

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The efficacy of “Care for Child Development (CCD)” intervention on Improvement of the developmental skills of orphanage children

Protocol summary

Study aim

Evaluation of efficacy of the "Care for Child Development (CCD)" on cognitive, communication, motor and social-emotional skills

Design

Two orphanages from the capital cities of east and west Azerbaijan provinces were selected as control and intervention groups. Children who were between 4- 42 months was selected from each orphanage by random and were matched. "Care for Child Development (CCD)" package was implemented for three sessions a week, each session lasting 2 hours, for three months. CCD was designed by the World Health Organization and UNICEF as an intervention to enhance the development of children. It provides information and recommendation for cognitive stimulation and social support of young children through sensitive and responsive caregiver-child interaction. At the end of the intervention, all of the children in both control and intervention groups were assessed by using Age and Stages Questionnaire(ASQ) and Bayley Diagnostic test (BSID). The BSID is one of the most widely used tools in the world for assessing the growth and development of children at the age of 1 to 42 months which assesses the development of children in 5 domains. ASQ is a developmental screening tool for children aged 4 to 60 months. It has 19 age-specific questionnaires that assess the child's development in the areas of personal-social skills, motor, communication, and problem-solving skills. Data was compared using T-test analysis

Settings and conduct

This study was done in two orphanages. The intervention group received CCD but the control group didn't.

Participants/Inclusion and exclusion criteria

Children living in orphanage between 4-42 months from the east and west Azerbaijan provinces

Intervention groups

Intervention groups are the ones who received CCD and control groups are the ones who didn't.

Main outcome variables

Children's developmental skills including cognition, motor and communication

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220330054374N1**

Registration date: **2022-04-20, 1401/01/31**

Registration timing: **retrospective**

Last update: **2022-04-20, 1401/01/31**

Update count: **0**

Registration date

2022-04-20, 1401/01/31

Registrant information

Name

Nasrin Baraheni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3326 3958

Email address

nasrinbaraheni@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-06, 1400/09/15

Expected recruitment end date

2022-03-06, 1400/12/15

Actual recruitment start date

2021-12-19, 1400/09/28

Actual recruitment end date

2022-03-19, 1400/12/28
Trial completion date
 2022-03-30, 1401/01/10

Scientific title
 The efficacy of "Care for Child Development (CCD)" intervention on Improvement of the developmental skills of orphanage children

Public title
 Efficacy of "Care for Child Development (CCD)" on child development

Purpose
 Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
 Chronological age being at the age range of "4-42" months Living in the orphanage during the study
Exclusion criteria:
 Genetic syndromes Cleft lip and cleft palate Clear and diagnosed developmental problems Transfer of the subject's custody to a family, Being ill and the need for isolation in the orphanage Being hospitalized

Age
 From **4 months** old to **42 months** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **30**
 Actual sample size reached: **30**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Randomizing was done by using random number tables (simple randomization) . After determining the direction of reading the numbers, even numbers were given to Tabriz orphanage and odd numbers were given to Urmiya orphanage.

Blinding (investigator's opinion)
 Not blinded

Blinding description
Placebo
 Not used

Assignment
 Other

Other design features
 In this study cross-sectional research method was used in which some evaluations were done on control and intervention groups by professionals.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

0

City

Tabriz

Province

East Azarbaijan

Postal code

0000000

Approval date

2021-04-22, 1400/02/02

Ethics committee reference number

IR.TBZMED.REC.1399.741

Health conditions studied

1

Description of health condition studied

Developmental Delay

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Developmental skills

Timepoint

At the first and the end of study

Method of measurement

Bayley and ASQ

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Children living in Orphanage between 4-42 months of age

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Orphanages

Full name of responsible person

Zahra bagheri

Street address

Ehsan orphanage, 200 meters to Azad university,
Manzariyeh Ave., Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

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Phone

+98 41 3478 9151

Email

zbagheri041@gmail.com

Position

Not a faculty member

Latest degree

Master

Other areas of specialty/work

Occupational Therapy

Street address

Tabriz university main street ground floor, central
building

City

Tabriz

Province

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Phone

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Zahra Ebadi

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Tabriz university main street ground floor, central
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Phrc_mb@tbzmed.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Zahra Maleki

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Nasrin Baraheni

Position

Not a faculty member

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

Contact**Name of organization / entity**

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Full name of responsible person

Zahra Maleki

Position

Not a faculty member

Latest degree

Master

Other areas of specialty/work

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Phone

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Email

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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
secret

Study Protocol

No - There is not 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

No - There is not 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