

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 2026

The effect of a need-based program providers on stress, anxiety, depression and burden of caring families of children with attention deficit hyperactivity disorder

Protocol summary

Summary

The aim of this study was to determine the effect of requiring providers based on stress, anxiety, depression and burden of family caregivers. Inclusion criteria: Family caregiver to be considered as primary care and all have to assume his responsibilities! The family have a mental and physical ability to take care of children with ADHD! wishing to participate in the study! be able to communicate and follow the rules of the training session! Only care chronic condition like ADHD in the family! able to speak! read and write in Persian language! psychiatric drug and no drug is not consumed! In family training sessions (any other research project in the field) have not participated in the past! Care for children who range in age from 7-12 years (school age) and because of ADHD have at least one hospitalization. Children is not affected with any disease (physical disabilities, mental, autism, etc.). Exclusion criteria: family caregiver are not want to continue to participate in the training sessions! there is any problem, so be careful not to be able to continue to participate in the study! look out for a maximum of two sessions of the training sessions absence! The physical and psychological problems in family caregivers who can not presence in the meetings. This clinical trial study on 70 caregiver of children with ADHD. After easy sampling to qualify for inclusion samples randomly into two case and control groups. The case group will received 8 sessions in need-based training program and The control group will participated in two group sessions and to express their problems and experiences. Due to the compatibility of the primary outcome of this study, caregivers can reduce stress and anxiety and depression, as well as reduce the caregiver of burden.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201611232200N4**

Registration date: **2016-12-30, 1395/10/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-12-30, 1395/10/10

Registrant information

Name

Saeid Pahlavanzadeh

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1772 7861

Email address

pahlavanzadeh@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	The effect of a need-based program providers on stress, anxiety, depression and burden of caring families of children with attention deficit hyperactivity disorder
Public title	The effect of a need-based program on stress, anxiety, depression and care giver burden of families with children having attention deficit hyperactivity disorder
Purpose	Supportive
Inclusion/Exclusion criteria	Inclusion criteria: Family caregiver to be considered as primary care and all have to assume his responsibilities: The family have a mental and physical ability to take care of children with ADHD: wishing to participate in the study: be able to communicate and follow the rules of the training session:Only care chronic condition like ADHD in the family:able to speak:read and write in Persian language: psychiatric drug and no drug is not consumed: In family training sessions (any other research project in the field) have not participated in the past: Care for children who range in age from 7-12 years (school age) and because of ADHD have at least one hospitalization. Children is not affected with any disease (physical disabilities, mental, autism, etc.). Exclusion criteria: family caregiver are not want to continue to participate in the training sessions: there is any problem, so be careful not to be able to continue to participate in the study: look out for a maximum of two sessions of the training sessions absence: The physical and psychological problems in family caregivers who can not presence in the meetings.
Age	From 7 years old to 12 years old
Gender	Both
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 70
Randomization (investigator's opinion)	Randomized
Randomization description	
Blinding (investigator's opinion)	Double blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	
empty	

Ethics committees	
1	
Ethics committee	
Name of ethics committee	School of Nursing and Midwifery, Isfahan University of Medical Sciences
Street address	Hezar jarib street, Azadi Sq Esfahan Esfahan Iran, Islamic Republic Of
City	Esfahan
Postal code	
Approval date	2016-03-01, 1394/12/11
Ethics committee reference number	IR.MUI.REC.1394.1.194
Health conditions studied	
1	
Description of health condition studied	attention deficit hyperactivity disorder
ICD-10 code	F90
ICD-10 code description	Hyperkinetic disorders
Primary outcomes	
1	
Description	caregiver burden,Stress, anxiety, depression
Timepoint	Before, immediately after, a month after the intervention
Method of measurement	DASS & Zarit caregiver burden Questionnaire
Secondary outcomes	
1	
Description	quality of life
Timepoint	Before the intervention, after the intervention, one month after the intervention
Method of measurement	QOL Questionnaire
Intervention groups	
1	
Description	control group participated in 2 session
Category	Other

2

Description

Researcher set her intervention based on need-based program such as a supportive intervention in 8 sessions (on average) 75 minute classes for school-age children are family members (problems caused by this disorder this age range are more prominent) who are qualified to do.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Saeid Pahlavanzadeh

Street address

City

esfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Ashraf Kazemi

Street address

Hezar jarib St, Azadi Sq

City

Esfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Isfahan 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

Isfahan University of Medical Sciences

Full name of responsible person

Saeid Pahlavanzadeh

Position

Master of Science in Psychiatric Nursing / Registered Psychiatric Nursing and Midwifery Faculty

Other areas of specialty/work

Street address

Hezar jarib St, Azadi Sq

City

Isfahan

Postal code

Phone

+98 31 3668 7124

Fax

Email

pahlavanzadeh@nm.mui.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Saeid Pahlavanzadeh

Position

Master of Science in Psychiatric Nursing / Registered Psychiatric Nursing and Midwifery Faculty

Other areas of specialty/work

Street address

Hezar jarib St, Azadi Sq

City

Isfahan

Postal code

Phone

+98 31 3668 7124

Fax

Email

pahlavanzadeh@nm.mui.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Saeid Pahlavanzadeh

Position

Master of Science in Psychiatric Nursing / Registered Psychiatric Nursing and Midwifery Faculty

Other areas of specialty/work

Street address

Hezar jarib St, Azadi Sq

City

Isfahan

Postal code

Phone

+98 31 3668 7124

Fax

Email

pahlavanzadeh@nm.mui.ac.ir

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