Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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Iran (Islamic Republic of)
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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
۱۴۳۳۶ - ۷۱۳۴۸

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, laughte 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
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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
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Shiraz University of Medical Sciences
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Masoume Rambod
Position
Assistant Professor
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Person responsible for updating data

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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