Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of self care education By workshop method for mothers in prevention of self medication to children

Protocol summary

Study aim

General purpose: determination the effect of self care education By workshop method for mothers in prevention of self medication to children

Design

Clinical trials with community based control group, with parallel and randomized blocks, with a block size of 53 samples per group (106)

Settings and conduct

The present study is a randomized clinical trial study. The research population includes all mothers under the age of six years covered by health centers in Shazand. Methods: At first, the pretest will be taken from the control group and then the pretest and educational intervention will be performed for the test group. The control group will receive the usual care at the center. The research includes 5 sessions of 2 hours in a workshop that includes education self care in mild illnesses in children and self-medication in this regard and the expression of the complications and consequences of drug abuse for children based on cognitive theory constructs The Bandura Social will be taught .

Participants/Inclusion and exclusion criteria

Inclusion criteria: Mothers with child under the age of 6 years Mothers who have the ability to read and write Mothers self reported about not having mental problems Mothers with child without chronic disease Exclusion criteria: Mothers who are Health Ambassadors Unwillingness to continue to participate in research Absence of more than two consecutive sessions in classrooms

Intervention groups

Intervention group: Participate in training sessions includes 5 sessions 2 hours with self-care educational content in minor children's illnesses Control group: Get regular care at the health center

Main outcome variables

Self-care education based on the structures of social cognitive theory Self-care knowledge, Expectations of the consequences , Social support, Self efficacy in self care Mothers' practice in self medication

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180524039819N1**
Registration date: **2018-07-28, 1397/05/06**
Registration timing: **prospective**

Last update: **2018-07-28, 1397/05/06**
Update count: **0**

Registration date

2018-07-28, 1397/05/06

Registrant information

Name

Akram Naeimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 7171

Email address

a-naeimi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-30, 1397/05/08

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of self care education By workshop method for mothers in prevention of self medication to children

Public title

The effect education in prevention of self medication

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Mothers with child under 6 years of age Mothers who have the ability to read and write Mothers self-reported about not having mental problems Mothers with child without chronic disease

Exclusion criteria:

Mothers who are Health Ambassadors

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **106**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: block Random unit: Individual Randomization Tool: Online Software

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Use of Bandura Social Cognitive Theory

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Ghodss St,Keshavarz Blvd, Central Office of Tehran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2017-09-05, 1396/06/14

Ethics committee reference number

IR.TUMS.FNM.REC.1396.3391

Health conditions studied

1

Description of health condition studied

Prevention of self medication

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Practice on self medication

Timepoint

Before the beginning of the study and 3 months after the educational intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Knowledge and awareness

Timepoint

Before the beginning of the study and 3 months after the educational intervention

Method of measurement

Questionnaire

2

Description

Expect the outcome

Timepoint

Before the beginning of the study and 3 months after the educational intervention

Method of measurement

Questionnaire

3

Description

Social support

Timepoint

Before the beginning of the study and 3 months after the educational intervention

Method of measurement

Questionnaire

4

Description
Self-efficacy
Timepoint
Before the beginning of the study and 3 months after the educational intervention
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: 5 sessions of 2 hours, in a workshop for 2 months, the content of the education included self-care book on minor illnesses the part childhood approved by the Ministry of Health and Medical Education
Category
Prevention

2

Description
Control group: Get regular health care center care
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Comprehensive Health Services Centers number1
Full name of responsible person
Majid Shams
Street address
Enghelab Street, Imam Hossein Square,Comprehensive Health Services Center
City
Shazand
Province
Markazi
Postal code
3861818547
Phone
+98 86 3822 2050
Fax
+98 86 3822 6377
Email
shazandshabakeh@arakmu.ac.ir
Web page address
https://shazanddh.arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraeian
Street address
Ghods St,Keshavarz Blvd, Central Organization of the University, Sixth Department of Research and Technology
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3698
Email
rmo@tums.ac.ir
Web page address
http://vcr.tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Akram Naeimi
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Dr Mirkhani St. (Eastern Nusrat), Tavid Square, School of Nursing and Midwifery
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6692 7171

Fax
+98 21 6690 4252
Email
mnaeimi88@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Shahzad PashaeiPour
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Dr Mirkhani St. (Eastern Nusrat),Tavid Square. School of Nursing and Midwifery
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6692 7171
Fax
+98 21 6690 4252
Email
pashaeypoor.sh@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akram Naeimi
Position
Student Master
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Dr Mirkhani St. (Eastern Nusrat),Tavid Square,Faculty of Nursing and Midwifery
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6692 7171
Email
mnaeimi88@yahoo.com

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
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The main implications are interchangeable, including mothers'practice in self medication use and And the effect of education on the structures of social cognitive theory
When the data will become available and for how long
Start one year after printing results
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Access to data and documentation is available in accordance with Tehran University of Medical Sciences
From where data/document is obtainable
To access the data, I am referring to Akram Naeimi E-mail: mnaeimi88@yahoo.com
What processes are involved for a request to access data/document
The applicant receives the data after sending the email to the address given and presenting the goals of accessing the data and after clarifying the accuracy of the goals according to the criteria of the Tehran University of Medical Sciences and the magazine that scanned the article can access the data.
Comments