

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

Investigating the effect of consultancy of play therapy on social evolution (social maturity) of 12-24 months old children referring to selected comprehensive health centers in Kashan 1396-1397

Protocol summary

Study aim

The aim of this study is investigating the effect of consultancy of play therapy on social evolution (social maturity) of 12 to 24 months old children referring to selected comprehensive health centers in Kashan.

Design

In this study, 76 children from 12 to 24 months old who have been admitted to the study who visit the comprehensive health centers of the city of Kashan, are selected, and the social maturity scale is completed, if their score is less than half the full score. The randomization is divided into two groups of intervention and control and each participant is assigned a code.

Settings and conduct

The sampling method will be multistage, so that: firstly, three centers will be selected from the centers of the township, and in each center, according to the population of children aged one to two, available sampling according to the criteria for entering the research will be done. After selecting eligible individuals, they are randomly assigned to two groups of intervention and control.

Participants/Inclusion and exclusion criteria

Inclusion criteria The parents have at least literacy to read and write, be Iranian, 12 - 24 months old children whose age is Based on social growth scale, be at least one second year less than their calendar age, The child does not have known physical and mental illness, Parents' Satisfaction to Participate in the Study and Exit criteria Mothers' reluctance to continue to participate in the study, not attending maximum two sessions of consultancy sessions of play therapy, having any kind of physical and mental disabilities.

Intervention groups

Intervention group In this group, in addition to routine child care training and delivery of training packages, 6 sessions that are 30 minutes and weekly 2 sessions of

group consultancy of play therapy will be held, Control group they will receive ministry's routine training and training packages.

Main outcome variables

Increase the developmental score of children from 12 to 24 months

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160503027728N8**

Registration date: **2018-01-11, 1396/10/21**

Registration timing: **prospective**

Last update: **2018-01-11, 1396/10/21**

Update count: **1**

Registration date

2018-01-11, 1396/10/21

Registrant information

Name

Zohreh Mahmoodi

Name of organization / entity

Nursing&Midwifery faculty

Country

Iran (Islamic Republic of)

Phone

+98 26 3430 4433

Email address

zohrehmahmoodi@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of consultancy of play therapy on social evolution (social maturity) of 12-24 months old children referring to selected comprehensive health centers in Kashan 1396-1397

Public title

Investigating the effect of consultancy of play therapy on social evolution (social maturity) of 12-24 months old children referring to selected comprehensive health centers in Kashan 1396-1397

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

The parents have at least literacy to read and write 12 - 24 months old children whose age is Based on social growth scale, be at least one second year less than their calendar age be Iranian The child does not have known physical and mental illness Parents' Satisfaction to Participate in the Study

Exclusion criteria:

Mothers' reluctance to continue to participate in the study, not attending maximum two sessions of consultancy sessions of play therapy, having any kind of physical and mental disabilities.

Age

From **12 months** old to **24 months** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Available sampling and random blocks

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 Alborz University Of Medical Sciences

Street address

Taleghani Square,North Taleghai Blvd,Administrative City,Alborz University of Medical Sciences, Karaj, Iran

City

Karaj

Province

Alborz

Postal code

3149779453

Approval date

2017-12-30, 1396/10/09

Ethics committee reference number

Abzums.Rec.1396 .136

Health conditions studied**1****Description of health condition studied**

The social development of children 12-24 months

ICD-10 code

Z31.6

ICD-10 code description

Encounter for general counseling and advice on procreation

Primary outcomes**1****Description**

Social maturity of the child in Vineland scale

Timepoint

Before intervention and at the end of the consultation sessions

Method of measurement

Use of Social maturity of Vineland scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: this group, in addition to routine child care training and delivery of training packages, 6 sessions that are 30 minutes and weekly 2 sessions of group consultancy of play therapy will be held

Category

Behavior

2

Description

Control group:they will receive ministry's routine training and training packages.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashan health center (1)

Full name of responsible person

Dr. Zohreh Mahmoodi

Street address

Imam Reza Square, Phase 2 of Naji Abad,
Comprehensive Health Services Center No. 1

City

Kashan

Province

Isfahan

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Phone

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Email

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2

Recruitment center

Name of recruitment center

Kashan Center for Comprehensive Health Services
No. 2

Full name of responsible person

Dr Zohreh Mahmoodi

Street address

Amir Kabir Ave. Matini Hospital - Health Services
Center No. 2

City

Kashan

Province

Isfahan

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8719674591

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Email

health@kaums.ac.ir

3

Recruitment center

Name of recruitment center

Kashan Center for Comprehensive Health Services
No. 3

Full name of responsible person

Dr. Zohreh Mahmoodi

Street address

Teachers' Square, Bahonar Blvd, Health Services

Center No. 3

City

Kashan

Province

Isfahan

Postal code

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Phone

+98 31 5554 0503

Email

health@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr Azam Bagheri

Street address

Department of Nursing,Kashan University Of Medical
Science,GHotbe Ravandi Blvd,Kashan

City

kashan

Province

Isfahan

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81151-87159

Phone

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Email

asambagheri@yahoo.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Alborz 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

Alborz University Of Medical Sciences

Full name of responsible person

Dr Zohreh Mahmoodi

Position

PHD

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Department of Nursing, Alborz University Of Medical Science, Eshteraki St, Baghestan Blv Karaj, Karaj

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Alborz University Of Medical Sciences

Full name of responsible person

Dr Zohreh Mahmoodi

Position

PhD

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for updating data**Contact****Name of organization / entity**

Alborz University Of Medical Sciences

Full name of responsible person

Dr Zohreh Mahmoodi

Position

PhD

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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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

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

Title and more details about the data/document

as an English article we published data.

When the data will become available and for how long

10 month later

To whom data/document is available

Alborz & Kashan University Of Nursing and Midwifery

Under which criteria data/document could be used

Path analysis

From where data/document is obtainable

Dr Zohreh Mahmoodi

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

send an email to Dr. Zohreh Mahmoodi

Comments