Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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) - occurance 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 Rehablitation

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 Performence 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- effciency 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

City
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
PhD Student of Occupational Therapy

Other areas of specialty/work

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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