

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)

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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

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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