

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Measuring the Effectiveness of Group-Based Proper Nutrition-Training Therapy on Tendency to Food Diversity and Anxiety in Preschool Children with Avoidance / Restriction Disorders

#### Protocol summary

avoidance / restriction of food; Anxiety in children

##### Study aim

evaluation of the effectiveness of group nutrition training based on play therapy on anxiety and tendency to food diversity in preschool children with avoidance disorder / food restriction

##### Design

Clinical trial with control group, double-blind, randomized, phase 3 on 10 patients. Excel software rand function was used for randomization.

##### Settings and conduct

The aim of this study was to evaluate the effectiveness of group nutrition training based on play therapy on anxiety and tendency to food diversity in preschool children with avoidance / restriction disorder in Sanandaj. Its design is a quasi-experimental pre-test-post-test with a control group and a follow-up stage. A blind one-way study in which the analyzer was unaware of any of the processes.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Having diagnostic criteria for DSM5 based on avoidance / restriction disorder; Children who do not have a clear physical illness; They are between 3 and 5 years old Exclusion criteria: Children undergoing medical treatment and absence of more than two sessions in psychotherapy sessions.

##### Intervention groups

The intervention begins with 2 group training sessions for the mothers of the experimental group. The experimental group then receives 120 minutes of intervention for 8 sessions, but the control group does not receive any intervention. At the end of the intervention, for each of the children, the two groups of eating behavior and anxiety questionnaires are completed again by their mothers. One month after the intervention, follow-up is performed.

##### Main outcome variables

Tendency to food diversity among children with

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220128053843N1**

Registration date: **2022-03-22, 1401/01/02**

Registration timing: **retrospective**

Last update: **2022-03-22, 1401/01/02**

Update count: **0**

##### Registration date

2022-03-22, 1401/01/02

##### Registrant information

##### Name

aboubakr karimi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 87 3373 2001

##### Email address

aboubakr.karimi@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-01-31, 1400/11/11

##### Expected recruitment end date

2022-03-02, 1400/12/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Measuring the Effectiveness of Group-Based Proper Nutrition-Training Therapy on Tendency to Food Diversity and Anxiety in Preschool Children with Avoidance / Restriction Disorders

**Public title**

educational nutrition package based on group play therapy for preschool children

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Having DSM5-based criteria for avoiding / avoiding eating disorders (such as being low in weight and energy and having some anxiety) Children whose scores on each subscale of the Eating or Avoidance Problems Questionnaire are a standard deviation above average Children who do not have a clear physical illness They are between 3 and 5 years old Failure to receive concomitant drug therapy for research purposes

**Exclusion criteria:**

Children who have been on medication, such as those taking anti-anxiety medications Absence from more than two sessions in psychotherapy sessions.

**Age**

From **3 years** old to **5 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Data analyser

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

30 identified children with avoidance disorder / food restriction; They were organized in 2 groups of 15 (experimental and control) by simple randomization method. The following random number table was used for randomization: First, the researcher's colleague determined to read the numbers in the table, from top to bottom. Next, he considered odd numbers for the experimental group and even numbers for the control group. Then he put his hand on one of the numbers and moved from top to bottom and recorded the numbers and assigned them to the experimental and control groups.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

In a completely randomized manner, children were divided into two groups, in which the researcher did not know. But after dividing and forming groups because of 10 sessions, education is accepted by the plan of the plan, it is inevitably aware of the type of treatment.

Children were notified after the formation of groups, which program is supposed to be implemented. Only an analysis of none of the processes, so the one-blind study will be

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethics Committee of Payame Noor University

**Street address**

saheli- Farhangian Town - Shayan Alley 10

**City**

Sanandaj

**Province**

Kurdistan

**Postal code**

6616978156

**Approval date**

2021-11-20, 1400/08/29

**Ethics committee reference number**

IR.PNU.REC.1400.242

**Health conditions studied****1****Description of health condition studied**

Avoidant-Restrictive Food Intake Disorder (ARFID)

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Trends in children's food diversity based on Wardell, Guthrie, Sanderson and Rapaport (2001) Children Eating Behavior Questionnaire

**Timepoint**

Before intervention, after intervention, one month after intervention

**Method of measurement**

The Wardell, Guthrie, Sanderson, and Rapaport (2001) Children Eating Behavior Questionnaire was used.

**2****Description**

Reducing Child Anxiety Based on the Revised Childhood Anxiety Scale (CMAS) by Reynolds and Richmond (1987)

#### **Timepoint**

Before intervention, after intervention, one month after intervention

#### **Method of measurement**

The Revised Child Anxiety Scale (CMAS) by Reynolds and Richmond (1987) has been used.

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

Intervention group: The intervention started with 2 group training sessions for mothers in the experimental group. Therapeutic group of young children with eating disorders; It requires the cooperation and serious participation of their mothers in the treatment process. For this reason, in the intervention, 2 sessions are provided for educating mothers. In the first session, parenting style and child nutrition were taught, and in the next session, a number of package therapy games were introduced and taught to mothers. The experimental group then received 120 minutes of 120 minutes of group nutrition training through play therapy. The titles of the intervention sessions are as follows: Healthy eating, dietary diversity, adding healthy eating concepts to the vocabulary, recognizing anxiety and relaxation education, developing interest in a variety of foods, teaching nutritional skills and eating habits, teaching problem-solving skills, preventing relapse. In each session, 2 games were played with children, and the names of the games are as follows: Knowing the types of food, dream pillows, guests playing and setting the table, breathing journey, what is wrong? I'm a turtle, an agricultural truck, pasta, playing card games, making bubbles, making a healthy meal, breathing gig, storytelling with pictures, running after talking, popcorn and the five senses.

##### **Category**

Treatment - Other

#### **2**

##### **Description**

Control group: The control group did not receive any intervention.

##### **Category**

Treatment - Other

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Behzisti Organization

##### **Full name of responsible person**

Aref Rahimi

##### **Street address**

Bolvar Shebli

##### **City**

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##### **Phone**

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##### **Email**

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### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

###### **Name of organization / entity**

Iranian academic center for education culture and research

###### **Full name of responsible person**

Research Assistant

###### **Street address**

Saheli

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###### **Web page address**

<https://acecr.ac.ir/fa>

##### **Grant name**

##### **Grant code / Reference number**

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

Yes

##### **Title of funding source**

Iranian academic center for education culture and research

##### **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**

Iranian academic center for education culture and research

**Full name of responsible person**

Aboubakr Karimi

**Position**

PhD in Clinical Psychology - Governor Advisor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

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

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**Full name of responsible person**

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**Position**

Advisor to the Governor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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

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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Some of the data, such as the main outcome, can be shared

**When the data will become available and for how long**

Start of access period 1 month after printing the results

**To whom data/document is available**

Anyone can

**Under which criteria data/document could be used**

Use of data, citing the source

**From where data/document is obtainable**

Email me aboubakr.karimi@yahoo.com

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

Up to one week after receiving the application, which will be sent to me via email, the files will be sent to the applicant.

**Comments**