

# 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

##### Postal code

8719336365

##### Phone

+98 31 5542 9357

##### Email

health@kaums.ac.ir

### 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

##### Postal code

8719674591

##### Phone

+98 31 5533 1136

##### 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

8714873398

##### 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

##### Postal code

81151-87159

##### Phone

+98 31 5554 0021

##### 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

**City**

Karaj

**Province**

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**Postal code**

561-31452

**Phone**

+98 26 3455 1034

**Email**

zohrehmahmoodi2011@gmail.com

**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**

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zohrehmahmoodi2011@gmail.com

**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**

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**Postal code**

561-31452

**Phone**

+98 264551034

**Email**

zohrehmahmoodi2011@gmail.com

**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**