Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Orem-Based Education on the Care Self-Efficacy of Adolescents Engaging in Non-Suicidal Self-Injury

Protocol summary

Study aim

The Effect of Orem-Based Education on Care Self-Efficacy in Adolescents Engaging in Non-Suicidal Self-Injury

Design

This is a parallel-group, randomized controlled clinical trial with 36 patients. Randomization is performed using SPSS software.

Settings and conduct

Participants were recruited through Ibn Sina Hospital and Imam Reza Clinic and were randomly assigned to the intervention and control groups. Links to the questionnaires were sent to all participants before and after the study. The intervention group received educational content tailored to their physical, social, emotional, and psychological needs in the form of audio and video materials delivered via a social media platform. The control group continued their usual psychological treatments, if any, during the study period and received the educational materials after completion of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: History of self-injurious behavior Living with parents Willingness to participate in the study Parental consent for adolescent participation in the study Exclusion criteria: Presence of Psychotic Disorders in the Adolescent.

Intervention groups

The intervention group consisted of 18 adolescents with self-injurious behavior who received Orem-based self-care intervention tailored to their physical, social, emotional, and psychological needs. The control group included 18 adolescents with self-injurious behavior who continued their usual psychological treatments, if any, during the intervention period, and were provided with the educational materials after completion of the study.

Main outcome variables

Caring self-efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250810066806N1**
Registration date: **2025-08-24, 1404/06/02**
Registration timing: **registered_while_recruiting**

Last update: **2025-08-24, 1404/06/02**
Update count: **0**

Registration date

2025-08-24, 1404/06/02

Registrant information

Name

Elham Mirshah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3738 3895

Email address

mirshah70@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-08-23, 1404/06/01

Expected recruitment end date

2025-09-11, 1404/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Orem-Based Education on the Care Self-Efficacy of Adolescents Engaging in Non-Suicidal Self-Injury

Public title
The Effect of Education on the Care Self-Efficacy of Adolescents Engaging in Non-Suicidal Self-Injury
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
History of Self-Injury Behavior Living with Parents Willingness to Participate in the Study Parental Consent for the Adolescent's Participation in the Study
Exclusion criteria:
Presence of Psychotic Disorders in the Adolescent
Age
From **11 years** old to **20 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
The random sequence was generated by an independent statistician using block randomization with variable block sizes (4 and 6) and stratified by gender in SPSS software. To ensure allocation concealment, the sequence was placed in opaque, sealed, and sequentially numbered envelopes to prevent any prediction of group assignments in advance. Screening and enrollment of eligible participants were conducted by Researcher 1. After completion of the enrollment process and obtaining informed consent, the next envelope in sequence was opened, and group allocation was determined by Researcher 2, after which participants were assigned to the intervention or control groups.
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 Shiraz University of Medical Sciences
Street address
Shiraz, Namazi Square, Entrance of Namazi Hospital, Faculty of Nursing and Midwifery, Hazrat Fatemeh(S)
City
Shiraz
Province
Fars
Postal code
۱۳۱۱۹ - ۷۱۹۳۶
Approval date
2024-06-01, 1403/03/12
Ethics committee reference number
IR.SUMS.NUMIMG.REC.1403.052

Health conditions studied

1

Description of health condition studied
Self-injury
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Care self-efficacy
Timepoint
Pre-intervention and immediately post-intervention
Method of measurement
Questionnaire for Assessing Care Self-Efficacy in Adolescents with Mental Disorders

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The questionnaires will be provided to the study participants via an online link. After completing the questionnaires, participants assigned to the intervention group will be enrolled in a virtual messaging network. Following an orientation session, the prepared educational materials—based on Orem's Self-Care Model in the physical, social, psychological, and emotional domains—will be delivered in the form of video files, podcasts, and narrated PowerPoint presentations, developed by the Virtual Faculty. The materials will be shared with participants at a rate of two files per week over a four-week period.In the physical self-care domain, the training will focus on regular sleep, timely screening, exercise, proper medication use, and healthy nutrition, with the aim of improving the overall well-being of patients.In the emotional self-care domain, which emphasizes the recognition and processing of

emotions in a healthy manner, the goal is to support patients in coping more effectively with life challenges, enhancing resilience, and fostering self-compassion. Topics include mindfulness, journaling, establishing healthy boundaries, and improving emotional communication.In the social self-care domain, with the aim of strengthening the sense of belonging, participants will receive training in areas such as joining groups and associations, active listening, and communication management.In the psychological self-care domain, targeting mental health promotion, the educational content will cover stress management, anger management, positive thinking, and goal setting.For each domain, four video files will be prepared by a specialist and shared with participants through the virtual network. After the four-week intervention, the questionnaires will again be distributed by the researcher to both the intervention and control groups, and the data will be collected for analysis.

Category

Lifestyle

2

Description

Control group: Participants in the control group, after completing the baseline questionnaires, will continue to receive their usual care, such as visits with a psychologist or psychiatrist, if these services are already part of their routine treatment plan. At the end of the intervention period, the post-test questionnaires will be distributed to them via an online link. After data collection is completed, the educational materials provided to the intervention group will also be made available to the control group.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Ibn-e-Sina Hospital

Full name of responsible person

Shahrzad Yektatalab

Street address

Hafez St., Ibn-e-Sina Hospital

City

Shiraz

Province

Fars

Postal code

71466-76541

Phone

+98 71 3228 9601

Email

sinahosp@sums.ac.ir

2

Recruitment center

Name of recruitment center

Imam Reza Clinic

Full name of responsible person

Shahrzad Yektatalab

Street address

Imam Reza Specialized and Subspecialized Clinic, next to Namazi Hospital, Namazi Square, Shiraz, Iran

City

Shiraz

Province

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Postal code

71348-14734

Phone

+98 71 3212 7000

Email

emamreza@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Shahrzad Yektatalab

Street address

Central Building of Shiraz University of Medical Sciences, Zand Street, opposite Palestine Street, Shiraz, Iran

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71348-14336

Phone

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Shahrzad Yektatalab

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Hazrat Fatemeh (S) Faculty of Nursing and Midwifery, at the entrance of Namazi Hospital, Namazi Square, Shiraz, Iran

City
Shiraz

Province
Fars

Postal code
71936-13119

Phone
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Email
nurs_midwif@sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Shahrzad Yektatalab

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Elham Mirshah

Position
Student

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
Hazrat Fatemeh (S) Faculty of Nursing and Midwifery, at the entrance of Namazi Hospital, Namazi Square, Shiraz, Iran

City
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Fars

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Phone
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Email
mirshah70@gmail.com

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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The de-identified individual data collected during the trial, including baseline characteristics and outcome measures, will be available upon reasonable request. No personally identifiable information will be shared. The datasets will be provided in electronic format after de-identification.

When the data will become available and for how long
The access period begins six months after the publication of the results.

To whom data/document is available
Researchers affiliated with scientific institutes and universities

Under which criteria data/document could be used
The data can be utilized for longitudinal and retrospective research purposes.

From where data/document is obtainable
Elham Mirshah Email: mirshah70@gmail.com Hazrat Fatemeh (S) Faculty of Nursing and Midwifery, Namazi Square, Shiraz, Iran

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

The requester can specify the reason and extent of access to the data, state the objectives of their study, and submit the request via email. Within one week after the request is received, the data will be provided if no specific issues exist.

Comments