# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## Design and validation of the effectiveness of interactive meta-diagnostic treatment software for social anxiety disorder

## Protocol summary

**Study aim**
Design and evaluation of the effectiveness of interactive meta-diagnostic treatment software for social anxiety disorder.

**Design**
Purposeful and voluntary sampling, 6 people will be trained individually with interactive software for 10 treatment sessions.

**Settings and conduct**
Umm Al-Imam High School in Robat Karim will be the place of study. First, the diagnostic interview and the social phobia test complete, then Android App is installed each session will taught for 10 sessions. Each session will automatically test the software.

**Participants/Inclusion and exclusion criteria**
Six participants will be purposefully and judiciously will select from Umm Al-Imam School in Robat-Karim. Admission requirements: Must have social anxiety. Age between 15 and18. Exclusion criteria: no coexistence disorder with social anxiety

**Intervention groups**
Interactive software: This software designed in the Android environment with the Java programming language includes trans-diagnostic treatment methods for social anxiety disorder. 1. The software includes the test part of Connor Social Panic Questionnaire. Scores above 20, represent disorder. 2. Next, the diagnostic interview is based on the diagnostic and statistical guide of mental disorders 5th-edition. 3. Then we specify the goal setting table. What are the advantages and disadvantages of changing? 4. Then we try to get the precedents, answers and repetitive behaviors which repeat it when they get excited. 5. Teaching emotion and excitement. People with emotional disorders always want to suppress their emotions by avoiding. 6. Next, emotional driven behaviors will determine for the person identifies and corrects the behaviors that occur subconsciously with anxiety. 7. Practice mindfulness and being here and now is given to the authorities. 8. Practicing judgment and non-judgment is the last stage of treatment.

**Main outcome variables**
Social Anxiety

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20220406054427N3**
Registration date: **2022-06-25, 1401/04/04**
Registration timing: **registered_while_recruiting**

Last update: **2022-06-25, 1401/04/04**
Update count: **0**

**Registration date**
2022-06-25, 1401/04/04

**Registrant information**

**Name**
Ghazal Zandkarimi

**Name of organization / entity**
Alzahra University

**Country**
Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2022-06-22, 1401/04/01

**Expected recruitment end date**
2022-08-21, 1401/05/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Design and validation of the effectiveness of interactive meta-diagnostic treatment software for social anxiety disorder

**Public title**

Evaluation of the effectiveness of interactive meta-diagnostic software for social anxiety disorder

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Having social anxiety disorder No other comorbid mental disorder due to clinical specialist approval No use of arbitrator and other intervention at the same time as the course of treatment in this study

**Exclusion criteria:**

No other comorbid mental disorders

**Age**

From **15 years** old to **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **6**

**Randomization (investigator's opinion)**

N/A

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Single

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Al-Zahra University

**Street address**

Alzahra University, Deh Vanak St.

**City**

Tehran

**Province**

Tehran

**Postal code**

1371158545

**Approval date**

2022-04-06, 1401/01/17

**Ethics committee reference number**

IR.ALZAHRA.REC.1401.003

## Health conditions studied

### 1

**Description of health condition studied**

Social Anxiety Disorder

**ICD-10 code**

F40.1

**ICD-10 code description**

Social phobias

## Primary outcomes

### 1

**Description**

Social Anxiety Disorder

**Timepoint**

Measurements will be performed twice at the beginning of the study, then each time after each treatment session, for a total of 8 measurements, and then after one month of follow-up re-measurements.

**Method of measurement**

Social Panic Questionnaire (Connor, 2000)

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: The aim of this study was to design and evaluate the validity of effective interactive meta-diagnostic treatment software for social anxiety disorder. Sampling of the intervention group was purposeful and voluntary. In this study, 6 people will be individually trained with interactive software made of 8 sessions of treatment. Participants from the Umm al-Imam School in Robat Karim must be suffering from social anxiety. Age between 15 and 18 years, absence of comorbidity disorder and medication and other intervention during the study were the criteria for admission and not participating in more than two sessions of treatment and use of medication or other treatment during the study were among the exclusion criteria. Interactive software: This software designed in Android environment with Java programming language includes meta-diagnostic treatment methods for social anxiety disorder 1. The software includes the test section of Connor Social Panic Questionnaire, if a person gets a score above 20, he has a disorder. 2. The next step is the diagnostic interview

based on DSM-5 criteria. If a person has a disorder syndrome, the system will give him feedback.3. Then we specify the goal setting table for the references. What are the advantages and disadvantages of changing or not? 4. In the next step: we try to gain an understanding of the emotions and behavioral behaviors of the clients. Understanding emotions and behaviors means understanding a person's antecedents, responses, and repetitive behaviors, which he or she repeats when he or she becomes emotional. 5. Teaching emotion and excitement. People with emotional disorders always want to suppress their emotions by avoiding it. In the next step, based on the perception of emotions and behaviors of the individual, we determine the behaviors caused by emotion. Our goal is to identify behaviors that evoke emotion, to identify and correct behaviors that occur subconsciously when experiencing anxiety. 7. Practice mindfulness and being in the here and now at this stage is given to the authorities. Practicing judgment and non-judgment is the last step in treatment. At this stage, the patient learns to distinguish between his judgment and non-judgment phases and realizes that he is the one who creates negative emotions for himself by judging.

**Category**
Treatment - Devices

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Omalaemmeh High School
**Full name of responsible person**
Mrs Gholozadeh Correspondent Manager
**Street address**
Imam Khomeini Street, Nasirshahr, Robat Karim
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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Refah University College
**Full name of responsible person**
Dr. Ghazal Zandkarimi
**Street address**
Gol Mohammadi Street, beginning of People's Street, Baharestan
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**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
No
**Title of funding source**
Refah University College
**Proportion provided by this source**
100
**Public or private sector**
Private
**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**
Refah University College
**Full name of responsible person**
Mahdeh Sadat Hashemi Mofrad
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MA University Student
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Faculty Member of IT Group
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## 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**
Undecided - It is not yet known if there will be 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**
Interactive software will be provided to treatment clinics for use after completion and usability. The results and data of this study will be presented to clinical professionals and students in this field after correspondence and fact-checking.
**When the data will become available and for how long**
Up to one year after the publication of the article
**To whom data/document is available**
Clinical professionals and psychology students
**Under which criteria data/document could be used**
To study anxiety disorders and integrated protocol treatment
**From where data/document is obtainable**
Ms. Hashemi Mofrad to email: ms.hashemimofrad@gmail.com
**What processes are involved for a request to access data/document**
The applicant submits an email to the submitted email and provides his / her full details. The applicant must be a clinical specialist or a psychology student. The name of the university must be clear. After confirming the information, the applicant would send the information to him.
**Comments**