

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The Effect of a Telenursing Program on Self-Management of Gastrointestinal Symptoms in Adolescent with Cancer Undergoing Chemotherapy

Protocol summary

Self-management of gastrointestinal symptoms

Study aim

Determining the effect of a telenursing program on the self-management of gastrointestinal symptoms in adolescents with cancer undergoing chemotherapy

Design

Clinical trial with control group, intervention group, randomized, on 66 patients. The data collected from all three stages will be analyzed using statistical analysis of variance tests in SPSS software.

Settings and conduct

After obtaining a written permission from Shahid Beheshti School of Nursing and Midwifery and Graduate Education Management, the student goes to the selected hospitals in Tehran with a letter of introduction and necessary permits for sampling. Then he will enter the research environment by introducing himself and explaining the objectives of the research and the steps of the work, with the approval of the authorities.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. The age of teenagers should be between 12-18 years. 2. Adolescents with leukemia, lymphoma, osteosarcoma and glioma cancer. 3. Adolescents have undergone chemotherapy at least once. 4. Have the ability to take care of themselves. 5. Have access to the Internet and an electronic device (computer, laptop, mobile phone and tablet). 6. Be fluent in Persian language and have the ability to answer the questionnaire questions. Exclusion criteria: 1. Fill out the questionnaire incompletely. 2. During chemotherapy, the patient becomes ill and needs hospitalization. 3. During the treatment, due to the patient's condition, it is necessary to be transferred to another center.

Intervention groups

The intervention is planned in six sessions and the duration of each session will be 45 to 60 minutes. Then the data collected from all three stages will be analyzed.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161024030474N6**

Registration date: **2023-06-21, 1402/03/31**

Registration timing: **registered_while_recruiting**

Last update: **2023-06-21, 1402/03/31**

Update count: **0**

Registration date

2023-06-21, 1402/03/31

Registrant information

Name

Azam Shirinabadi Farahani

Name of organization / entity

School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21886553668

Email address

farahani1381@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-20, 1402/03/30

Expected recruitment end date

2023-09-16, 1402/06/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of a Telenursing Program on Self-Management of Gastrointestinal Symptoms in Adolescent with Cancer Undergoing Chemotherapy

Public title

The Effect of a Telenursing Program on Self-Management of Gastrointestinal Symptoms in Adolescent with Cancer Undergoing Chemotherapy

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Adolescents with leukemia, lymphoma, osteosarcoma and glioma. Adolescents should be between 12-18 years old. Adolescents have undergone chemotherapy at least once. Have the ability to take care of themselves. Having access to the Internet and an electronic device (computer, laptop, mobile phone and tablet). Be fluent in Persian language and have the ability to answer the questionnaire questions.

Exclusion criteria:

Fill out the questionnaire incompletely. During chemotherapy, the patient becomes ill and needs to be hospitalized. During the treatment, due to the patient's condition, it is necessary to be transferred to another center.

Age

From **12 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Complex permuted-block randomization method was used for randomization. In addition to establishing a balance in the number of people between the two groups, this method will prevent any prediction in order to determine the intervention sequence. The random sequence of blocks will be obtained through STATA software. In this study, 11 blocks of 6 are selected. The first block will be randomly selected and the next blocks will be selected sequentially from the first random selection. There are three people in the intervention group and three people in the control group in each block.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee in Research Schools of Pharmacy, Nursing and Midwifery Shahid Beheshti University

Street address

Shahid Behesht School of Nursing and Midwifery-near Niayesh crossroads - Valiasr St

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2023-02-14, 1401/11/25

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1401.244

Health conditions studied**1****Description of health condition studied**

cancer

ICD-10 code

Z85.7

ICD-10 code description

Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues

Primary outcomes**1****Description**

Self-management of gastrointestinal symptoms caused by chemotherapy

Timepoint

Before the intervention, immediately after the intervention, 1 month after the intervention

Method of measurement

The self-management questionnaire of gastrointestinal symptoms in adolescents was developed by the researcher

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention is planned in six sessions and the duration of each session will be 45 to 60 minutes. In the first session, familiarization with the patients is taken before the test. In the second session, an explanation is given about cancer chemotherapy and side effects of the intervention group. In the third, fourth, and fifth sessions, nursing care is given for diarrhea, constipation, nausea, and vomiting, and in the sixth session, post-test, answering questions and reviewing materials, and after one month after the tool intervention, again It will be completed by all patients. Then the data collected from all three stages will be analyzed.

Category

Other

2

Description

Control group: There is no intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hossein Hospital

Full name of responsible person

Dr. Mozghan Hashemieh

Street address

Imam Hossein (AS) Medical Research Training Center., Shahid Madani St., Tehran.

City

Tehran

Province

Tehran

Postal code

1185817311

Phone

+98 21 7343 3000

Email

info@sbmu.ac.ir

2

Recruitment center

Name of recruitment center

Tajrish Shohadaye Hospital

Full name of responsible person

Dr. Farideh Mosavi

Street address

Tajrish Shohadaye Educational Medical Center., Shahadati St., Tajrish Square., Tehran.

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 2271 8000

Email

pr-shohada@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

Street address

Shahid Beheshti University of Medical Sciences, next to Taleghani hospital, Yaman Street, Shahid Chamran highway.

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2243 9780

Email

farahani1381@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azam Shirinabadi Farahani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Shahid Behesht School of Nursing and Midwifery-near
Niayesh crossroads - Valiasr St

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21886553668

Fax

+98 21 8820 2518

Email

farahani1381@sbm.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azam Shirinabadi Farahani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Shahid Behesht School of Nursing and Midwifery-near
Niayesh crossroads - Valiasr St

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21886553668

Fax

+98 21 8820 2518

Email

farahani1381@sbm.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azam Shirinabadi Farahani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Shahid Behesht School of Nursing and Midwifery-near
Niayesh crossroads - Valiasr St

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21886553668

Fax

+98 21 8820 2518

Email

farahani1381@sbm.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The Effect of a Telenursing Program on Self-Management of Gastrointestinal Symptoms in Adolescent with Cancer Undergoing Chemotherapy

When the data will become available and for how long

Immediately after the publication of the article

To whom data/document is available

Research team

Under which criteria data/document could be used

After call with corresponding author

From where data/document is obtainable

farahani1381@sbm.ac.ir

What processes are involved for a request to access data/document

About a month

Comments