Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effectiveness of Pivotal Response Treatment in decreasing behavioral and communicative problems in autistic boys between 8-12 years old

Protocol summary

Summary

Objectives: The aim of this research is assessing effectiveness of Pivotal Response Treatment in decreasing behavioral and communicative problems in autistic boys between 8-12 years old. Design: This is a randomized clinical trial (RCT) with pre- and post test assessment. Setting and Conduct: One group will receive the PRT therapies and other group no treatment. ADI-R test, which is a standard measure, will be used as pre- and post-test to assess the efficacy of PRT. Participants: We design a in 24 children with autism described in DSM-4. The study population will be randomized into intervention and control groups. Intervention: The intervention group receive PRT during 10 weeks, while the control group will not be under this treatment as their previous year. Main outcome measurement variables: We expect to see increasing the socialization abilities in the intervention group after PRT.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205259854N1**
Registration date: **2012-10-10, 1391/07/19**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-10-10, 1391/07/19

Registrant information

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Recruitment status

Recruitment complete

Funding source

Beautiful Mind Rehabilitation Clinic

Expected recruitment start date

2012-06-07, 1391/03/18

Expected recruitment end date

2012-09-08, 1391/06/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Pivotal Response Treatment in decreasing behavioral and communicative problems in autistic boys between 8-12 years old

Public title

Pivotal Response Treatment (PRT) in Autism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion: 8-12 years old; diagnosis of Autism by Psychiatrist based on DSM IV; no other treatment; Exclusion: Other neurological disorder such as cerebral palsy; seizure; metabolic disorder; change in drugs during the intervention;

Age

From **8 years** old to **12 years** old

Gender

Male

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

1

Registry name
-
Secondary trial Id
-
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Islamic Azad University of Tonekabon
Street address
Educational complexity of Islamic Azad University of Tonekabon, Vali Abad
City
Tonekabon
Postal code
Approval date
2012-08-23, 1391/06/02
Ethics committee reference number
15920701882006

Health conditions studied

1

Description of health condition studied
Autism Spectrum Disorder
ICD-10 code
F84.0
ICD-10 code description
Childhood autism

Primary outcomes

1

Description
Socialization
Timepoint
Pre- intervention and 10 weeks after intervention
Method of measurement
ADI- R Questionnaire

Secondary outcomes

1

Description
Declining communication problems and stereotype behaviors
Timepoint
Pre- intervention and 10 weeks after intervention
Method of measurement
ADI- R Questionnaire

Intervention groups

1

Description
Pivotal Response Treatment in intervention group will be done for 20 sessions during 10 weeks. PRT is a behavioral treatment which therapist will select the intervention based on client's response and is completely client center.
Category
Rehabilitation

2

Description
Control group include autistic children who are not under any treatment and also will not receive any other during the research period.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Peyke Honar Autism School
Full name of responsible person
Elham Vadi
Street address
West 44 Alley, Kalantari Sq., Yousef Abad
City
Tehran

2

Recruitment center
Name of recruitment center
Beautiful Mind Rehabilitation Clinic
Full name of responsible person
Mojtaba Soltanlou
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No. 3, 16th Alley, Parvaneh St., Nasr bridge
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Islamic Azad University - Tonekabon Branch
Full name of responsible person
Dr Khalil Pour Shamsian
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Tonekabon
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, Islamic Azad University - Tonekabon Branch
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

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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