ISRCTN13311651 https://doi.org/10.1186/ISRCTN13311651

# 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
[X] 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?
1. Prof. Dr. Yati Afiyanti, yatikris@ui.ac.id
2. Dr Dyah Juliastuti, dyah_ja@universitasichsansatya.ac.id

# Contact information

### Type(s)
Principal Investigator

### Contact name
Prof Yati Afiyanti

### ORCID ID
https://orcid.org/0000-0001-9382-6714

### Contact details
Faculty of Nursing
Universitas Indonesia
Depok
Indonesia
16424
+62 (0)813 1549 3320
yatikris@ui.ac.id

### Type(s)
Public, Scientific


### Contact name
Dr Dyah Juliastuti

### ORCID ID
https://orcid.org/0000-0002-4159-9166

### Contact details
Program Study of Nursing
Faculty of Health Sciences
Universitas Ichsan Satya
Tangerang Selatan
Indonesia
15414
+62 (0)852 1805 2224
dyah_ja@universitasichsansatya.ac.id


## 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**
Jl. Letjen S. Parman Kav. 84-86 Slipi
Jakarta
Indonesia
11420

# Sponsor information

### Organisation
University of Indonesia

### Sponsor details
Gedung Pusat administrasi Universitas
Kampus Universitas Indonesia
Depok
Indonesia
16424
+62 (0)21 7867 222
pusadmui@ui.ac.id

### Sponsor type
University/education

### Website
http://www.ui.ac.id/

### 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

### 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 |