

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 Deavaices

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 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

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 Sharyari 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**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**