Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Oct 2026

Studying the effect of a designed pretend play interventional planning on the play participation of 4-8 years old Tehranian children with Attention Deficit Hyperactivity Disorder (ADHD)

Protocol summary

Study aim
The effect of occupational therapy protocol with the focus of pretend play on improving play skills and participation in children with ADHD the effect of OT protocol with the focus of pretend play on improving the score of pretend play (ChIPPA) and the participation questionnaire (CPQ and I-CPAS)

Design
double-blind clinical trials in parallel groups will perform in a pre-estimated 81 samples that may change after the pilot study on a limited number (8 people). The announcement of the study will be published on social media and more specifically in the Iranian association of attention deficit - hyperactivity disorder. Focused groups will be designed for children with ADHD and their stakeholders. semi-structural interviews and baseline assessments of participation and play and also diagnosis of ADHD will be done. According to the interview content, some measurements will be added. Regarding results of questionnaires and interviews, 16 sessions of occupational therapy intervention with a focus on pretend play will be completed. after the 8th week, all the tests will perform again. For the follow-up, after 8 weeks we will take tests again.

Settings and conduct
Iranian Association of attention deficit hyperactivity disorder If we cannot get all the samples here, we will cover other samples from the occupational therapy and rehabilitation clinics in Tehran. Interventions will be delivered by trained occupational therapists who do not have access to measurements results. The assessment will be done by another person and statistical analysis will be done by a third person (the main researcher)

Participants/Inclusion and exclusion criteria
children with attention deficit hyperactivity disorder between4-8 years old based in Tehran no other major disorder

Intervention groups
in-person intervention online intervention

Main outcome variables
play and play skills (pretend play) participation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211106052975N1**
Registration date: **2021-12-13, 1400/09/22**
Registration timing: **prospective**

Last update: **2021-12-13, 1400/09/22**
Update count: **0**

Registration date
2021-12-13, 1400/09/22

Registrant information

Name
Minoo Dabiri Golchin

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2218 0037

Email address
minoodabiri@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-22, 1400/10/01

Expected recruitment end date
2022-03-21, 1401/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the effect of a designed pretend play interventional planning on the play participation of 4-8 years old Tehranian children with Attention Deficit Hyperactivity Disorder (ADHD)

Public title

Play in children with Attention Deficit Hyperactivity Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

earning 34 or more in Conner's scale set in Tehran and speaking Persian Internet access able to read and write (parents) Age limit between 4-8 years old

Exclusion criteria:

comorbidity of Autism, cerebral palsy, mental retardation no intent to continue the project from the children side or their parents receiving play therapy interventions or other interventions that research committee assume them as disruptor absence more than two sessions

Age

From **4 years** old to **8 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **81**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

two kinds of interventions are in-person and online two therapists (in-person and online) are unaware of each other secondary evaluations and baseline evaluation will be done by another person Statistical analysis will be done by a third person.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics committees of University of Social Welfare and Rehabilitation Sciences

Street address

koodakyar st, Velenjak

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Tehran

Province

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Postal code

1985713871

Approval date

2021-11-17, 1400/08/26

Ethics committee reference number

IR.USWR.REC.1400.203

Health conditions studied

1

Description of health condition studied

attention deficit hyperactivity disorder

ICD-10 code

F90

ICD-10 code description

Attention-deficit hyperactivity disorders

Primary outcomes

1

Description

play

Timepoint

before intervention, right after intervention (after 8 weeks), 8 weeks later

Method of measurement

The "Child Initiated Pretend Play Assessment" (ChIPPA)

2

Description

Participation

Timepoint

0-8-16 weeks after intervention

Method of measurement

"Children Participation Questionnaire"

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Children with ADHD who receive in-person interventions. Intervention will deliver in 8 weeks, twice a week (16 sessions). These interventions will be delivered by trained occupational therapists with a protocol that is designed during participatory action research. The content of these sessions is focused on pretend play. Each session is 45 minutes.

Category

Rehabilitation

2

Description

Intervention group: Children with ADHD that receive online interventions. These interventions are same as the first group interventions but parents are provided with the protocol. Parents will deliver by intervention.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Iranian Association of ADHD

Full name of responsible person
Hooshang Mirzaie

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
University of social welfare and rehabilitation sciences

Full name of responsible person
Hamid Reza Khankeh

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Grant name

Grant code / Reference number

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

Title of funding source
University of social welfare and rehabilitation 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
University of social welfare and rehabilitation sciences

Full name of responsible person
Minoo Dabiri Golchin

Position
Ph.D. candidate

Latest degree
Master

Other areas of specialty/work
Occupational Therapy

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Person responsible for updating data

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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
No - There is not 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
IDP: after making participants unrecognizable, data will be published in an article. in this paper, we will describe play and participation relations among different age groups. these variables relations will be assessed with demographic characteristics and will be published. study protocol: will publish in a paper Statistical analysis: will publish in the paper Informed consent form: Is published in proposal clinical study report: will publish in a paper

When the data will become available and for how long
IDP: after the baseline assessments will be accessible. public access is defined for 1401. other documents: depended on the acceptance process, will be accessible in 1401

To whom data/document is available
After publishing the paper, it will be accessible for researchers.

Under which criteria data/document could be used
The access depends on the journal that we will publish the work.

From where data/document is obtainable
reach out to mdabiriot@gmail.com for any related information

What processes are involved for a request to access data/document
we cannot reveal data before publishing them in journals. Please be patient for publication.

Comments