Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The efficacy of emotional diet intervention on behavioral and electrophysiological changes in young children with autism symptoms exposed to digital nanning

Protocol summary

Study aim

In this study, we investigate the effect of emotional diet intervention (parent-child emotional communications improvement and care style correction) on electrophysiological (QEEG) changes and behavioral symptoms improvement of young children who have exposed to digital nanning and have autism symptoms.

Design

In this research, 30 eligible children with autism symptoms, who referring to Ava autism center, choose. The children assign randomly into two intervention group.

Settings and conduct

After selecting the sample group, pre-test will take at the Children's Medical Center and the intervention provide in the center of Tehran Autism, and the post-test and follow up will take again in the Children's Medical Center.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The child is exposed to digital devices for most of waking hours (direct exposure to active and passive digital devices), The ages between 2- 6؛
Exclusion criteria: Receive simultaneous intervention.

Intervention groups

The first intervention group: In this group, we remove digital devices from the child's life and they received emotional diet intervention for two months. The second group intervention: In this group, only digital devices removed from the child's life and intervention is not provided.

Main outcome variables

Brain Electrophysiological Frequency Bands؛ Executive Functions؛ Autism Symptoms؛ repetitive behaviors؛ Child-Parent Relationship

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161210031330N3**
Registration date: **2018-02-04, 1396/11/15**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-04, 1396/11/15**
Update count: **0**

Registration date

2018-02-04, 1396/11/15

Registrant information

Name
Saeid Sadeghi
Name of organization / entity
Shahid Beheshti University of Iran, Daneshjo
Country
Iran (Islamic Republic of)
Phone
+98 919 833 4575
Email address
saeid.sadeghi@mail.sbu.ac.ir

Recruitment status

Recruitment complete

Funding source

Researcher

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The efficacy of emotional diet intervention on behavioral and electrophysiological changes in young children with autism symptoms exposed to digital nanning

Public title
The impact of digital devices on the brain and the behavior of young children and their treatment by enriching the parent-child relationship
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The child beexposed to most of his waking hours directly to digital devices (in direct connection with active and passive digital devices). The child be between 2 and 6 years of age.
Exclusion criteria:
The child simultaneously with this intervention reciving other rehabilitation.
Age
From **2 years** old to **6 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Individuals are randomly assigned to one of two study groups with the help of a random number table and receive the intervention of the same group.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University
Street address
Institute for Cognitive & Brain Sciences, Shahid Beheshti University, Shahid Shahryari SQ, Shahid Chamran Highway, Tehran
City
Tehran
Province
Tehran
Postal code
1983969411
Approval date
2017-10-07, 1396/07/15
Ethics committee reference number
SBU.ICBS 96/1020

Health conditions studied

1

Description of health condition studied
Autistic disorder
ICD-10 code
F84.0
ICD-10 code description
Autistic disorder

Primary outcomes

1

Description
QEEG
Timepoint
Before the intervention, after the intervention and two months after the intervention
Method of measurement
EEG device with 32 channels

2

Description
Executive functions
Timepoint
Before the intervention, after the intervention and two months after the intervention
Method of measurement
The standard BRIEF executive function assessment questionnaire

3

Description
Autism Sign
Timepoint
Before the intervention, after the intervention and two months after the intervention
Method of measurement
CARS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The emotional richment intervention program has three levels: o First level: Connect with the child emotionally and build emotionally band o Second Level: parent-child interaction o Third level: child-parent interaction

Category

Lifestyle

2

Description

Control Group: Remove Digital Devaices

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Ava autism center

Full name of responsible person

Hamid Reza Pouretemad

Street address

No. 2, Deadlock. 4, Seventh Avenue, North Amir Abad

City

Tehran

Province

Tehran

Postal code

1984845497

Phone

+98 21 8863 3715

Email

iran3240@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran National Science Foundation

Full name of responsible person

Nosratollah Zargham

Street address

No. 33, Fifth street, North Amir Abad

City

Tehran

Province

Tehran

Postal code

1439634665

Phone

+98 21 8216 1173

Email

pr@insf.org

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran National Science Foundation

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

The Shahid Beheshti University

Full name of responsible person

Hamid Reza Pouretemad

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Institute for Cognitive & Brain Sciences, Shahid Beheshti University, Chamran High Way, Daneshjo Blvod, Shahid Beheshti University, Shahid Shahryari SQ, Chamran Higway

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 2990

Fax

Email

pr.office@mail.sbu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

The Shahid Beheshti University

Full name of responsible person

Saeid Sadeghi

Position

PhD Candidate

Latest degree

Master

Other areas of specialty/work

Psychology

Street address
Institute for Cognitive & Brain Sciences, Shahid Beheshti University, Shahid Shahryari SQ, Chamran High Way
City
Tehran
Province
Tehran
Postal code
1983969411
Phone
+98 21 2243 1617
Fax
Email
saeidsadeghi.psychologist@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
The Shahid Beheshti University
Full name of responsible person
Saeid Sadeghi
Position
PhD Candidate
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
Institute for Cognitive & Brain Sciences, Shahid Beheshti University, Shahid Sharyari SQ, Chamran High Way
City
Tehran
Province
Tehran
Postal code
1983969411
Phone
+98 21 2243 1617
Fax
Email
saeidsadeghi.psychologist@gmail.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Behavioral data file, study protocol, informed consent form and clinical study reports after unidentifiable people is shareable.
When the data will become available and for how long
The beginning of the access period is 1 year after the publication of the results.
To whom data/document is available
Behavioral data of this research will be available only for researchers that working in universities.
Under which criteria data/document could be used
Use of the data is allowed only for review articles.
From where data/document is obtainable
Saeid Sadeghi Mobile number: 0098 9120132485 Phone number: 0098 21 22431617 Email: saeidsadeghi.psychologist@gmail.com Address: Institute for Cognitive & Brain Sciences, Shahid Beheshti University, Shahid Shahryari SQ, Chamran Highway
What processes are involved for a request to access data/document
Researchers who want to access the data must get a letter from the university at their place of work and send to the responsible person's email address, then the data will be available in less than 1 month.
Comments