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FoRSHE-X digital health intervention to improve quality of life during chemotherapy among gynecological cancer survivors in Indonesia: pilot and feasibility study

Submission date
29/02/2024

Recruitment status
No longer recruiting

Registration date
11/03/2024

Overall study status
Completed

Last Edited
19/12/2024

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims

It is estimated that ten million cancer-related deaths occurred in 2020. Low- and middle-income countries (LMICs) have a higher burden of cancer with more than 70% cancer-related fatalities. In the case of cervical cancer, the disparity is even more prominent, as 90% of new cases and deaths happened in LMICs. Given the immense cancer concerns in many LMICs, reducing premature death through promoting well-being has been listed as one of the targets of the Sustainable Development Goals (SDG). It is crucial to increase the country's capacity to provide quality care across the cancer care continuum, including survivorship care. As most Indonesian gynecological cancer survivors have unmet supportive care needs which may lower their quality of life and discontinue the treatment, digital interventions can solve cancer survivors' unmet needs for health information and physical and psychosocial support during chemotherapy. Digital health interventions can enhance communication between cancer patients and healthcare providers. Therefore, this study aims to (1) examine the feasibility and acceptability of a Fighting on distRess, Self-efficacy, Health Effects, and seXual issues (FoRSHE-X) intervention, and to (2) evaluate the impact of the study implementation on the level of distress, self-efficacy, side effects' knowledge and management, and sexual quality of life.

Who can participate?

Women, aged 18 years old or older, diagnosed with gynecological cancer undergoing chemotherapy in the Dharmais National Cancer Centre (DNCC), Jakarta, Indonesia, who are willing to participate in the FoRSHE-X intervention consisting of 10 weeks of social media-based education and tele-coaching program.

What does the study involve?

The researchers invite potential participants to be involved in this study while they are at the outpatient clinic or in the chemotherapy ward. If they fulfil the eligibility criteria to be part of this study, they are included in the information session at the DNC or through a Zoom meeting, in which they complete the online questionnaires and receive an explanation about the social-

media educational product (uploaded to the project Instagram and YouTube channel) and how tele-education and tele-coaching are performed in the next 10 weeks. After that, the participants attend individual tele-education and tele-coaching programs every week through Zoom or WhatsApp meetings in line with their chemotherapy program. In the middle and at the end of the study period, the participants re-complete the questionnaire and interview for study continuity and acceptability.

What are the possible benefits and risks of participating?
The study will support and accompany the participants to pass through the challenging chemotherapy time. It is expected that with adequate support all the participants can accomplish their cancer therapy. Moreover, the participants will receive an internet data plan worth IDR 100,000 per month for the 2.5-month duration of the research activities. They will also receive a compensation of IDR 100,000 at the end of the FoRSHE-X digital intervention to offset the time spent participating in this study. The participants who will also be interviewed after the provision of digital education and tele-coaching will receive IDR 100,000 as compensation for transportation and time used during the interview process.

Where is the study run from?
1. Universitas Indonesia (Indonesia)
2. Dharmais National Cancer Centre (DNCC) (Indonesia)

When is the study starting and how long is it expected to run for?
March 2023 to December 2024

Who is funding the study?
Direktorat Riset and Pengembangan, Universitas Indonesia (Grant number: NKB-343/UN2.RST /HKP.05.00/2023) (Indonesia)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NKB-343/UN2.RST/HKP.05.00/2023

Study information

Scientific Title
The development of FoRSHE-X digital intervention (education and tele-coaching) to improve the quality of life of gynecological cancer patients: pilot and feasibility study

Acronym
FoRSHE-X

Study objectives
The primary objectives are as follows
1. To examine the eligibility and acceptability of the participants towards the study intervention
2. To evaluate the feasibility of digital education, telecoaching, and intervention facilitators
3. To evaluate the process of the implementation
4. To evaluate the intervention sustainability or participants' involvement over time

The secondary objective is to evaluate the effectiveness of the study intervention on the participants':
1. Level of anxiety

2. Self-efficacy
3. Side effects' knowledge and management
4. Sexual quality of life

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 08/08/2023, The Committee of the Medical Research Ethics of the Dharmais Cancer Hospital (Jalan Letjen S. Parman Kav. 84-86, Slipi, Jakarta, 11420, Indonesia; +62 (0)21 5681570; dharmais@dharmais.co.id), ref: 259/KEPK/VIII/2023

2. approved 23/05/2023, FIK UI (Faculty of Nursing, Universitas Indonesia) Ethics Committee (UI campus, Depok, 16424, Indonesia; +62 (0)21 788 49 120; publicrelation-nursing@ui.ac.id), ref: KET-136/UN2.F12.D1.2.1/PPM.00.02/2023

Study design
Non-randomized mixed-methods (quasi-experimental single-group pretest-posttest design and semi-structured interview qualitative study)

Primary study design
Interventional

Study type(s)
Quality of life, Efficacy

Health condition(s) or problem(s) studied
Gynecological cancer survivors on chemotherapy

Interventions
Tele-coaching and tele-education: the FoRSHE-X intervention consists of 10 weeks of social media-based education and telecoaching.

