

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The effect of time-use training on stress in mothers of Children with intellectual disability Tehran 2017

Protocol summary

Study aim

The effect of time-use training on stress in mothers of children with intellectual disability

Design

In this experimental study, the population consisted of mothers of girl children with intellectual disability studying in governmental primary schools of Tehran in 2015. Two girls' schools (as clusters) located in the west region were selected by cluster random sampling. Using a coin toss, one was chosen as the experimental group and the other was considered as the control intellectual disability.

Settings and conduct

In each school, 60 families had the necessary conditions to enter the research. The researcher selected 48 families by assigning the number and using the random table. After providing the necessary information about the tools and obtaining an agreement, the tools were provided to the mothers of both groups. After the collection of tools, a 6-hour workshop was held. Subsequently, educational pamphlets were distributed on the topic of research. In the control group, after one day, the group was referred to the same district in the west of Tehran. The follow up was conducted in the experimental group for 6 weeks with written training on the institutionalization of training. Again, after 6 weeks, the questionnaire was completed again by the mothers. In the control group, after 6 weeks, the questionnaire was completed again by the mothers. After taking the test, the test was distributed among the mothers of the control group.

Participants/Inclusion and exclusion criteria

Nuclear family; one mentally disabled child; there is not physically disability in family; IQ of 70-50; school age (6 to 13 years old)

Intervention groups

The training of time management was held as a 6-hour workshop in one day at the school for mothers of the experimental group

Main outcome variables

Optimal use of time; reducing stress

General information

Reason for update

Acronym

ID

IRCT registration information

IRCT registration number: **IRCT20180924041110N1**

Registration date: **2018-10-22, 1397/07/30**

Registration timing: **retrospective**

Last update: **2018-10-22, 1397/07/30**

Update count: **0**

Registration date

2018-10-22, 1397/07/30

Registrant information

Name

Sanaz Arzhanghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8865 5366

Email address

sanarzhanghi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

2016-04-20, 1395/02/01

Actual recruitment end date

2016-08-22, 1395/06/01
Trial completion date
2016-08-22, 1395/06/01

Scientific title
The effect of time-use training on stress in mothers of Children with intellectual disability Tehran 2017

Public title
The effect of time-use training on stress in mothers of Children with intellectual disability

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
Have a nuclear family. Have a mentally disabled child. Other children of the family are not suffering from chronic physical or mental illness. An Inferior, Mental, Educable Child (with an IQ of 70-50). A mentally disabled child is at school age (6 to 13 years). Mother-careful mother is a disabled child.
Exclusion criteria:
Lack of participation in the time use training program
Cancellation of the study due to unwillingness
The presence of problems associated with mental disability, such as blindness, deafness and certain diseases in the child
Child care carers have the responsibility to take care of another person with a disability in their families or relatives

Age
From **6 years** old to **13 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **96**
Actual sample size reached: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
To collect the data, researcher first randomly selected two schools from an educational district and randomly assigned one of the schools to the experimental group and the other to the control group. First, the researcher, in collaboration with the health trainer and the school principal, reviewed the files in the school. Then, according to the criteria for entering the research, the samples were selected based on the goal and were invited to the school. It should be noted that the control group was separated from the two schools, which was done simultaneously at intervals of one day.

Blinding (investigator's opinion)
Single blinded

Blinding description
The study was conducted in two separate schools. The control group was a school and a experimental group was other school so the two groups did not know

Placebo

Not used
Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
دانشگاه علوم پزشکی شهید بهشتی
Street address
School of Nursing & Midwifery, Vali Asr Ave., Niayesh Cross Road
City
tehran
Province
Tehran
Postal code
1985717443

Approval date
2016-02-04, 1394/11/15

Ethics committee reference number
IR. SBMU. PHNM. 1394. 201

Health conditions studied

1

Description of health condition studied
Intellectual disability

ICD-10 code
F10-F19

ICD-10 code description
Mental and behavioral disorders due to psychoactive substance use

Primary outcomes

1

Description
stress

Timepoint
6 weeks

Method of measurement
'Resources and stress questionnaire'

Secondary outcomes

1

Description
stress score

Timepoint
6 weeks

Method of measurement

Resource and stress questionnaire

Intervention groups

1

Description

Intervention group: At first, 96 mothers (48 in the experimental group and 48 in the control group) had mentally disabled children in the study, of which 16 (8 from each group) according to the criteria for withdrawal And completion of the questionnaire was excluded and finally 80 subjects were included in the study. In the intervention group, which was a girls' school in west of Tehran, after receiving written consent, questionnaires were distributed to mothers for completion. Maternity Use Questionnaire and Resource & Stress Questionnaire. After completing the questionnaire, a 6-hour workshop was held on optimal use of time. Lecture methods, questions and answers, educational slideshows, training for the optimal use of time, including introduction, definitions, concepts, principles and rules of time management, time management barriers, and the ways to deal with time lagers as well as control Time stress, questions and answers were presented at the workshop, and educational pamphlet broadcasting related to the research topic was held. After 6 weeks, they returned to the school and distributed the questionnaires.

Category

Behavior

2

Description

Control group: At first, 96 mothers (48 in the experimental group and 48 in the control group) had mental retardation in the girl who were included in the study; 16 of them (8 from each group) according to the criteria for withdrawal And completion of the questionnaire was excluded. Finally, 80 subjects were enrolled in the study. In the control group, the girl's school was in the west of Tehran and the school was separate from the intervention group school. After obtaining written consent, the questionnaires were distributed to mothers. Maternity Use Questionnaire and Resource & Stress Questionnaire. After 6 weeks, they returned to the school again and the questionnaires were returned to their mothers. Then they presented educational pamphlets.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Governmental Exceptional School for Shahid Aslani Girl

Full name of responsible person

Meimanat Hosseini

Street address

SBMU School of Nursing & Midwifery, Vali Asr Ave., Niayesh Cross Road, Niayesh Complex,

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8865 5366

Email

meimanathosseini@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor for Research, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Meimanat Hosseini

Street address

SBMU School of Nursing & Midwifery, Vali Asr Ave., Niayesh Cross Road, Niayesh Complex,

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8865 5366

Email

meimanathosseini@yahoo.com

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, Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences
Full name of responsible person
Meimanat Hosseini
Position
Assistant professor, PhD.
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
SBMU School of Nursing & Midwifery, Vali Asr Ave.,
Niayesh Cross Road, Niayesh Complex,
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 8865 5366
Email
meimanathosseini@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Meimanat Hosseini
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Vali Asr Ave., Niayesh Cross Road, Niayesh Complex
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 8865 5366
Email
meimanathosseini@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sanaz Arzhangi
Position
nurse
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Vali Asr Ave., Niayesh Cross Road, Niayesh Complex,
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 8865 5366
Email
sanarzhang@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

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

The number of participants and result of the intervention after training

When the data will become available and for how long

Get access after 6 months after publish

To whom data/document is available

researcher

Under which criteria data/document could be used

Documentation is available on table of spss

From where data/document is obtainable

corresponding author

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

by email to corresponding author

Comments