

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Designing protocol of Contextual Interventions based on Dunn's model of sensory processing and the efficacy on child participation and parent competency among children with Autism Spectrum Disorder

Protocol summary

Summary

The current study is designed to construct Contextual Intervention manual based on Dunn's sensory processing framework and examine the effect on child participation and parent competency, among children with Autism Spectrum Disorders (ASD). The population of this study is all the families which have a child with ASD in Tehran. Participants are selected among families which refer to Nedaye-e-asr and Navid-e-asr rehabilitation centers regarding inclusion criteria and randomized through the list of the clients' names by taking every "K"th name. The assignment of centers to intervention/ control groups is randomized by closed pockets. 1) Base-line Phase: all participants are evaluated through Canadian Occupational Performance Measure (COPM) and Goal Attainment Scale (GAS) and Parent Self-efficiency Measure (PSEM), and during 4 weeks the participants receive the usual Occupational Therapy services, and then the evaluations repeat again. 2) Intervention Phase: The treatment group receives Contextual Interventions and usual Occupational Therapy (CI/OT) and the control group receives the usual Occupational Therapy services (OT) during 12 weeks. Contextual Interventions include 2 training group sessions and 10 individual coaching sessions. Then both groups are evaluated for the third time. 3) Follow up Phase: Both groups receive the usual occupational therapy services during 4 weeks, and then they are evaluated for the fourth time.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016100330113N1**

Registration date: **2017-03-24, 1396/01/04**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-03-24, 1396/01/04

Registrant information

Name

Zahra Pashazadeh Azari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, University of Social Welfare and Rehabilitation Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Designing protocol of Contextual Interventions based on Dunn's model of sensory processing and the efficacy on child participation and parent competency among children with Autism Spectrum Disorder

Public title

The effect of Contextual Interventions based on Dunn's model of sensory processing on child participation and parent competency among children with Autism Spectrum Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: families who have a child with ASD (based on the psychiatrist report in the rehabilitation center); age range of children 3 to 10 years; children have at least one sensory pattern outside typical; parents' education are at least diploma; parents' language abilities (well comprehension and expression of Persian); parents consent for participation in this research Exclusion Criteria: absence in training and treatment sessions (more than 2 sessions) - occurrence of epilepsy during research period and 6 month before it.

Age

From **3 years** old to **10 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Participants are selected regarding inclusion criteria and randomized through the list of the clients' names by taking every "K"th name. The assignment of centers to intervention/ control groups is randomized by closed pockets.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of University of Social Welfare and Rehabilitation

Street address

Koodakyar Street, Danshjoo Boulevard, Velenjak Avenue

City

Tehran

Postal code

Approval date

2016-05-23, 1395/03/03

Ethics committee reference number

IR.USWR.REC.1395.189

Health conditions studied

1

Description of health condition studied

Autism Spectrum Disorder

ICD-10 code

F84.5

ICD-10 code description

autistic psychopathy

Primary outcomes

1

Description

child participation

Timepoint

4 weeks before intervention, before intervention, after intervention, 4 weeks after intervention

Method of measurement

Canadian Occupational Performance Measure, Goal Attainment Scale

Secondary outcomes

1

Description

Parent Competency

Timepoint

4 weeks before intervention, before intervention, after intervention, 4 weeks after intervention

Method of measurement

Parent Self- efficiency Measure

Intervention groups

1

Description

Contextual Interventions: include 2 group sessions for sharing information, and 10 sessions for individual coaching. Occupational Therapy: include the usual occupational therapy interventions for children with ASD.

Category

Lifestyle

2

Description

Occupational Therapy: include occupational therapy interventions that are usual for children with ASD.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Nedaye-e-asr

Full name of responsible person

Zahra Pashazadeh Azari

Street address

No. 7, Eastern Hafez Street, Banihashem Avenue,
Resalat Highway

City

Tehran

2

Recruitment center

Name of recruitment center

Navid-e-asr Rehabilitation Center

Full name of responsible person

Zahra Pashazadeh Azari

Street address

Erfanian Street, Molavi Cross, Vali-e-asr Avenue

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, University of Social
Welfare and Rehabilitation Sciences

Full name of responsible person

Dr. Hamid Reza Khankeh

Street address

Koodakyar Avenue., Daneshjoo Bl., Velenjak Street

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Tehran

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

Yes

Title of funding source

Vice chancellor for research, University of Social Welfare
and Rehabilitation Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

University of Social Welfare and Rehabilitation
Sciences

Full name of responsible person

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Position

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*