

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The effect of family-centered early educational intervention on mental health and quality of life in mothers of children with down syndrome

Protocol summary

Study aim

The effect of family-centered educational early intervention on mental health and quality of life of mothers of children with down syndrome

Design

Single blind randomized educational trial with parallel control group

Settings and conduct

In membership mothers of down syndrome society in Isfahan in 2018, after inviting to a general educational workshop, General Health Questionnaire (GHQ) will be completed. Seventy eligible mothers will be randomly assigned into experimental and control groups. Both groups will be evaluated before of training workshop and three months later by the Depression Anxiety and Stress Scale (DASS21) and World Health Organization Quality Of Life BREF (WHOQOL-BREF).

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1 - Having a child with trisomy 21 by genetic karyotype 2 -Child's age 6 to 72 months 3 - Having informed consent 4 - Having no severe orthopedic problems or malformations, seizure, uncontrolled thyroid disturbances, severe congenital heart problems (in need for surgery), severe visual or auditory problems 5 - more than 23 score of the maternal health questionnaire 6- mother's ability to read, understand and answer the questions Exclusion criteria: 1 - Mental or physical illness of the mother or the child during the three months of intervention 2 - Previous participation mothers in similar training programs 3 - Having another child with chronic illness

Intervention groups

In each group, a general education workshop is organized separately. In the intervention group, we will conduct a booklet and theoretical and practical training to respond to specific needs in each mothers and weekly follow-up counseling sessions, but we will weekly routine follow-up in the control group.

Main outcome variables

Mental health: Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181117041673N1**

Registration date: **2018-12-30, 1397/10/09**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-30, 1397/10/09**

Update count: **0**

Registration date

2018-12-30, 1397/10/09

Registrant information

Name

Sahar Sadeghi Sedeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 1785 1460

Email address

sm.sadeghi163@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-03-06, 1397/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	The effect of family-centered early educational intervention on mental health and quality of life in mothers of children with down syndrome
Public title	The effect of family-centered educational intervention on mental health of mothers
Purpose	Education/Guidance
Inclusion/Exclusion criteria	
Inclusion criteria:	Having a child with trisomy 21 by genetic karyotype Mother's ability to read, understand and answer the question Having informed consent Child with 6 to 72 months of age Having no severe orthopedic problems or malformations, seizure, uncontrolled thyroid disturbances, severe congenital heart problems (in need for surgery), severe visual or auditory problems, and history of the neonatal infections (meningitis, encephalitis)
Exclusion criteria:	Previous participation in similar educational courses Having another child with chronic illness No participation in educational workshop
Age	From 19 years old to 45 years old
Gender	Female
Phase	N/A
Groups that have been masked	Data analyser
Sample size	Target sample size: 70
Randomization (investigator's opinion)	Randomized
Randomization description	Block randomization: In the membership list of the down syndrome society, block randomization will be formed 80 blocks based on the mothers ability to read and write and score more than 23 of the general health questionnaire(GHQ).Two random samples will be selected, by flipping a coin (head for intervention and tail for control) in each block.
Blinding (investigator's opinion)	Single blinded
Blinding description	general educational workshop for both intervention and control groups separately Weekly and similar follow up in both groups Educational intervention in the first group and routine intervention in the control group Register data with codes 1 and 2,Which is not specified for the data analyzer
Placebo	Not used
Assignment	Parallel
Other design features	

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of University of Social Welfare and Rehabilitation Sciences

Street address

Kodakyar Ave., Daneshjo Blvd., Evin Ave.

City

Tehran

Province

Tehran

Postal code

1985713871

Approval date

2018-03-09, 1396/12/18

Ethics committee reference number

ir.uswr.rec.1396.308

Health conditions studied

1

Description of health condition studied

Mental Health

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Quality of life

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Mental Health

Timepoint

Before the intervention and at the end of the intervention

Method of measurement

World Health Organization Quality Of Life BREF

2

Description

Depression

Timepoint

Before the intervention and at the end of the intervention

Method of measurement

Depression Anxiety and Stress scale(DASS21)

3

Description

Stress

Timepoint

Before the intervention and at the end of the intervention

Method of measurement

Depression Anxiety and Stress scale(DASS21)

4

Description

Anxiety

Timepoint

Before the intervention and at the end of the intervention

Method of measurement

Depression Anxiety and Stress scale(DASS21)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A 4-hour workshop will be conducted to educate mothers of children with down syndrome about the problems their children are facing, the effects on mothers and how to deal with them. Then In 4 meeting 2 hours, will be taught the theoretical and practical management of the sensory, motor, communication and activities of daily living deficits for each mother and follow-up phone calls would be placed every 7 days to 3 months.

Category

Lifestyle

2

Description

Control group: Education of Problems with Down Syndrome Children and their effects on family members and how to deal with them in a 4-hour workshop and weekly routine consultation and following for 3 months .

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Aseman Nili Down Syndrome Society of Isfahan

Full name of responsible person

Nozhat Ahmadi

Street address

No.49, Ayatollah Khademi Ave., Foroghi Ave.

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Email

info@asemannili.ir

Web page address

http://asemannili.org

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Amir Massoud Arab Loodaricheh

Street address

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Web page address

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

University of social welfare and rehabilitation 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

University of social welfare and rehabilitation sciences

Full name of responsible person

Hooshang Mirzaie

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Occupational Therapy

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The final results of the intervention will be published as article.

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available