

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The Effect of Pivotal Response Treatment on the Verbal Initiations Among 6-12 years old children with Autism Spectrum Disorder Using Behavioral and Electrophysiologic Analyses

Protocol summary

Study aim

Determination of the effect of pivotal response treatment on verbal initiation in 6 to 12 years old children with autism spectrum disorders using behavioral and electrophysiological analyzes

Design

A clinical trial with a controlled group with parallel groups, double-blind, randomized

Settings and conduct

20Autistic children in Arak are randomly assigned to one of the two groups without a mother's notice. Before and after the start of the study, verbal initiations are checked, and from each child is recorded electroencephalography. The treatment group receives 5 sessions of pivotal response treatment each week and the control group continues to their former treatment. At the end of treatment, verbal initiation and electroencephalographic data are analyzed without assessment' notice of the type of treatment for each child.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age(6-12 years old), autism spectrum disorder, Mean Length of Utterance of two words, No spontaneous questions, right handed Exclusion criteria: Missing more than 3 sessions, Disconnecting the child, Parental disagreement

Intervention groups

Intervention group(intervention with pivotal response treatment): The PRT intervention is based on the published manual: Teaching the Pivotal Behavior of Initiations to Children with Autism (Koegel 2011). PRT sessions will be conducted three times a week for two months, for a total of 24 one-hour sessions. Parents will be required to participate in the sessions at least twice a week for the entire two months of the study. Control group: the children of this group continue their usual treatment and will not receive any PRT. Parents will be

required to participate in the sessions at least twice a week for the entire two months of the study.

Main outcome variables

verbal initiation; absolute and relative power of brain's waves, coherence

General information

Reason for update

Due to the spread of the covid-19 pandemic and the closure of rehabilitation centers and the lack of families cooperation to participate in the research, the issue was discussed with the supervisor and the statistics consultant, and according to the letter sent from the Ministry of health affairs to the universities to reduce the sample size during the Corona period, and Significant results were obtained with the number of 10 samples in each group (total of 20 samples). The study was conducted with 20 samples.

Acronym

IRCT registration information

IRCT registration number: **IRCT20180617040124N1**
Registration date: **2019-04-23, 1398/02/03**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-30, 1401/11/10**

Update count: **2**

Registration date

2019-04-23, 1398/02/03

Registrant information

Name

Fereshteh Mohammadzaheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7756 1529

Email address

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Pivotal Response Treatment on the Verbal Initiations Among 6-12 years old children with Autism Spectrum Disorder Using Behavioral and Electrophysiologic Analyses

Public title

The Effect of Pivotal Response Treatment on children with Autism Spectrum Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Aged 6;0 to12 years old at the start of the study
Diagnosis of autism spectrum disorder: Participants must have a diagnosis of an autism spectrum disorder as assessed by a child psychiatrist or clinical psychologist according to DSM-V criteria before their baseline assessment. This judgment will be supported by the results of gold-standard diagnostic instruments—the GARS(Gilliam Autism Rating Scale)—administered by two speech pathologist high function autistic children: to earn score 30-36 in CARS Mean Length of Utterance(MLU) of at least two words No spontaneous questions in the speech no receive verbal initiation training while entering the study no receive other behavioral treatments during treatment in the intervention group All participants must be right handed parents must agree to participate in the intervention sessions the loss of other Health impairment such as visual or hearing impairments the loss of epilepsy or brain injury the loss of other psychiatric Disorders ((e.g., schizophrenia, ADHD) the loss of spike wave in EEG Do not take medication or take similar medications

Exclusion criteria:

Parental dissatisfaction or disagreement to continue attending treatment sessions Disconnecting the child in the study Missing more than 3 sessions of treatment sessions

Age

From 6 years old to 12 years old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: 20

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization: According to inclusion and exclusion criteria, 20children are selected and each of them is assigned a number from 1 to 20. then, The numbers are placed in a bag and drawn into lottery and alternating placed in the intervention and control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, participants are not given information on which treatment group they are located. Also, the person who analyzes the data is unaware of the allocation of people in the type of group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Science

Street address

South Worker, Enghelab Ave, Rehabilitation College

City

Tehran

Province

Tehran

Postal code

1148965141

Approval date

2018-12-19, 1397/09/28

Ethics committee reference number

IR.TUMS.FNM.REC.1397.173

Health conditions studied

1

Description of health condition studied

Autism

ICD-10 code

F84.0

ICD-10 code description

Autistic disorder

Primary outcomes

1

Description

Verbal initiation ability

Timepoint

Before and after treatment

Method of measurement

Parents report and parent's interaction with her child

Secondary outcomes

1

Description

Power spectral density

Timepoint

Before and after treatment

Method of measurement

Quantitative Electroencephalography

Intervention groups

1

Description

Intervention group(intervention with pivotal response treatment): The PRT intervention is based on the published manual: Teaching the Pivotal Behavior of Initiations to Children with Autism (Koegel 2011). This manual focuses on verbal initiations, mostly in the form of questions. In this intervention, items will be selected according to the child's preference for question-asking sessions. PRT sessions will be conducted in a one-on-one setting three times a week for two months, for a total of 24 one-hour sessions. Parents will be required to participate in the sessions at least twice a week for the entire two months of the study. and ask them to practice with their children three times a day.

Category

Rehabilitation

2

Description

Control group: the children of this group continue their usual treatment and will not receive any PRT. Parents will be required to participate in the sessions at least twice a week for the entire two months of the study. The parents must be willing work with their children three times a day.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Baran occupational therapy center

Full name of responsible person

Zahra soleymani

Street address

Ostadan Ave., Qods Blvd., Madar Town

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Markazi

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3818144679

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ahmad Rezaei

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ghods Ave., Keshavarz Blvd., Tehran University of Medical Science

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rmo@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical 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

Tehran University of Medical Sciences

Full name of responsible person

Zahra Soleymani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Speech therapy

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Position

phd student

Latest degree

Master

Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Zahra Soleymani

Position

Assistant Professor

Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Fereshteh Mohammadzaheri

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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

Not applicable

Title and more details about the data/document

The results of the original outcome are published.

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Researchers working in scientific and academic institutions and those working in the field of autism

Under which criteria data/document could be used

To research and use in the treatment of children with autism

From where data/document is obtainable

E-mail with Dr. Zahra Soleymani and Fereshteh Mohammadzaheri. f-mzaheri@razi.tums.ac.ir
soleymaniz@tums.ac.ir

What processes are involved for a request to access data/document

Once the email is viewed, it will be sent within a week.

Comments