

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Aug 2026

Adaptation of “Care for Child Development “ program based on response-to- intervention and evaluation of its effectiveness on development skills in at risk children and Caregivers skills

Protocol summary

Study aim

The objective of present study was to investigate The impact of “Care for Child Development “ program on Sensitivity and Responsiveness skills in mothers of children at risk of development delays. In addition, its impact on children's developmental skills is also evaluated

Design

The experimental group was exposed to an Four sessions training of “Care for Child Development “ program but the people in control group received no program

Settings and conduct

Child Developmental Center, Tabriz University of Medical Sciences,

Participants/Inclusion and exclusion criteria

mothers of children who are at Risk of Developmental Delay

Intervention groups

In this study, the intervention group received three levels of "Child Care Development" program, but the control group did not receive this intervention. Intervention group caregivers received the knowledge and skills needed to care for child development at three levels. At the end of each intervention level, progress and responsiveness to educational interventions were measured, and subjects (children) were either excluded or entered the next level according to the outcome of the intervention

Main outcome variables

the Sensitivity and Responsiveness skills of mothers- development skills in at risk children

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191101045298N1**

Registration date: **2020-03-05, 1398/12/15**

Registration timing: **retrospective**

Last update: **2020-03-05, 1398/12/15**

Update count: **0**

Registration date

2020-03-05, 1398/12/15

Registrant information

Name

Ali Bahari Gharehgoz

Name of organization / entity

Allameh Tabataba'i University

Country

Iran (Islamic Republic of)

Phone

+98 41 3386 2612

Email address

a.bahari@atu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-03, 1398/01/14

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

2019-04-03, 1398/01/14

Actual recruitment end date

2019-06-10, 1398/03/20

Trial completion date

2019-08-23, 1398/06/01

Scientific title

Adaptation of “Care for Child Development “ program based on response-to- intervention and evaluation of its

effectiveness on development skills in at risk children and Caregivers skills

Public title
The impact of the program of "Care for Child Development" on child and caregivers

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
children who are at Risk of Developmental Delay
Children in the range of 4 to 36 months
Exclusion criteria:
patient dissatisfaction Neuro-developmental disorders

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**
Actual sample size reached: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study using Convenience Sampling, 50 children under the age of three years who were referred to Tabriz Comprehensive Center for Development were selected and divided randomly (simple randomization- random number table) into two experimental and control groups. reading the table is from top to bottom. even numbers are considered as intervention group and odd numbers are considered as control group

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences

Street address

Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2019-01-07, 1397/10/17

Ethics committee reference number

IR.TBZMED.REC.1397.823

Health conditions studied

1

Description of health condition studied

Children at Risk of Developmental Delay

ICD-10 code

F88

ICD-10 code description

Other disorders of psychological development

Primary outcomes

1

Description

Sensitivity and Responsiveness Skills- Development Skills

Timepoint

Before and After intervention

Method of measurement

The Social-Emotional Assessment/Evaluation Measure
Family Profile - Maternal Caregiving Quality Scale -Age
and Stages Questionnaires(ASQ)-Bayley

Secondary outcomes

empty

Intervention groups

1

Description

This program is designed by the World Health Organization to empower caregivers. In this program, caregivers stand in need of three basic skills to make the optimum change in child: (1) Sensitivity: being aware of the child's movements, gestures and voice and interpreting it, (2) Responsiveness: responding in a timely manner and qualitatively to the child's signs and symptoms and (3) Learning enrichment and bonding. The number of sessions is four sessions. first : Introduction to program - Concept of development and its aspects - Factors affecting child development - Developmental delay - Child development monitoring. second: Who is caregiver and how can child care be maintained? - Essential skills to care for and improve child development (Sensitivity - Responsiveness and Enriching the Environment). third: Methods of stimulating and boosting child development - Concept and significance of communication - Communication methods - Importance of playing - Support strategies for child play by caregiver - Play things - Types of toys for children. fourth: Play recommendation activities and communication through six age groups - Identifying obstacles and solutions given

by program - Final monitoring of development

Category

Behavior

2

Description

The control group received routine care

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz child development center

Full name of responsible person

Ali Bahari Gharehgoz

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Tabriz child development center north Tavanir bol.,
Valiasr , Tabriz, Iran

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Email

alibahari1@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Allameh Tabataba'i University

Full name of responsible person

Mohammad Asgari

Street address

Allameh Tabataba'i University Dehkadeh-ye-Olympic,
Tehran, Tehran Provinc

City

Tehran

Province

Tehran

Postal code

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Phone

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Email

drmasgari423@gmail.com

Grant name

Allameh Tabataba'i University

Grant code / Reference number

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

Yes

Title of funding source

Allameh Tabataba'i University

Proportion provided by this source

1

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

Tabriz University of Medical Sciences

Full name of responsible person

Ali Bahari Gharehgoz

Position

Non-academic staff

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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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

Section of data

When the data will become available and for how long

Six months after publication

To whom data/document is available

Researchers

Under which criteria data/document could be used

Research

From where data/document is obtainable

Email

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

after a week

Comments

Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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