

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

The effect of occupation-centered interventions on self-determination of female adolescents at risk of Emotional-Behavioral Disorders according to MOHO

Protocol summary

Study aim

The effect of occupation-centered interventions on self-determination of female adolescents at risk of Emotional-Behavioral Disorders according to MOHO

Design

In this research, 54 adolescents at risk of Emotional-Behavioral Disorders who through Youth Self Report are screened. Then, patients are randomly divided into two control and intervention groups via block randomization and a code is allocated to each one of them.

Settings and conduct

The research is practical and is implemented as RCT in mental health clinic of the Faculty of Rehabilitation of Iran University of Medical Sciences on girls studying at high schools in Tehran. Data collection is done by unknowing evaluator and data is analyzed by unknown statisticians.

Participants/Inclusion and exclusion criteria

Entry requirements: age 14- 16; female gender; cutting score (50-70) in youth self report; studying in high school Conditions of failure to enter: lack of cooperation; Two consecutive absences or four absentee sessions throughout the sessions

Intervention groups

The study was conducted with 54 participants in two groups of control and intervention with 27 people. Participants in the intervention group are divided into three groups of 5 to 7 people. The allocation of people in each group is done in accordance with the uniformity and participation in the interests of the participants according to the MOHO interests form. Therapeutic intervention will be provided to the intervention group for 8 sessions of 90 minutes per week (according to available resources and articles).

Main outcome variables

independent variable: occupation-centered interventions;
dependent variable: student self-determination; self-

determination (parent perception); executive function;
Communication and Interaction Skills; Achievement

General information

Reason for update

The reason for the update is to request a change in the sample size and also to report the termination of the clinical trial. Evidence, texts and research were reviewed and the probability of sample loss was considered. and the sample size increased from 40 to 54 samples, which after sampling and sample drop (7 people lost in the control group), the intervention ended with 47 patients (intervention=27) and (control=20).

Acronym

IRCT registration information

IRCT registration number: **IRCT20171231038153N1**
Registration date: **2018-02-07, 1396/11/18**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-29, 1399/05/08**

Update count: **1**

Registration date

2018-02-07, 1396/11/18

Registrant information

Name

Narges Shafaroodi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

2018-01-21, 1396/11/01

Actual recruitment end date

2018-03-20, 1396/12/29

Trial completion date

2018-06-21, 1397/03/31

Scientific title

The effect of occupation-centered interventions on self-determination of female adolescents at risk of Emotional-Behavioral Disorders according to MOHO

Public title

The effect of occupation-centered interventions on self-determination of adolescents

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 14 to 16 years Female gender Gain cutting scores (above 60) in the test of Youth Self Report Studying in high school

Exclusion criteria:

Lack of cooperation in intervention Two consecutive absence occasions Or four absentee sessions in total

Age

From **14 years** old to **16 years** old

Gender

Female

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **54**

Actual sample size reached: **47**

Randomization (investigator's opinion)

Randomized

Randomization description

Three-stage cluster sampling(Education areas, schools, students) Restricted randomization methods and Permuted block randomization will be used to select students. Randomization tool is Random number table . allocation concealment is done as intervention and control groups are not known

Blinding (investigator's opinion)

Single blinded

Blinding description

Collection of research data are conducted by evaluators who are unaware of the participants in the intervention and control group. Analysis of the research data is analyzed by statisticians who are unaware of the groups

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Iran university medical sciences

Street address

Iran University of Medical Sciences, Hemat Highway next to Milad Tower, Tehran

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Postal code

۱۳۹۶۱۴۵۳۵

Approval date

2017-12-28, 1396/10/07

Ethics committee reference number

9321525001 .IR.IUMS.REC.1396

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

At risk of Emotional-behavioral disorders

ICD-10 code

F01-F99

ICD-10 code description

Behavioral and emotional disorders with onset usually occurring in childhood and adolescence.

Primary outcomes**1****Description**

student self-determination is a 92-item self-report instrument that measures both affective and cognitive aspects of the student's self-determination.including General Positive, General Negative, Specific Positive, and Specific Negative. The general subscales relate to a student's sense of global self-determination, while the specific subscales relate primarily to application in their education, home, and related environmental settings. The positive subscales indicate self-determination in areas of perceived strength, while the negative subscales indicate areas of perceived weakness in self-determination.

Timepoint

At the begining of interventio; At the end of intervention (after 8 weeks) and after 10 weeks (follow up)

Method of measurement

Self-Determination Student Scale

2

Description

Self-Determination Parent Perception Scale: Parents' perceptions of their child's self-determination behaviors, abilities and skills.

Timepoint

At the Beginning of intervention ; At the end of intervention (after 8 weeks) and after 10 weeks (follow up)

Method of measurement

Self-Determination Parent Perception Scale (PPS)

Secondary outcomes

1

Description

Communication and Interaction Skills: Refers to behaviors that one can communicate with others through these behaviors, which leads to positive responses and negative responses.

Timepoint

At the Beginning of intervention; At the end of intervention (after 8 weeks) and after 10 weeks (follow up).

Method of measurement

In this research, Communication skills include 20 items that are classified into three areas of physicality , information exchange and relations Which is measured by the communication and interaction skills assessment(ACIS).

2

Description

Executive function:Executive functions are an idiomatic term that covers all of the complex cognitive processes that are required for task-oriented, difficult or new assignment tasks.

Timepoint

At the Beginning of intervention; At the end of intervention (after 8 weeks) and after 10 weeks (follow up).

Method of measurement

In this research, execution function is measured by three software programs, TOWER OF LONDON TEST; Go No Go; BART TASK.The decision making, problem solving, and risk-taking are evaluated.

3

Description

Academic Achievement: The ability to prove success in acquiring an outcome for which learning experiences are projected.

Timepoint

First semester;The end of the academic year

Method of measurement

In this study, academic achievement is the average of the second-order scores of school.

Intervention groups

1

Description

Intervention group: The content of the intervention will be based on the protocol contained in the STEPS To Self-Determination Curriculum, with permission from the authors of the book.Designing a set of occupations based on the interests and culture of adolescents participating in intervention and Confirming at a meeting of experts .Participants in the intervention group are divided into three groups of 5 to 7 people.Assignment of people in each group is done in accordance with the uniformity and participation in the interests of the participants according to the form of MOHO Interests.The intervention will be held for 8 sessions of 90 minutes per week (according to available resources and articles) for the intervention group.

Category

Behavior

2

Description

Control group: Includes 20 students at risk for emotional-behavioral disorders that do not receive any intervention.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Secondary school girls of 1-4-7-11 of Tehran city

Full name of responsible person

Elahe Hojati Abed

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Elahe Hojati Abed

Position

PHD Student in Occupational Therapy

Latest degree

Master

Other areas of specialty/work

Occupational Therapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Not applicable

Data Dictionary

Not applicable