

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Adaptation and Implementation of " Care for Child Development" (CCD) intervention in the health system and Nurseries

Protocol summary

Study aim

Ccd is basically a child development care program in the form of behavioral intervention and caregiver interaction with the child

Design

A clinical trial with a control group with parallel groups, two-way blind ^{صهفا} randomization, on 1000 children and their parents

Settings and conduct

The study method is a mixed study. CCD is basically a child development care program in the form of behavioral intervention and caregiver interaction with the child. Execution steps include: 1. Situational analysis of early childhood developmental status (ECD) of young children (prenatal up to 3 years) 2. Holding a panel of experts 3. Design CCD instructions and approve it by experts 4. Holding an introductory training workshop 5. Holding the compliance panel in the presence of all stakeholders 6. The program begins with the supervision of the Ministry of Health, in other words, the intervention. In this phase, the instructors, who during the two introductory workshops and the instructor training workshop that was held in the previous stages, train people to provide services in the form of internal and intra-provincial workshops. The qualitative stage has been determined before the panel of experts. The result and effectiveness of the service is evaluated with the help of monitoring and evaluation tools that have been prepared and standardized in the previous step.

Participants/Inclusion and exclusion criteria

All children under the age of three and their parents, health care providers, and child care providers in designated centers for sampling are candidates for inclusion in the study. The unwillingness of parents to cooperate will prevent them from entering.

Intervention groups

parents caregivers children

Main outcome variables

The effectiveness of CCD service on parents' knowledge

and attitude

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100503003857N2**

Registration date: **2022-05-23, 1401/03/02**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-23, 1401/03/02**

Update count: **0**

Registration date

2022-05-23, 1401/03/02

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

61192357

Email address

mshariat@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-06-22, 1401/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Adaptation and Implementation of " Care for Child Development" (CCD) intervention in the health system and Nurseries

Public title

Adaptation and Implementation of " Care for Child Development" (CCD) intervention

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

All children under the age of three with seemingly healthy development (ASQ scores above minus 2 in all developmental areas) can participate in this program. The caregiving mothers, nurses, and pregnant mothers with relative physical and mental health are also eligible to participate in the program.

Exclusion criteria:

In any part of the study, if the child is found to be developmentally delayed or disturbed, or if the caregiver has a serious mental or physical health problem that may interfere with communication and play with the child, the caregiver and the child will be excluded from the study. After exclusion, this mother or child will be referred for specialized services.

Age

To **3 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **1000**

More than 1 sample in each individual

Number of samples in each individual: **2**

Interviewing and filling out questionnaires before and after counseling and training sessions

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be simple using the table of random numbers in EXCEL software.

Blinding (investigator's opinion)

Double blinded

Blinding description

The parents of the two intervention and control groups are unaware of the quantity and quality of education received in the other group and are unaware that education is part of the study process or is a routine instruction received by all parents. Also, the outcome assessor is unaware of the assignment of each child to each group during the study period and only monitors and reports on the child's developmental status.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

the Ethics committee of Imam-Khomeini Hospital Complex, Tehran University of Medical Sciences

Street address

Keshavarz Blvd., Intersection of Dr. Gharib Street

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2021-06-16, 1400/03/26

Ethics committee reference number

IR.TUMS.IKHC.REC.1400.093

Health conditions studied

1

Description of health condition studied

adapting and implementing " Care for Child Development" (CCD) intervention in the health system and children's institutional care system of Iran

ICD-10 code

ICD-10 code description

2

Description of health condition studied

knowledge and skills of caregivers

ICD-10 code

ICD-10 code description

3

Description of health condition studied

knowledge and skills of health care providers, care givers, and midwives

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The effectiveness of CCD service on parents' knowledge and attitude

Timepoint

Prior to the consultation, pre-intervention evaluations will

be performed with valid questionnaires. This consultation will be done twice and two weeks apart for the caregiver. After the second consultation, the evaluation will be performed two months after the intervention.

Method of measurement

Tool No. 1: Checklist of Counseling for Care for Child Development. Tool No. 5: Family Environment Assessment. Tool No. 6: Parent's Sensitivity and Responsiveness Questionnaire. Tool No. 7: Mother's Knowledge and Attitude Questionnaire. Tool No. 8: Pre-Test and Post-Test Used in the TOT Workshop

Secondary outcomes

1

Description

The effectiveness of CCD service on the skills of caregivers

Timepoint

The caregiver skills assessment will be performed before and after the intervention. A follow-up evaluation will be performed two months after the end of the sessions.

Method of measurement

Tool No. 2: Caregiver (Parent) Report of the Service Provider Skills. Tool No. 3: Interview with the Service Provider. Tool No. 4: Service Provider Skills Observation Questionnaire

Intervention groups

1

Description

Intervention group: Parents receiving counseling sessions

Category

Behavior

2

Description

Control group: Lack of counseling sessions

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Mamak Shariat

Street address

Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1419711141

Phone

+98 21 6119 2052

Email

mshariat@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mamak Shariat

Street address

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City

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1419733141

Phone

+98 21 6119 2052

Email

mshariat@tums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

UNICEF organization

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Foreign

Category of foreign source of funding

UN agencies and international organizations

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mamak Shariat

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Others

Street address

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City

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mamak Shariat
Position
Professor
Latest degree
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Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mamak Shariat
Position
Professor
Latest degree
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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

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The information entered in each tool examined at any stage of the study can be shared by all individuals after unidentified individuals.

When the data will become available and for how long

After preparing the report and article resulting from the plan

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

If the person in question provides sufficient explanations of the type of data use, the data will be provided to him after sending a written request. For example, continuing the study process in children over 3 years old.

From where data/document is obtainable

Sending a written and official request to the person responsible for data collection and maintenance to the email address mshariat@tums.ac.ir

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

After submitting the request and examining how to use the data in consultation with the project partners, the data will be provided to the applicant within a maximum of one month.

Comments