Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the Effectiveness of Digital Storytelling by Peers and Routine Treatment on Changes in Self-Efficacy and Rumination in Individuals with Colorectal Cancer.

Protocol summary

Study aim
Determining the impact of peer-delivered digital storytelling on self-efficacy and rumination in patients with colorectal cancer

Design
This is a clinical trial with a control group, featuring parallel groups, single-blind, Non-random allocation , Phase I, conducted on 70 patients.

Settings and conduct
Study Location: The sections of the Cancer Institute at Imam Khomeini Hospital, Tehran; Participants: Individuals with colorectal cancer; Type of Blinding: Single-blind. Due to the potential for intervention leakage, the participants in the control group are sampled first, and after a short pause and the discharge of the last participant in the control group, the participants in the intervention group are sampled.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Individuals aged 18 to 65 years diagnosed with stage I-III colorectal cancer; willingness to participate in the research; proficiency in Persian; ownership and ability to use a smartphone; access to the internet and social media; literacy in reading and writing. Exclusion Criteria: Diagnosis of recurrent or metastatic colorectal cancer; known cognitive or psychiatric disorders as reported by the patient.

Intervention groups
Intervention Group: Participants in the intervention group will be invited to attend storytelling sessions in addition to their routine care. These sessions will consist of four two-hour online meetings with peers, researchers, and a psychologist. Control Group: Participants in the control group will receive standard care, which includes routine self-care education provided by a nurse during care procedures or upon discharge.

Main outcome variables
Self-efficacy; rumination

General information

Reason for update
The expected start date of participant recruitment was updated to align with the study's planned timeline.

Acronym

IRCT registration information
IRCT registration number: **IRCT20241022063461N1**
Registration date: **2025-01-22, 1403/11/03**
Registration timing: **prospective**

Last update: **2025-09-28, 1404/07/06**
Update count: **1**

Registration date
2025-01-22, 1403/11/03

Registrant information

Name
Sajjad Soofi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 81 3256 5624

Email address
s-soofi@razi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-08-23, 1404/06/01

Expected recruitment end date
2025-12-21, 1404/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Effectiveness of Digital Storytelling by Peers and Routine Treatment on Changes in Self-Efficacy and Rumination in Individuals with Colorectal Cancer.

Public title
Digital storytelling in cancer
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Individuals aged 18 to 65 with stage I-III colorectal cancer Willingness to participate in the research Proficiency in the Persian language Possession of and ability to use a smartphone Access to the internet and social media Having at least basic literacy skills (reading and writing)
Exclusion criteria:
Having recurrent or metastatic colorectal cancer Suffering from known cognitive or psychiatric disorders as reported by the patient Suffering from physical disabilities such as blindness or deafness Addiction to drugs, alcohol, or psychoactive substances
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Due to the possibility of intervention leakage, the control group participants will enter the study first, and after a short break and the discharge of the last control group participant, the intervention group participants will enter the study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of School of Nursing and Midwifery & Rehabilitation; Tehran University of
Street address
13th Floor, Block A, Central Headquarters of the Ministry of Health, Treatment and Medical Education, Simaye Iran Street, Between Falamak Jonubi and Zarafshan, Shahrak-e Quds (West), Iran.
City
Tehran
Province
Tehran
Postal code
1467664961
Approval date
2024-10-06, 1403/07/15
Ethics committee reference number
IR.TUMS.FNM.REC.1403.127

Health conditions studied

1

Description of health condition studied
Colorectal cancer
ICD-10 code
C19
ICD-10 code description
Malignant neoplasm of rectosigmoid junction

Primary outcomes

1

Description
The self-efficacy score in the General Self-Efficacy Questionnaire
Timepoint
Pre-test, immediately after, and one month later
Method of measurement
Scherer and Maddux General Self-Efficacy Questionnaire

2

Description
The rumination score in the Nolen-Hoeksema and Morrow Rumination Questionnaire
Timepoint
Pre-test, immediately after, and one month later
Method of measurement
Nolen-Hoeksema and Morrow Rumination Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group: this intervention offers participants, in addition to routine care, the opportunity to participate in digital storytelling sessions aimed at improving self-efficacy and reducing rumination. These sessions will be held weekly over four weeks, focusing on storytelling films created by peers and overseen by specialists. During the sessions, participants will familiarize themselves with group norms and provide feedback on their own and others' experiences, while relevant scientific recommendations will be offered at each session. The meetings will include 14 to 16 participants, peers, a senior researcher, and a psychologist, conducted online at times chosen by the patients .To create digital stories, specific guidelines will be provided to selected individuals, who will be asked to write scenarios based on their experiences. These scenarios will then be reviewed by specialists and transformed into films. The production stages will include identifying images, creating a story flowchart, and combining the final media elements. At the end of the program, transportation costs for peers will be covered, and gifts will be presented as a form of appreciation.

Category
Rehabilitation

2

Description
Control group: They will receive standard care, which includes routine self-care education provided by a nurse during care procedures or at discharge. It is important to note that the control group will be followed up by phone every two weeks to assess if they meet the exit criteria for the study, at which point they may be removed from the study. One month after participating in the research, contact will be made with the research units, and the questionnaires will be completed again.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Cancer Institute of Imam Khomeini Hospital, Tehran

Full name of responsible person
Sajjad Soofi

Street address
Dr. Gharib Street, Keshavarz, Boulevard

City
Tehran

Province
Tehran

Postal code
۱۴۱۹۷۳۳۱۴۱

Phone
+98 21 6658 1625

Email
Imamhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Ali Akbari Sari

Street address
Vice Chancellor for Research and Technology, 6th Floor, Central Administration of the University, Corner of Qods Street, Keshavarz Boulevard

City
Tehran

Province
Tehran

Postal code
1417653761

Phone
+98 21 8163 3698

Email
vcr@sina.tums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Sajjad Soofi

Position
Master's student in Nursing

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
Unit3, Mahestan Complex5, Boustan Alley, Saadi Street, Phase 2, Farhangian Town.

City
Hamadan

Province
Hamadan
Postal code
6519992517
Phone
+98 81 3256 5624
Fax
Email
s-soofi@razi.tums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Sajjad Soofi
Position
Master's student in Nursing
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Unit3, Mahestan Complex5, Boustan Alley, Saadi Street, Phase2, farhangian Town.
City
Hamadan
Province
Hamadan
Postal code
6519992517
Phone
+98 81 3256 5624
Fax
Email
s-soofi@razi.tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Sajjad Soofi
Position
Master's student in Nursing
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Unit3, Mahestan Complex5, Boustan Alley, Saadi Street, Phase 2, Farhangian Town
City
Hamadan
Province
Hamadan
Postal code
6519992517
Phone
+98 81 3256 5624
Fax
Email
s-soofi@razi.tums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not 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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
- Contributors' Data File (All Data) - Clinical Study Report (All Data) - Informed Consent Form (All Data)
When the data will become available and for how long
Access will begin in the Spring of 2025.
To whom data/document is available
Researchers employed in academic and scientific institutions.
Under which criteria data/document could be used
In case of using the data in scientific research
From where data/document is obtainable
Sajjad Soofi sajjadsoofi205@gmail.com
What processes are involved for a request to access data/document
Applicants can submit their requests via email, and a response will be provided within a maximum of 24 hours after receiving the email.
Comments