Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

F-MZAHERI@RAZI.TUMS.AC.IR

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
Befor 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
City
Arak
Province
Markazi
Postal code
3818144679
Phone
+98 86 3366 6363
Email
fereshteh.mz@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ahmad Rezaei
Street address
ghods Ave., Keshavarz Blvd.,Tehran University of Medical Sciense
City
Tehran
Province
Tehran
Postal code
1148965141
Phone
+98 21 8163 3698
Email
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
Street address
Sout Worker., Enghelab Ave
City
Tehran
Province
Tehran
Postal code
1148956111
Phone
+98 21 7753 5132
Email
soleymaniz@tums.ac.ir

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
Ph.D.
Other areas of specialty/work
Speech therapy
Street address
Southern worker., Enghelab Ave
City
Tehran
Province
Tehran
Postal code
1148956111
Phone
+98 21 7753 5132
Email
soleymaniz@tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Fereshteh Mohammadzaheri
Position
phd student
Latest degree
Master
Other areas of specialty/work
Speech therapy
Street address
Sout Worker., Enghelab Ave
City
Tehran
Province
Tehran
Postal code
1148956111
Phone
+98 21 7753 5132
Email
f-mzaheri@razi.tums.ac.ir

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