

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### The Impact of Group Reality Therapy Based on Choice Theory on Social Anxiety and Self-efficacy of Students with Cell Phone Addiction

#### Protocol summary

##### Study aim

The main objective : Determining the effect of group reality therapy based on selection theory on social anxiety and self-efficacy of students with cell phone dependence. Secondary objectives: 1. Determining and comparing the social anxiety of students with cell phone dependence in the two groups of test and control before and after the intervention; 2. Determining and comparing the self-efficacy of students with mobile phone dependence in two experimental and control groups before and after the intervention.

##### Design

Clinical trial with intervention and control groups that are selected by simple random allocation by sampling method.

##### Settings and conduct

Sampling place: from virtual groups of nursing students studying ( due to corona virus coditions). How to do it: In a simple random allocation and by lottery method. A total of 52 people enter the study and are assigned to two groups of test and control.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Students who were undergraduate nursing in Tehran University of Medical Sciences. 2. Students who received a score higher than 43 from the Kuh-e-He mobile phone dependency questionnaire. 3. Students who are not under another educational or medical program at the same time as the educational program. Exclusion criterion: Absence of more than two sessions in reality therapy sessions.

##### Intervention groups

The intervention group learns reality therapy based on selection theory in 6 sessions of 1.5 hours and the control group does not learn any intervention or training.

##### Main outcome variables

If the positive effect of group reality therapy based on choice theory on social anxiety and self-efficacy of individuals, administrators and educational policy makers can use this therapeutic approach as a group in schools,

universities and all young people to manage low self-efficacy and social anxiety due to dependence.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210424051059N1**

Registration date: **2021-06-21, 1400/03/31**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-06-21, 1400/03/31**

Update count: **0**

##### Registration date

2021-06-21, 1400/03/31

##### Registrant information

##### Name

kimiya darabi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8825 5169

##### Email address

kimiyad74@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-05-29, 1400/03/08

##### Expected recruitment end date

2021-06-29, 1400/04/08

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The Impact of Group Reality Therapy Based on Choice Theory on Social Anxiety and Self-efficacy of Students with Cell Phone Addiction

**Public title**

The Impact of Group Reality Therapy Based on Choice Theory on Social Anxiety and Self-efficacy of Students with Cell Phone Addiction

**Purpose**

Treatment

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

Students who were undergraduate nursing in Tehran University of Medical Sciences. Students who received a score higher than 43 from the Kuh-e-He mobile phone dependency questionnaire. Students who are not under another educational or medical program at the same time as the educational program.

**Exclusion criteria:**

Absence of more than two sessions in reality therapy sessions

**Age**

From **15 years** old to **25 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **52**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

All nursing students, members of the Tehran School of Nursing and Midwifery, were asked to complete an online questionnaire on demographic information and cell phone dependence, if possible and desired. Then, 58 students were randomly selected from the students completing the questionnaire based on the inclusion criteria, and were divided into two groups of test (intervention) and control by simple random allocation using the lottery method. First, a list of eligible people was prepared, then a number from one to 58 was assigned to each of them, and by drawing lots, the numbers were written on pieces of paper and placed in a container and mixed well to make a sample. With a certain volume of each intervention and control group was determined. According to the method of determining the sample size based on the opinion of the professor of statistics, a maximum of 58 people entered the study, of which 52 people in total and 26 people in each test and control group, taking into account the loss of 10% of the sample.

**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 the School of Nursing and Midwifery and the School of Rehabilitation, Tehran Uni

**Street address**

Office of the Vice Chancellor for Research, First Floor, Building No. 1 of the Faculty of Medicine, North Door of the University, Poursina St, Ghods St, Enghelab St.

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733171

**Approval date**

2020-08-23, 1399/06/02

**Ethics committee reference number**

IR.TUMS.FNM.REC.1399.083

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

Mobile Dependence

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

Mobile Dependence: A score above 43 of the Kuh-e Hey Mobile Dependency Questionnaire

**Timepoint**

At the beginning of the study: to determine the conditions for inclusion in the study

**Method of measurement**

Using Kuh-e-Hey mobile phone dependency questionnaire

**2****Description**

Social Anxiety: The score that a person gets from the Jorabak Social Anxiety Questionnaire.

**Timepoint**

At the beginning and end of sampling

## Method of measurement

Using Jorabak Social Anxiety Questionnaire

3

### Description

Self-efficacy: is the score that the subject obtains in the Scherer and Maddox (1982) self-efficacy questionnaire.

### Timepoint

At the beginning and end of sampling

### Method of measurement

Using Scherer and Maddox self-efficacy questionnaire

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: Teaching them 6 sessions of 1/5 hour reality therapy based on selection theory

### Category

Treatment - Other

2

### Description

Control group: Not receiving any intervention and training

### Category

Treatment - Other

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

School of Nursing and Midwifery, Tehran University of Medical Sciences

#### Full name of responsible person

Kimiya Darabi

#### Street address

Tohid Square, Dr. Mirkhani St. (Eastern Nusrat)

#### City

Tehran

#### Province

Tehran

#### Postal code

1419733171

#### Phone

+98 21 6692 7171

#### Email

kimiyad74@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Dr. Mehrnaz Granmaye

#### Street address

Tohid Square, Dr. Mirkhani St. (Eastern Nusrat)

#### City

Tehran

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#### Postal code

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#### Phone

+98 21 6105 4567

#### Email

fnm-researchdeputy@tums.ac.ir

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Tehran 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

Tehran University of Medical Sciences

#### Full name of responsible person

Kimiya Darabi

#### Position

Master student of psychiatric nursing

#### Latest degree

Bachelor

#### Other areas of specialty/work

Nursery

#### Street address

Tehran, School of Nursing and Midwifery, Dr. Mirkhani St. (Eastern Nusrat), Tohid Square.

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Kimiya Darabi

**Position**

Master of student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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## Person responsible for updating data

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**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Kimiya Darabi

**Position**

Master of student

**Latest degree**

Bachelor

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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**

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

**Data Dictionary**

Not applicable