

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of virtual child disease management program on caregiver burden and social adjustment in parents of children with coagulation factor deficiencies

Protocol summary

Study aim

The effect of virtual child disease management program on caregiver burden and social adjustment in parents of children with coagulation factor deficiencies

Design

A clinical trial with control group, parallel group randomized trial, a single blinded

Settings and conduct

Setting: Hemophilia center of Shahid Ayatollah Dastgheib Hospital, Data collector and statistician are blind.

Participants/Inclusion and exclusion criteria

The inclusion criteria are parents of a child with factor deficiencies aged 1-11 years, and have access to the Internet and social networks. Parents who are a known case of mental diseases, participated in a similar program, faced with major crises during the past 3 months; their child has congenital, chromosomal, neuro-muscular and systemic diseases would be excluded from the study.

Intervention groups

Intervention group: Child disease management intervention consists of physical intervention such as management of pain, bleeding, and factor; psychological intervention includes coping, positive thinking, laughter and nature therapy; How to participate in social activities and communication will be in social intervention; spiritual interventions include hope, and prayer. Interventions are provided through a social network for 8 weeks. Control group: In this group, any of the interventions of the intervention group is presented. These parents go to a hemophilia center to get a factor or to treat the bleeding, and they may usually be briefed on how to use the factor when their child has bleeding.

Main outcome variables

Parental care burden and Parental social adjustment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130616013690N9**

Registration date: **2021-04-12, 1400/01/23**

Registration timing: **prospective**

Last update: **2021-04-12, 1400/01/23**

Update count: **0**

Registration date

2021-04-12, 1400/01/23

Registrant information

Name

Masoume Rambod

Name of organization / entity

Shiraz University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 71 1647 4258

Email address

rambodm@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-19, 1400/01/30

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of virtual child disease management program on caregiver burden and social adjustment in parents of children with coagulation factor deficiencies

Public title

The effect of virtual child disease management program on parents of children with coagulation factor deficiencies

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Parents with a child in the age range of 1-11 years
Parents of a child with coagulation factor deficiencies
Parents' oriented to time, person and place
Parents' living with this child in the same house
Parents' access to the Internet and social networks

Exclusion criteria:

Parental participation in a similar disease management program over the past 3 months
Parents suffering from known mental diseases such as depression, anxiety, and psychosis
The child suffering from congenital, chromosomal, neuro-muscular and systemic diseases

Age

From **1 year** old to **11 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Firstly, 60 parents who their child have a record in the Hemophilia Center will be selected using a table of random numbers. Then, a random allocation software will be used to create 15 blocks with a block size of four. in order to create a list of block randomization, refer to following website is done:
<https://www.sealedenvelope.com/simple-randomiser/v1/lists>. Then, based on this generated list (BABA, ABBA, BAAB, BABA, AABB, ...), the subjects will be allocated into the intervention (B) or control (A) groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

In order to perform blinding, assistant researcher who collects data before and after the intervention, as well as statistician who analyzes the data, are blinded to the groups and the assignment of individuals in the groups.

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

Vice chancellor for research affairs, seven floor,
Shiraz University of Medical Science, beside Helal
Ahmar, Zand Ave, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

۷۴۳۳۶ - ۷۱۳۲۸

Approval date

2020-11-16, 1399/08/26

Ethics committee reference number

IR.SUMS.REC.1399.930

Health conditions studied

1

Description of health condition studied

Hemophilia A

ICD-10 code

D66

ICD-10 code description

Hereditary factor VIII deficiency

2

Description of health condition studied

Hemophilia B

ICD-10 code

D67

ICD-10 code description

Hereditary factor IX deficiency

3

Description of health condition studied

Von Willebrand's disease

ICD-10 code

D68.0

ICD-10 code description

Von Willebrand's disease

Primary outcomes

1

Description

Caregiver burden

Timepoint

Before and 8 weeks after the intervention

Method of measurement

The HEMophilia associated CAREgiver Burden scale (HEMOCAB)

2

Description

Parental Social adjustment

Timepoint

Before and 8 weeks after the intervention

Method of measurement

Bell's Social Adjustment Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, child disease management intervention focuses on all human dimensions, including physical, psychological, social and spiritual dimensions. The content will be provided to the participants through pamphlets, PowerPoint and videos (MP4) prepared with Camtasia Studio software by WhatsApp. Physical interventions focus on how hemophilia disease and its limitations in pediatric, bleeding, pain, arthropathy, and physical activities are managed. In the psychological dimension, how to coping with child' illness, how you deal with child hemophilia, your perception to child disease, positive thinking, laughter therapy and nature therapy are done. Social interventions include disease management in society, such as how to participate in social and job activities, and how to interact between parents, child with others, and how to child to school. Spiritual interventions include hope, prayer, and communication with God. The duration of the intervention is 8 weeks. During these 8 weeks, the prepared content is uploaded on the social network (WhatsApp) on a daily basis. Confirmation of receipt of the program is then obtained from each participant and they are asked to watch, hear or read the presented material the next day and if they have any questions, ask their questions. The program continues until the end of the eighth week.

Category

Lifestyle

2

Description

Control group: This group would receive the routine care

by hemophilia center and would not receive any of the interventions of the intervention group. The parents of this child come to the Hemophilia center to receive a factor or to treat the bleeding. They may be briefed at the center on how to use the factor when the child has bleeding.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hemophilia Center of Shahid Ayatollah Dastgheib Hospital affiliated to Shiraz University of Medical

Full name of responsible person

Masoume Rambod

Street address

Nursing and Midwifery University, Namazee Sq, Zand Ave, Shiraz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Abbas Rezaieanzadeh

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Vice chancellor for research affairs of Shiraz University of Medical Sciences, Zand Street, Shiraz, Iran

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Grant name

21635

Grant code / Reference number

Masoume Rambod

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

Masoume Rambod

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Others

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Position

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Other areas of specialty/work

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

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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

Primary outcomes would be shared.

When the data will become available and for how long

Starting 6 months after publication article

To whom data/document is available

People and researchers working in academic institutions

Under which criteria data/document could be used

Data are provided for information only.

From where data/document is obtainable

Data is available via email rambodma@yahoo.com.

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

Data is available via email rambodma@yahoo.com.

Comments