasis on self-management and physical activity versus traditional follow-up
Key inclusion and exclusion criteria	Inclusion criteria: (1)histologically verified cervical cancer (restricted to squamous cell carcinoma, adenocarcinoma, or adenosquamous carcinoma), endometrial cancer, ovarian cancer (restricted to epithelial type), or vulvar cancer; (2) scheduled for follow-up after completed primary standard treatment; (3) able to complete patient-reported outcome measures independently in Norwegian; (4) ≥ 18 years; and (5) able to provide informed consent. Exclusion criteria: (1) participation in a clinical treatment trial; (2) ongoing intravenous maintenance treatment (e.g., bevacizumab); (3) cervical cancer patients treated with trachelectomy.
Study type	Quasi-experimental multicenter clinical study with intervention hospitals and control hospitals
Date of first enrolment	November 2019
Target sample size	754
Recruitment status	Recruiting
Primary outcome(s)	Patient empowerment
Key secondary outcomes	Health-related QoL; physical activity; health economy; changes in biomarkers

Protocol version

Date	Original
12.02.19	Amendment #1 Added one investigator.
14.09.19	Amendment #2 Correction of typographical errors in tables
09.10.19	Amendment #3 Blood tests at recurrences. Specification of inclusion/exclusion criteria (patients on *intravenous maintenance therapy* cannot be included)
22.10.19	Amendment #4 More detailed information on budget
30.10.19	Amendment #5 Outcome regarding biomarkers moved from secondary to tertiary outcome
06.11.19	Amendment #6 Correction of typographical errors
09.12.20	Amendment #7 Enrollment date adjusted. Removed Erythrocyte sedimentation rate from the blood tests. Emphasized that the LETSGO-app will not be uninstalled in low-risk group at 12 months. Sexuality added as secondary outcome. Added information on questionnaires used for evaluating physical activity, fear of recurrence of cancer and sexuality.