Intervention Type
Behavioural

Primary outcome(s)
1. Recruitment rate: the number of eligible/potential participants who accept the invitation to participate in the study and sign the consent to participate in the study for at least a 10-week period.
2. Response rate: the participants' complete responses to the questionnaire at baseline or pre-intervention time (T0), in the middle of the intervention period or at the end of working phase I (T1) and at the end of working phase II or at the end of the overall study period (T2).
3. Participation rate: the number of participant attendances in social-media educational and tele-coaching activities over the 10-week period.
4. Facilitators' satisfaction and barriers were explored using semi-structured interviews at the end of the study period or after all digital health interventions were delivered to the participants.
5. Participant satisfaction rates measured using a study instrument adapted from the Telehealth Satisfaction Survey by AHRQ, U.S. Department of Health & Human Services at the end of the 10-week study period of telehealth interventions.

6. Attrition rate analyzed as the rate of participant retention till the end of the 10-week study period.
7. Qualitatively, participants will be interviewed for their perspectives on intervention adherence, barriers, and acceptability of the recruitment processes, intervention design, and outcome measurements at the end of the study.

Key secondary outcome(s))
1. Sociodemographic data of the participants (i.e. age, education, marital status, employment, ethnicity, and religious affiliation) and clinical data (i.e. gynecological cancer type and stage, and cancer treatment details) assessed at the beginning of the study period.
2. Distress measured using a Distress Thermometer from the NCCN Distress Management Panel at baseline or pre-intervention time (T0), in the middle of the intervention period or at the end of working phase I (T1) and at the end of working phase II or at the end of the overall study period (T2).
3. Knowledge and practice regarding chemotherapy side effects are measured using the chemotherapy side effect questionnaire, outlined by Almohammadi, et al. (2020), at baseline or pre-intervention time (T0), in the middle of the intervention period or at the end of working phase I (T1) and at the end of working phase II or at the end of the overall study period (T2).
4. Self-efficacy is measured using the self-efficacy for managing chronic disease 6-item scale (SEMCD6) initially developed by the Stanford Patient Education Research Center at baseline or pre-intervention time (T0), in the middle of the intervention period or at the end of working phase I (T1) and at the end of working phase II or at the end of the overall study period (T2).
5. Sexual quality of life (SQoL-F) is measured using Sexual Quality of Life-Female (SQOL-F) at baseline or pre-intervention time (T0), in the middle of the intervention period or at the end of working phase I (T1) and at the end of working phase II or at the end of the overall study period (T2).

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. Female aged 18 years or older
2. Being diagnosed with gynecological cancer (including cervical, ovarian, uterine, vulvar, vaginal, and fallopian tube cancer)
3. Receiving chemotherapy at the DNCC
4. Having a smartphone
5. Willing and physically or cognitively able to participate in the study and follow the study procedures
6. Being able to communicate in Bahasa Indonesia

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
19

Key exclusion criteria
Patients diagnosed with severe neurological conditions such as unmanaged mental health diagnosis, current metastases to the brain, delirium, and dementia, as well as those with any prior history of receiving chemotherapy or cancer recurrence.

Date of first enrolment
10/10/2023

Date of final enrolment
09/06/2024

Locations

Countries of recruitment
Indonesia

Study participating centre
Dharmais Cancer Hospital
Jl. Letjen S. Parman Kav. 84-86 Slipi
Jakarta
Indonesia
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Sponsor information

Organisation
University of Indonesia

ROR
https://ror.org/0116zj450

Funder(s)

Funder type

Government

Funder Name
Direktorat Riset and Pengembangan, Universitas Indonesia

Alternative Name(s)
Directorate of Research and Development, Directorate of Research and Development of the University of Indonesia, R&D Directorate, Directorate of Research and Community Engagements Universitas Indonesia, Directorate of Research and Community Engagement UI, Directorate for Research and Development - Universitas Indonesia, Direktorat Riset & Pengembangan, Risbang, Risbang UI, Directorate of Research and Community Engagement UI, Direktorat Riset dan Pengabdian Masyarakat UI, DRPM UI

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
Indonesia

Results and Publications

Individual participant data (IPD) sharing plan
Not available, unless anonymous data inside the publication

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		18/12/2024	19/12/2024	Yes	No
Participant information sheet			08/03/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol (preprint)		22/02/2024	08/03/2024	No	No