

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

Sanandaj

Province

Kurdistan

Postal code

6616978156

Phone

+98 87 3373 2001

Email

aboubakr.karimi@yahoo.com

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

City

Sanandaj

Province

Kurdistan

Postal code

6616978156

Phone

+98 87 3182 2070

Email

aboubakr.karimi@yahoo.com

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

Street address
Shayan 10 Ave, Farhangiyen- Saheli

City
Sanandaj

Province
Kurdistan

Postal code
6616978156

Phone
+98 87 3373 2001

Email
aboubakr.karimi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kurdistan Governorate

Full name of responsible person
Aboubakr Karimi

Position
Adviser to the Governor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
Saheli

City
Sanandaj

Province
Kurdistan

Postal code
6616978156

Phone
+98 87 3373 2001

Email
aboubakr.karimi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Kurdistan Governorate

Full name of responsible person
Aboubakr Karimi

Position
Advisor to the Governor of Kurdistan

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
Saheli

City
Sanandaj

Province
Kurdistan

Postal code
6616978156

Phone
+98 87 3373 2001

Email
aboubakr.karimi@yahoo.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

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