

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 11/03/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/12/2024	Condition category Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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 distRes, 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 Dharmas 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. Dharmas 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

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

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

Secondary study design

Semi-structured interview qualitative phenomenology study

Study setting(s)

Hospital, Internet/virtual

Study type(s)

Quality of life, Efficacy

Participant information sheet

See study outputs table

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 measure

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.

Secondary outcome measures

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).

Overall study start date

31/03/2023

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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

30

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**

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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

Publication and dissemination plan

- 1. Publication of the protocol in PLOS ONE
- 2. Publication of the results in Scopus-indexed journal

Intention to publish date

01/08/2024

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?
Participant information sheet			08/03/2024	No	Yes
Protocol (preprint)		22/02/2024	08/03/2024	No	No
Protocol article		18/12/2024	19/12/2024	Yes	No