Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Oct 2026

Investigating the effect of the Teach-back method on Parents Knowledge and Performance in relation to the Safety Care of Children with Autism (Randomized Controlled Trials)

Protocol summary

Study aim

Determining the impact of feedback-based training on parents' knowledge and performance about the safety care of children with autism.

Design

Clinical trial with control group, parallel group, one blind strain, Random Allocation software randomization, Random Block software randomization list.

Settings and conduct

Implementation of the intervention in coordination with the officials of the centers and parents on certain days during 3 weeks, one day a week, and one-hour training sessions a day. Only the statistician will not be aware of the assignment of samples to the control and intervention groups, and therefore, blinding will be done only for the statistician.

Participants/Inclusion and exclusion criteria

Entry criteria for parents: being responsible for taking care of a child with autism; having a file of the child under their care in the welfare center; having a smartphone. Non entry criteria : parents suffering from psychological illness based on self-report; a child suffering from other chronic diseases.

Intervention groups

Before the start of the first session, they will be divided into 4 groups of 9 people, on the first day, the goals of the research plan will be explained to the parents, and if they have any questions beyond the goals, they will be referred to the psychologist of the center. At the end of all three sessions, the parents' understanding of the training provided By asking them to repeat the material, they will be measured and in case of incomplete or wrong understanding, the educational material will be repeated and reviewed again. To ensure the parents' understanding, scenarios will be presented for group discussion. For the control group, no training or action will be taken, and at the end, The study will be uploaded for this group's use of the content of the educational package.

Main outcome variables

Primary outcome awareness, secondary outcome performance.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240510061727N1**
Registration date: **2024-05-21, 1403/03/01**
Registration timing: **prospective**

Last update: **2024-05-21, 1403/03/01**
Update count: **0**

Registration date

2024-05-21, 1403/03/01

Registrant information

Name

Maryam Moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3355 3202

Email address

mrymrdi99@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-05-22, 1403/03/02

Expected recruitment end date

2024-07-06, 1403/04/16

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of the Teach-back method on Parents Knowledge and Performance in relation to the Safety Care of Children with Autism (Randomized Controlled Trials)

Public title
Investigating the effect of the Teach-back method on Parents Knowledge and Performance in relation to the Safety Care of Children with Autism
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Parents should be willing to participate in the research. Parents are responsible for taking care of autistic children. The file of the child with autism is under the care of the parents in the welfare center of Rasht city. Parents should take care of a child with autism at home. Parents should have a smartphone. Parents should have access to the Internet and virtual networks. Parents should be able to use mobile phones and virtual networks.
Exclusion criteria:
Parents have a psychological illness based on self-report. The child is suffering from other chronic diseases (physical and psychological). Parents have participated in educational and support programs similar to the intervention in the last year.
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization of the samples will be used based on the Random Allocation software, in this study, according to the sample size, using the block randomization method, 9 blocks of 4 will be divided into intervention and control groups. To generate the randomization list, Random Block software will be selected and the sequence of entering the samples in the educational intervention and non-educational intervention groups will be selected based on the list of cases of children with autism in the centers covered by the Rasht Welfare Department. For concealment, the sequence list is kept in a sealed envelope with the supervisor (Dr. Yasman Yaghoubi), and after obtaining permission to conduct the research and the necessary coordination, the envelope is opened and read daily in the relevant centers.
Blinding (investigator's opinion)
Single blinded
Blinding description
Given that the researcher knows the characteristics of the control and intervention group participants, there is no possibility of blinding the researcher. On the other hand, the program is explained in the consent form that is given to the participants, and therefore the participants will be assigned to the control and intervention groups, so there will be no possibility of blinding the participants. Only the statistician will not be aware of the assignment of samples to the control and intervention groups, and therefore, blinding will be done only for the statistician.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Guilan University of Medical Sciences
Street address
Namjo St., in front of Azodi Stadium.
City
Rasht
Province
Guilan
Postal code
41446-66949
Approval date
2024-05-01, 1403/02/12
Ethics committee reference number
IR.GUMS.REC.1403.042

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

In this study, the awareness and performance of parents of children with autism are measured about preventive care; For this purpose, awareness is the primary outcome.

Timepoint

It will be done 2 times, before the start of the first training session and one month after the last training session.

Method of measurement

A researcher-made questionnaire in the field of parents' awareness about the safe care of children with autism, which questionnaires have been reviewed by 11 faculty members of Shahid Beheshti School of Nursing and Midwifery in Rasht, the content validity ratio in these two questionnaires has been acceptable, and the content validity index has been approved for The awareness questionnaire is 0.92. To determine the internal consistency of the awareness questionnaire, Richardson20 was used. The Richardson20 coefficient was obtained as 0.717 after removing question 17, so this tool with 24 questions has acceptable internal consistency. To determine the external consistency of the awareness questionnaire, the ICC coefficient and Test-Retest coefficient were used. became. The Test-Retest coefficient of the two knowledge questionnaires was 91.4% and the ICC coefficient was 0.952; Therefore, the awareness tool has acceptable reliability in terms of external stability.

Secondary outcomes

1

Description

The secondary outcome is performance.

