

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 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 and 18. 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)

Phone

+98 21 3507 4315

Email address

zandkarimi@refah.ac.ir

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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1381158545

Phone

+98 21 4459 4906

Email

Taskhiri@gmail.com

Web page address

<https://gama.ir/school/detail/8354/20%ملائمه20%م>

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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zandkarimi@refah.ac.ir

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

Position

MA University Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Refah University College

Full name of responsible person

Dr. Ghazal Zandkarimi

Position

Faculty member of Psychology Group

Latest degree

Ph.D.

Other areas of specialty/work

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

Refah University College

Full name of responsible person

Dr. Zahra Askarikejad

Position

Faculty Member of IT Group

Latest degree

Ph.D.

Other areas of specialty/work

Health Technology Assessment

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