

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### Effect of an Emotion Regulation Training intervention on Social Functioning of Patients with Psychiatric Disorders

#### Protocol summary

##### Study aim

To evaluate the effect of an emotion regulation training intervention on social functioning of patients with psychiatric disorders

##### Design

intervention and control group, followed immediately after the intervention and three months later, A convenient sample of 60 patients with psychiatric disorder divided randomly into study and control group (30 patients in each). the selection of sample based on the following . only one center (psychiatric inpatient department of Tanta University Hospital. )

##### Settings and conduct

psychiatric inpatient department of Tanta University Hospital, with a capacity of 31 beds divided into two wards for men (17 beds) and two wards for women (14 beds). respect for all patients, right of autonomy .The intervention don't produce any harm or pain to the patients. fairness must be considered ;all the intervention group receive the same training exercises and numbers of session . The study subjects have the right to withdrawn from this study at any time without any negative impact on services they are currently receiving or will be received in the future.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria:able to communicate relevantly, and agree to participate in the study Diagnosis according to DSM-5 criteria Exclusion criteria: Any evidence of organic brain disease, mental retardation, and or substance use disorder and acute stage of illness.

##### Intervention groups

The intervention group will divided into subgroups. Each subgroup ranged between 4 to 6 patients. intervention group will receive 10 training sessions (with a series of 12 training exercise) , each session lasting from (60-90) minutes; 3 times per week for a period of 4 weeks.the control will receive the routine care that provided in the hospital .

##### Main outcome variables

social functioning

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200402046920N1**

Registration date: **2020-04-09, 1399/01/21**

Registration timing: **prospective**

Last update: **2020-04-09, 1399/01/21**

Update count: **0**

##### Registration date

2020-04-09, 1399/01/21

##### Registrant information

##### Name

Souzan Harfush

##### Name of organization / entity

Tanta university , Faculty of Nursing

##### Country

Egypt

##### Phone

+20 40 3331841

##### Email address

suzan.ahmed@nursing.tanta.edu.eg

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-30, 1399/02/11

##### Expected recruitment end date

2020-07-30, 1399/05/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Effect of an Emotion Regulation Training intervention on Social Functioning of Patients with Psychiatric Disorders

**Public title**

Effect of an Emotion Regulation Training intervention on Social Functioning of Patients with Psychiatric Disorders

**Purpose**

Supportive

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

Able to communicate relevantly Agree to participate in the study Diagnosis according to DSM-5 criteria for the psychiatric disorders

**Exclusion criteria:**

Any evidence of organic brain disease, mental retardation, and or substance use disorder Acute stage of illness.

**Age**

From 18 years old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 60

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

- The control and study group will be assigned using simple randomization , by picking their codes up from a pool. The first two-selected codes will be assigned for the control group and the second two for the study group. The process was repeated till the required number obtained.

**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 committe of faculty of medicine ,tanta university

**Street address**

Algeish street ,tanta,Algharibia, Egypt,faculty of medicine

**City**

Tanta

**Postal code**

31111

**Approval date**

2018-08-18, 1397/05/27

**Ethics committee reference number**

32502/08/18

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

emotional disturbance( problems in identification ,understanding,and expression of emotion )

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

social functioning

**Timepoint**

before intervention ,immediately after intervention, and three months later

**Method of measurement**

using social functioning scale

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: • The intervention group divided into subgroups. Each subgroup ranged between 4 to 6 patients. • The emotion regulation training program will conducted through 10 training sessions with a series of 12 training exercise , each lasting from (60-90) minutes; 3 times per week for a period of 4 weeks. Session 1: The first and second exercise intended to help the subjects to recognize emotion • Understanding emotional words: expressing emotion by using emotion word cards (e.g., happy) • Learning emotional words: matching emotional word cards and emotional face cards. Session 2: the third and fourth exercises intended to help the subjects to identify emotion • Finding emotional words: choosing emotional word cards from emotional face cards that represent different emotions. • Identifying emotion by context: choose emotional word cards from a short film cartoon that represent certain emotions. Stage two: Emotion expression training : The aim of this stage was to help the patient to express emotions. This stage comprised four exercises that was conduct into three

sessions. Session 3: The fifth and sixth exercise intended to help the subjects to express emotions • Making facial expression: the patients expressed emotions by emotional face cards. • Facial expression relay: Identifying one's facial expression and passing it to the next person. This procedure was applied on all emotional face cards where each patient in the group will draw different facial expressions Session 4:- the seventh exercise was performed to help the patients to express emotion by using image. • Storytelling and watching a film and expressing emotion: The researcher asked the patients to write or draw their feelings after emotional storytelling and watching a film cartoon. Session 5: -The eighth exercise in this session was to help the patients to express emotion by using sentence. • Expressing emotion using written instructions: Each patient by turn was pick a card with a written instruction of certain emotional expression in a group. Stage three: Emotion application training. The aim of this stage was to help the patient to share their feelings, understand complex emotion and emotional inference. This stage comprised three exercises that conducted into two sessions. Session 6: - the ninth exercise was applied to help the patients to share their feelings: • Emotional mask: making emotional mask by drawing one's feeling on a mask then wearing each emotional mask and expressing their feelings. Session 7: - the tenth and eleventh exercises were used to help the patients to understand complex emotion and emotion inference: • Making facial expressions by context: expressing feelings using written emotional sentences. • Exercising emotional inference: making up a story with emotional sentence cards. Stage four: Emotional control training. This stage conducted into 2 sessions ; the aim of this stage is to help the patient to develop self -awareness and cope with negative emotions. The researcher used the following learning strategies during the program: modeling, role play/ behavioral rehearsal, getting participant's feedback (e.g. providing corrective feedback) and positive reinforcement (e.g. praising a client's efforts).

### Category

Treatment - Other

## 2

### Description

Control group: will receive the routine care that provided in the hospital

### Category

Other

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

psychiatric inpatient department of Tanta University Hospital

#### Full name of responsible person

Professor Mai Issa

#### Street address

Algeish street,Tanta, Algharibia ,Egypt

### City

Tanta

### Postal code

31111

### Phone

+20 40 3336666

### Email

maieissa@hotmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Tanta university

#### Full name of responsible person

Professor Magdy Abd elraof saba

#### Street address

Algeish street,

### City

Tanta

### Postal code

31111

### Phone

+20 40 3317928

### Email

tanta\_unv@unv.tanta.edu.eg

### Web page address

https://tanta.edu.eg

### Grant name

### Grant code / Reference number

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

No

### Title of funding source

Tanta university

### 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

Tanta university , Faculty of Nursing

#### Full name of responsible person

Souzan Harfush

#### Position

Lecturer of psychiatric nursing

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Psychiatrics

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tanta university , Faculty of Nursing

**Full name of responsible person**

Souzan Harfush

**Position**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

no further information

**Study Protocol**

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

**Statistical Analysis Plan**

Not applicable

**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