Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

Public title
The effect of FRIENDS educational program on resilience and health related quality of life of adolescents with hemophilia
Purpose
Education/Guidance
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
Age
From **13 years** old to **19 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
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
Other design features

Secondary Ids

empty

Ethics committees

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-Boyrahmad
Postal code
7591741417
Approval date
2022-07-05, 1401/04/14
Ethics committee reference number
IR.YUMS.REC.1401.046

Health conditions studied

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

Primary outcomes

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

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

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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Seyed Amin Hossaini Motlagh

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Yasuj 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

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data

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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