

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The impact of Group Cognitive Therapy on the hope and happiness of patients with Ostomy referred to Ostomy Center in Kerman

Protocol summary

Study aim

Determining the effect of behavioral cognitive therapy training on the mean score of happiness and hope of ostomy patients

Design

The hope and happiness questionnaire will give to the ostomy people, then among those who get lower scores of hope and happiness, will select by randomly for training (60 patient).

Settings and conduct

The research place is the Kerman Ostomy Center. Cognitive behavioral training will give one day per week for 12 sessions of 90 minutes by a psychologist, after completing the training period, participants will complete the Hope and Happiness Questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Having at least one intestinal or urinary Ostomy to form temporary or permanent; At least one month has passed since the Ostomy surgery; The patient is a resident of Kerman. Exclusion criteria: patients less than 19 years old; Return the Ostomy to the abdominal cavity ; absence of more than 2 sessions in the training program. History of participation in similar training classes.

Intervention groups

A group of patients who have lower scores of hope and happiness are intervention groups and the training will give to them and the average score of hope and happiness will compare before and after training.

Main outcome variables

hope and happiness

General information

Reason for update

Acronym

GCT

IRCT registration information

IRCT registration number: **IRCT20170516033997N3**

Registration date: **2018-05-22, 1397/03/01**

Registration timing: **prospective**

Last update: **2018-05-22, 1397/03/01**

Update count: **0**

Registration date

2018-05-22, 1397/03/01

Registrant information

Name

Tahereh Ramezani

Name of organization / entity

Kerman University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 34331325220

Email address

t_ramezani@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-05, 1397/03/15

Expected recruitment end date

2019-06-05, 1398/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of Group Cognitive Therapy on the hope and happiness of patients with Ostomy referred to Ostomy Center in Kerman

Public title

The impact of Group Cognitive Therapy on the hope and happiness of patients with Ostomy

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 19 years and over Having at least one intestinal or urinary Ostomy to form temporary or permanent At least one month has passed since the Ostomy surgery The patient is a resident of Kerman

Exclusion criteria:

Aged 18 years or less Return the Ostomy to the abdominal cavity Missing more than two sessions in the training classes History of participation in similar training classes

Age

From **19 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

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 Comity in Vice Chancellor for Research and Technology, Kerman University of Medical Sciences

Street address

Street Ibn Sina, Tahmasebabad Crossroads, kerman,Iran.

City

Kerman

Province

Kerman

Postal code

۷۶۱۸۷۴۷۶۵۳

Approval date

2018-05-10, 1397/02/20

Ethics committee reference number

IR.KMU.REC.1396/2001

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

Happiness and hope of patients

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

hope of patients with Ostomy

Timepoint

Before and a month after training

Method of measurement

questionner

2**Description**

happiness of patients with Ostomy

Timepoint

Before and a month after training

Method of measurement

questionner

Secondary outcomes

empty

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

Intervention group:All participants in this study are intervention group. The hope and happiness questionnaire will be available to the individuals in the form of available sampling, then among those who got lower scores of hope and happiness, will train by experienced psychologists in form of Cognitive Therapy for 12 sessions of 90 minutes, in one day weekly and the results are compared before and after the training.

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Center of Patients with stomy

Full name of responsible person

Zakieh Farmitani

Street address

Shahid Bahonar Hospital, Shahid Gharani St.

City
Kerman
Province
Kerman
Postal code
7613747181
Phone
+98 34 3222 8939
Email
ostomykerman@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Dr. Abbas Pardakhty
Street address
Tahmasebabad Crossroads-Street Ibn Sina-Deputy of
research and technologyof Kerman University of
Medical Sciences-Vice Chancellor for Research

City
Kerman
Province
Kerman
Postal code
76169-13555
Phone
+98 34 3226 3855
Fax
+98 34 3226 3857
Email
abpardakhty@kmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Tahereh Ramezani

Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Health Promotion
Street address
Kerman University of Medical Sciences Campus ,
beginning around Seven Alavi Garden,Kerman
City
Kerman
Province
Kerman
Postal code
7616913555
Phone
+98 31325220
Email
t_ramezani@kmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Tahereh Ramezani
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Health Promotion
Street address
Kerman University of Medical Sciences Campus ,
beginning around Seven Alavi Garden, Kerman
City
Kerman
Province
Kerman
Postal code
1355576169
Phone
+98 34 3132 5220
Email
t_ramezani@kmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Tahereh Ramezani
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Health Promotion
Street address

Kerman University of Medical Sciences Campus ,
beginning around Seven Alavi Garden, Kerman

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3132 5220

Email

t_ramezani@kmu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

No - There is not 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The results of before and after training about happiness and hope of patients will give related to the people.

When the data will become available and for how long

Access to results 3 months after receiving the research results

To whom data/document is available

Patients, Ostomy Center, Nurses and Clinical Officers

Under which criteria data/document could be used

The results of the research are equally available to applicants without any impediment.

From where data/document is obtainable

The researcher will provide the information through personal contact or personal email.

What processes are involved for a request to access data/document

After receiving the email from the caller, information immediately will send for them in the same day.

Comments