

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Sep 2026

### The effect of psychological empowerment on using coping mechanisms, stress, anxiety and depression in hemophiliac adolescents in comparison without taking it

#### Protocol summary

##### Summary

The aim the present study is to examine the effects of psychological empowerment on the use of coping strategies, stress, anxiety and depression in adolescents with hemophilia. Participants are 60 adolescents with hemophilia who referred to Dastgheyb Hospital. They will divide to intervention and control groups using block randomization method. Main inclusion criterion is having 13 to 19 years old and main exclusion criterion is more than one day absence from intervention sessions. Participants do not aware of their group. Eight psychological empowerment sessions forecast for intervention group, will be two sessions per week and each session takes about an hour and a half. Coping strategies used by patients will be compared before and after intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201502079267N4**

Registration date: **2015-07-25, 1394/05/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-07-25, 1394/05/03

##### Registrant information

###### Name

Giti Setoodeh

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3647 4254

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Shiraz University of Medical Sciences

##### Expected recruitment start date

2015-02-20, 1393/12/01

##### Expected recruitment end date

2015-04-20, 1394/01/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of psychological empowerment on using coping mechanisms, stress, anxiety and depression in hemophiliac adolescents in comparison without taking it

##### Public title

The effect of psychological empowerment on psychological outcome in hemophiliac adolescents

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: 1- ages between 13 and 19 years old; 2- no obvious physical or mental disability; 3- being interested for participation in the research. Exclusion criteria: 1- absence in the case of more than one session; 2- withdraw from further cooperation at every stage of the research; 3- the experience of bereavement or other adverse conditions during psychological intervention

##### 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**

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethic Committee of Shiraz University of Medical Sciences

**Street address**

Zand Street, Shiraz University of Medical Sciences

**City**

Shiraz

**Postal code**

**Approval date**

2015-02-08, 1393/11/19

**Ethics committee reference number**

CT-9374-7364

**Health conditions studied**

1

**Description of health condition studied**

hemophilia

**ICD-10 code**

D66,D67

**ICD-10 code description**

Hereditary factor VIII deficiency; Hereditary factor IX deficiency

**Primary outcomes**

1

**Description**

Coping mechanisms

**Timepoint**

Immediately and one month after the intervention

**Method of measurement**

Lazarus Questionnaire

**Secondary outcomes**

1

**Description**

Anxiety, stress and depression

**Timepoint**

Immediately and one month after the intervention

**Method of measurement**

DOSS- 21 Questionnaire

**Intervention groups**

1

**Description**

Intervention group will attend in 8 sessions of psychological empowerment. Psychological empowerment interventions are a group of interventions, including awareness among the patients about the nature of the disease, hemophilia and its symptoms, strategies for problem-solving skills and strategies to reduce stress, depression and anxiety.

**Category**

Rehabilitation

2

**Description**

Control group does not receive any intervention but they are monitored for comparing with the intervention group.

**Category**

Rehabilitation

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Dastgheib Hospital

**Full name of responsible person**

Azam Karami

**Street address**

Quran Street, Ebnesina Psychiatry Hospital

**City**

Shiraz

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Vice chancellor for research, Shiraz University of Medical Sciences

**Full name of responsible person**

Basir Hashemi

**Street address**

Zand Street, Shiraz University of Medical Sciences

**City**

Fars

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Shiraz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

**Person responsible for general inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Basir Hashemi

**Position**

Vice chancellor for research, Shiraz University of Medical Sciences

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**Full name of responsible person**

Giti Setoodeh

**Position**

Master of Science, Faculty member

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

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Azam Karami

**Position**

Nursing Post-graduate student

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*