

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 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

###### Name

Mojtaba Soltanlou

###### Name of organization / entity

University of Tabriz

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6623 6219

###### Email address

soltanlou@razi.tums.ac.ir

##### 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

**Street address**

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

**Street address**

Educational complexity of Islamic Azad University of  
Tonekabon, Vali Abad

**City**

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

#### Contact

**Name of organization / entity**

University of Tabriz

**Full name of responsible person**

Mojtaba Soltanlou

**Position**

PhD Student of Cognitive Neuroscience

**Other areas of specialty/work**

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**Web page address**

<http://www.tabrizu.ac.ir/fa/index.htm>

### Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

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**Full name of responsible person**

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### Person responsible for updating data

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**Web page address**

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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*