

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

The effect of FRIENDS educational program on resilience and health related quality of life of adolescents with hemophilia

Protocol summary

Study aim

Determining The effect of FRIENDS educational program on resilience and health related quality of life of adolescents with hemophilia

Design

Clinical trial with control group, with single, randomized groups, 60 patients

Settings and conduct

Approval of the research plan in the university ethics committee. At the beginning of the study, complete the demographic characteristics checklist, the Liebenberg and Ungar's Child and Youth Resilience Measure-28 item and Health Related Quality of Life Questionnaire "KIDSCREEN-27 item. In the intervention group, The participants will be exposed to the FRIENDS program training for children and adolescents in two intervention groups of 15 people during 10 sessions of 60 minutes for 10 weeks at the Comprehensive Hemophilia Center. immediately after completing the training, complete the Liebenberg and Ungar's Child and Youth Resilience Measure-28 item and Health Related Quality of Life Questionnaire "KIDSCREEN-27 item. The training venue is the conference hall of Educational and therapeutic center of Martyr Ayatollah Dastgheib, which has audio-visual facilities.

Participants/Inclusion and exclusion criteria

Admission requirements: age group 13 to 19 years old; at least elementary education. Conditions of non-entry: having another chronic disease; simultaneous participation in similar training sessions.

Intervention groups

Intervention group: the participants in this group are exposed to the FRIENDS program training for children and adolescents in two intervention groups of 15 people during 10 sessions of 60 minutes for 10 weeks at the Comprehensive Hemophilia Center. Control group: non-intervention: this training group will not be given.

Main outcome variables

Resilience and health related quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220712055451N1**

Registration date: **2022-07-22, 1401/04/31**

Registration timing: **prospective**

Last update: **2022-07-22, 1401/04/31**

Update count: **0**

Registration date

2022-07-22, 1401/04/31

Registrant information

Name

Fatemeh Keshavarz

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3612 5223

Email address

keshavarz.ftm.2017@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-01-20, 1401/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of FRIENDS educational program on resilience and health related quality of life of adolescents with hemophilia		Other design features	
Public title The effect of FRIENDS educational program on resilience and health related quality of life of adolescents with hemophilia		Secondary Ids empty	
Purpose Education/Guidance		Ethics committees	
Inclusion/Exclusion criteria Inclusion criteria: Consent to participate in the study and sign the informed consent form by the parent and the adolescent Simultaneously obtaining a score of less than 74 in the resilience questionnaire and a score of less than 50 in the quality of life questionnaire related to overall health At least elementary education Age group 13 to 19 years old Exclusion criteria: Having another chronic disease The presence of mental disorders requiring immediate treatment (such as: psychiatric symptoms, substance dependence, and suicide) and treatment with antidepressants, anxiety medications, or psychotherapy programs or psychological interventions. Existence of severe stressors in life (such as parents' divorce or bereavement) during the research Simultaneous participation in similar training sessions History of participating in similar training courses in the last six months		1 Ethics committee Name of ethics committee Ethics committee of Yasuj University of Medical Sciences Street address Yasuj University of Medical Sciences, Shahid Motahari Blvd., Yasuj, Kohgiluyeh and Boyer-Ahmad, Islamic Republic of Iran City Yasuj Province Kohgilouyeh-va-Boyer-Ahmad Postal code 7591741417 Approval date 2022-07-05, 1401/04/14 Ethics committee reference number IR.YUMS.REC.1401.046	
Age From 13 years old to 19 years old		Health conditions studied	
Gender Both		1 Description of health condition studied Adolescents with hemophilia ICD-10 code D66 - D67 ICD-10 code description Hereditary factor VIII deficiency; Hereditary factor IX deficiency	
Phase N/A		Primary outcomes	
Groups that have been masked <i>No information</i>		1 Description Resilience Timepoint The level of patients' resilience at the beginning of the study (before the start of the intervention) and immediately after the start of the study Method of measurement Liebenberg and Ungar's Child and Youth Resilience Measure-28 item	
Sample size Target sample size: 60		2 Description Health related quality of life Timepoint The level of patients' health related quality of life at the beginning of the study (before the start of the	
Randomization (investigator's opinion) Randomized			
Randomization description Random allocation of blocks in such a way that blocks of size 2, 4 and 6 will be used. For example, in the case where the block size is 2, we will have two states AB and BA (A and B are the intervention and control groups). In order to create the sequence and concealment, the online software with the following address will be used and a special randomization code will be generated: Sealed Envelope Ltd. 2021. Create a blocked randomization list. [online] Available from: http://www.sealedenvelope.com/simple-randomizer/v1/lists [Accessed 16 July 2022]			
Blinding (investigator's opinion) Not blinded			
Blinding description			
Placebo Not used			
Assignment Parallel			

intervention) and immediately after the start of the study

Method of measurement

Health Related Quality of Life Questionnaire
"KIDSCREEN-27 item"

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the participants in this group will be exposed to the FRIENDS program training for children and adolescents in two intervention groups of 15 people during 10 sessions of 60 minutes for 10 weeks at the Comprehensive Hemophilia Center.

Category

Lifestyle

2

Description

Control group: non-intervention: this training group will not be given.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Educational and therapeutic center of Martyr Ayatollah Dastgheib

Full name of responsible person

Fatemeh Keshavarz

Street address

Educational and therapeutic center of Martyr Ayatollah Dastgheib, Next to National Park, Hafez St., Shiraz, Fars, Islamic Republic of Iran

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keshavarz.ftm.2017@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Seyed Amin Hossaini Motlagh

Street address

Yasouj University of Medical Sciences, Shahid Motahari Blvd., Yasuj, Kohgiluyeh and Boyer-Ahmad, Islamic Republic of Iran

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nursing@yums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yasouj 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

Yasouj University of Medical Sciences

Full name of responsible person

Fatemeh Keshavarz

Position

Msc student in pediatric nursing

Latest degree

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Other areas of specialty/work

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Position

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Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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