

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Effect of supportive care for pain using virtual networks on pain management and quality of life in patients with Gastrointestinal cancer

Protocol summary

Study aim

Determining the effect of pain supportive care program using virtual social network on pain management and quality of life of patients with gastrointestinal cancer

Design

This study is a randomized clinical trial. Participants will be randomly assigned to the intervention and control groups through block randomization technique.

Settings and conduct

The statistical population is all patients with cancer who are referred to Ayatollah Khansari Hospital and Imam Reza Clinic in Arak. For the intervention group, in addition to the section trainings, the trainings are sent as a message on the social network daily. In the control group, only section trainings are used. The instruments used include demographic questionnaire, standard 30-item quality of life questionnaire and the third questionnaire of pain self-management list.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: age ≥ 18 , Individuals with gastrointestinal Cancer diagnosis undergoing treatment, obtaining a score above or above the pain questionnaire, ability to read and write, having a smartphone, access and ability to use virtual social media .

Intervention groups

The participants in the interventional group in addition to the hospital routin education will receive education messages through virtual social network about cancer, signs and symptoms, tratments and its side effects, pain management(taking medications, relaxation techniques, massage therapy, music therapy and...)

Main outcome variables

Gender, age, marital status, level of education, type of treatment, stage of cancer,duration of illness, type of cancer, quality of life, pain management

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220128053848N1**

Registration date: **2022-04-01, 1401/01/12**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-01, 1401/01/12**

Update count: **0**

Registration date

2022-04-01, 1401/01/12

Registrant information

Name

Mitra norbakhsh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3383 8268

Email address

mitranorbakhsh19@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-06-22, 1401/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of supportive care for pain using virtual networks on pain management and quality of life in patients with Gastrointestinal cancer

Public title

Effect of supportive care virtual networks

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over eighteen years
Definitive medical diagnosis of cancer being treated at least 6 months after diagnosis
Get a score average of or above the pain questionnaire
Ability to read and write
Having a smart phone
Access and ability to use and familiarize with the function of social media by the patient or a member of the patient's family

Exclusion criteria:

Patient's unwillingness to cooperate in research

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

This study is a block randomization method in which the randomization unit is performed individually. First, all 70 subjects are collected. In this clinical trial, 8 groups of blocks including 4 participants in the intervention group and 4 participants in the control group are divided into two groups. A random number table is used for randomization.

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 of Arak University of Medical Sciences

Street address

A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak, Markazi Province, Iran

City

Arak

Province

Markazi

Postal code

۳۸۱۹۶۹۳۳۴۰

Approval date

2021-11-10, 1400/08/19

Ethics committee reference number

IR.ARAKMU.REC.1400.192

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

Diseases of the digestive system

ICD-10 code

2D8Y

ICD-10 code description

Malignant neoplasm metastasis in other specified digestive system organ

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

Quality of life in this study
The score obtained by the study participants from the standard questionnaire of 30 questions on quality of life of cancer patients

Timepoint

Before the intervention, one month after the intervention, three months after the intervention

Method of measurement

EORTC Quality of Life Questionnaire

2**Description**

Pain management in this study is the score obtained by the patient from the pain self-management list.

Timepoint

Before the intervention, one month after the intervention, three months after the intervention

Method of measurement

PSMC questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In addition to the hospital routine education, participants in the intervention group, will receive a set of educational messages about cancer, signs and symptoms, treatments and its side effects, pain management, and appropriate strategies to improve quality of life in the form of educational text messages, pictures and videos related to self-care and pain management. They will receive 3-5 messages daily (8

am to 8 pm) for one month. They will ask to send the message" I read the message" after seeing every message and answer the question about the weekly education content. The participants question will answer by researchers.

Category

Behavior

2

Description

Control group: Participants in this group receive hospital routine education.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Khansari Hospital

Full name of responsible person

Mitra Norbakhsh

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the end of University Street, Arak, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Saeed Changizi Ashtiani

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Web page address

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Grant name

Grant code / Reference number

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

No

Title of funding source

Arak medical sciences university, Vice chancellor for research and technology

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

Arak University of Medical Sciences

Full name of responsible person

Mitra Norbakhsh

Position

Master of science student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Nazi Nejat

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Ph.D

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The results of the study will be published as a final report in the library of Arak University of Medical Sciences.

When the data will become available and for how long

The time period for accessing the data is available in September 2022.

To whom data/document is available

Teachers, students, and if the esteemed director of Ayatollah Khansari Hospital agrees, all clients who refer to this hospital can access the data.

Under which criteria data/document could be used

The necessary condition for using scientific data of this plan is that they should be diligent in preserving data and preventing data theft.

From where data/document is obtainable

For documentary access, you can refer to the library of Arak University of Medical Sciences or the library of Ayatollah Khansari Hospital in Arak.

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

You can use this document first by referring to the mentioned libraries and after presenting your ID card and your position.

Comments