

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The impact of Roy adaptation model on social adaptation and resilience in mothers of children with Intellectual Disability 6-14 year

Protocol summary

Study aim

Determination effect of ROY theory on social adjustment and resilience of mothers of children with intellectual disability

Design

A clinical trial with an intervention and a control group; Target-based sampling in the first stage; Simple random in the second stage

Settings and conduct

Schools and centers of welfare and exceptional education Getting Permission from the University's Vice-Chancellor - Receiving the Ethics Code - Referring to the Welfare Organization - Referring to the centers and schools - Selecting Mothers - Setting up the intervention and control groups - Conducting interventions in the intervention group with a four-dimensional content content theory of compatibility - Completion of questionnaires by two groups

Participants/Inclusion and exclusion criteria

Entry : Having intellectual disability child- Ability to read and write Non-compliance:Dissatisfied with entering the study

Intervention groups

ntervention in the intervention group: 1- Physiological training includes: activity - relaxation and adequate sleep - oxygenation and circulation - fluids - galactoliitis - endocrine - proper daily activity - adequate and adequate nutrition - correct and normal bowel movements - exercise 2. Teaching about the dimension of the concept of self: self-physical-self-concept-self-relation with others- self-knowledge of the external and internal - work, communication, emotions, thoughts and beliefs-appearance and apparent changes-increase and decrease in weight-beliefs And religious values-the correct way 3. Teaching in the role play, including: How to respond to the expectations of people around them-Stress control 4. Education in the dimension of affiliation: Mother relationship with spouse, family, friends, Interventions in the control : Providing educational

package after the completion of the research

Main outcome variables

Social compatibility- resilience

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180120038449N1**

Registration date: **2018-04-04, 1397/01/15**

Registration timing: **retrospective**

Last update: **2018-04-04, 1397/01/15**

Update count: **0**

Registration date

2018-04-04, 1397/01/15

Registrant information

Name

ATEFE BAZRAFSHAN

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3333 1675

Email address

atefe-bazrafshan@aliabadiu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-21, 1396/09/30

Expected recruitment end date

2018-01-20, 1396/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The impact of Roy adaptation model on social adaptation and resilience in mothers of children with Intellectual Disability 6-14 year

Public title
The impact of Roy adaptation model on social adaptation and resilience in mothers of children with Intellectual Disability

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Have at least one child with Intellectual Disability
Exclusion criteria:
Mother's unwillingness to participate in research

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple random method

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Chalus Islamic Azad University

Street address

Aliabad Katoul Islamic Azad University, Aliabad Katoul City, Golestan Province

City

Aliabad katol

Province

Golestan

Postal code

46691-46611

Approval date

2016-11-21, 1395/09/01

Ethics committee reference number

IR.IAU.CHALUS.REC.1395.9

Health conditions studied

1

Description of health condition studied

intellectual disability

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Social compatibility of mothers of mentally retarded children

Timepoint

before the intervention

Method of measurement

Bell Compliance Questionnaire

2

Description

Resilience of mothers of mentally retarded children

Timepoint

Before intervention

Method of measurement

Conner and Davidson Resilience Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, education based on ROY nursing theory in four dimensions of physiological needs, self-understanding, affiliation and role play.(Educational content:Activity - Relaxation and adequate sleep - Oxygenation and circulation - Fluids and volculolates - Endocrine glands - Correct daily activity - Proper and adequate nutrition - Correct and normal bowel movements - Exercise - Prevention of hypertension, diabetes and blood lipids - Sufficient liquids and nutrients - The need for examination and examination of women's health problems and how to prevent them, such as AIDS and gonorrhoea-Smoking and addiction tendenciesSelf-Physical Self-Self-Self-Relationship with Others-Self-Expression-Self-Recognition-Work, Communications, Emotions, Thoughts and Ideas-Appearance and Appearance-Increases and Losses-Beliefs and Religious Values-Correct Expression of Sentiment- Solutions to

problem solving and how to deal with problems-Correct communication with others-Anger controlHow to respond to the expectations of those around you-Stress control-Fit expectations with abilitiesMother relationship with husband, family, friends, centers and other supportive resources - Family importance - Correct family relationships - Affect groups and group activities on the person

Category

Lifestyle

2

Description

Control group: in the control group lack of training

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Exceptional training center under the age of 14

Full name of responsible person

Ahmad Saberi

Street address

Emam Khomeini

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Province

Golestan

Postal code

4971939345

Phone

+98 17 3333 1675

Email

atefe-bazrafshan@aliabadiau.ac.ir

2

Recruitment center

Name of recruitment center

Shahid Forghani Exceptional School, 1st and 2nd

Full name of responsible person

Maryam Ghojoghi

Street address

Dadhah Enghelab

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3

Recruitment center

Name of recruitment center

Shahid Bahonar Exceptional School

Full name of responsible person

Maryam Yazarlo

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mr.Roohalla Samiee

Street address

Ayat

City

Aliabad Katol

Province

Golestan

Postal code

4941793451

Phone

+98 17 3422 4500

Email

atefe-bazrafshan@aliabadiau.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Atefe Bazrafshan

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Hamid Hojati

Position

PHD Nursing

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mrs.Nafiseh Hekmati Pour

Position

PHD student

Latest degree

Master

Other areas of specialty/work

Nursery

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

Not applicable

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

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

Data Dictionary

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