Timepoint

It will be done 2 times, before the start of the first training session and one month after the last training session.

Method of measurement

A researcher-made questionnaire in the field of parents' performance in connection with the safe care of children with autism, the questionnaires have been reviewed by 11 faculty members of the Shahid Beheshti College of Nursing and Midwifery in Rasht, the content validity ratio has been acceptable and the content validity index has been approved for the questionnaire. The performance is 0.94. Alpha Cronbach's coefficient was used to check the internal consistency of the performance questionnaire, and the alpha Cronbach's coefficient was 0.901, so this instrument has acceptable internal consistency with 25 questions. Also, the ICC coefficient and Test-Retest coefficient were used to determine the external stability of the performance tool. The test-retest coefficient of two performance questionnaires was 99.2% and the ICC coefficient was 0.981; Therefore, the performance tool has acceptable reliability in terms of external stability.

Intervention groups

1

Description

Intervention group: Before the start of the first training session, the questionnaires will be sent privately to the intervention group through the Ita and Baleh messenger, in coordination with the center officials and parents, the training will be carried out on specific days in the respective centers, before the start of the first training session of the group participants. intervention, they will be divided into 4 groups of 9 people, on the first day, the goals of the research project will be explained to the parents again, the main goal of the research will be education about safety care, and if they have any questions outside of the goals, they will be referred to the psychologist of the center. According to the program, during 3 weeks, one day per week and one hour per day, educational sessions will be held, so that in the first session, the prepared educational content will be presented through interactive lectures to the participants who are present in the groups. At the end of the first session, the participants are asked to write down the topics that are unclear to them or need more training on a sheet and provide them to the researcher. In the second session, the educational content according to the course plan, and then based on the needs assessment of each group, vague topics will be prepared separately and presented in an interactive lecture style in different groups, at the end of the second session, a survey of the participants regarding the proposal for improvement The solution will be implemented to help awareness and practice in connection with the safety care of children with autism. In the third session, the educational content will be prepared and presented according to the course plan and then based on the results of the survey in the second session. At the end of all three sessions, the parent's understanding of the given education will be measured by asking them to repeat the content. In case of incomplete or wrong understanding, the educational materials will be repeated and reviewed, and scenarios will be presented for group discussion to ensure parents' understanding. After one month from the last training session, the questionnaires of parents' awareness and performance regarding the safety care of children with autism will be provided to the learners through the messenger Ita and Baleh , to measure the level of awareness and performance of parents of children with autism.

Category

Lifestyle

2

Description

Control group: No training or action will be taken for the control group, before the start of the first training session in the intervention group, the questionnaires will be sent privately to the control group through the Ita and Baleh messenger, and again one month after the last training session in the intervention group, the questionnaires will

be sent through It will be sent to the control group. After receiving the questionnaires, following the response of the control group, to use the educational content for the parents of this group, the educational package will be uploaded at the end of the study.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Rasht Welfare Department

Full name of responsible person
Mozhgan Akhavan Zia

Street address
Nurse Street

City
Rasht

Province
Guilan

Postal code
4193713413

Phone
+98 13 3336 8900

Fax
+98 13 3336 8725

Email
info@ Behzisty-Guilan.ir

Web page address
http://www.behzisty-guilan.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Dr. Pirouz Samidoust

Street address
Namjo St., Shahid Siyadati St., in front of 17 Shahrivar Hospital.

City
Rasht

Province
Guilan

Postal code
41446-66949

Phone
+98 13 3333 6394

Fax
+98 13 3333 6395

Email
research@gums.ac.ir

Web page address
https://gums.ac.ir/

Grant name

Grant code / Reference number

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

Title of funding source
Rasht 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
Rasht University of Medical Sciences

Full name of responsible person
Maryam Moradi

Position
Master student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
Shahid Beheshti Highway - Student Street

City
Rasht

Province
Guilan

Postal code
41469-39814

Phone
+98 13 3355 3202

Fax
+98 13 3355 0097

Email
Mrymrdi99@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Yasaman Yaghobi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Shahid Beheshti Highway - Student Street

City

Rasht
Province
Guilan
Postal code
41469-39814
Phone
+98 13 3355 3202
Fax
+98 13 3355 0097
Email
Yaghobiyasaman@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Maryam Moradi
Position
Master student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Shahid Beheshti Highway - Student Street
City
Rasht
Province
Guilan
Postal code
41469-39814
Phone
+98 13 3355 3202
Fax
+98 13 3355 0097
Email
Mrymrdi99@gmail.com

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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Part of individual data in demographic questionnaire. Total awareness and performance data.
When the data will become available and for how long
The access period starts one year after the results are published.
To whom data/document is available
All researchers in academic institutions and businesses.
Under which criteria data/document could be used
No decision has been made yet.
From where data/document is obtainable
Dr. Yasman Yagoubi, assistant professor of Rasht University of Medical Sciences, email address yaghobiyasaman@yahoo.com Maryam Moradi, Master student of Rasht University of Medical Sciences, email address mrymrdi99@gmail.com
What processes are involved for a request to access data/document
It will be sent as soon as possible after the checks done by the researcher.
Comments