Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 selecte 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

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Iran (Islamic Republic of)

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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
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Postal code
7613747181
Phone
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Email
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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
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Fax
+98 34 3226 3857
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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
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Person responsible for updating data

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Email

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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