Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Determining the Effectiveness of Acceptance and Commitment-Based Approach and Solution-Based Approach on Mental Health and Quality of Life of Burn Patients: A clinical trial

Protocol summary

Study aim
Determining the Effectiveness of Acceptance and Commitment-Based Approach and Solution-Based Approach on Mental Health and Quality of Life of Burn Patients

Design
This study is a parallel blind clinical trial on 45 patients with intervention and control group (15 patients in each group). Restricted randomization method in the form of block randomization will be used to allocate patients into intervention and control groups.

Settings and conduct
Location: Velayat Hospital (Rasht, Iran). The researcher is blinded and samples are randomly selected.

Participants/Inclusion and exclusion criteria
شرایط ورود: سوختگی درجه 2 عمیق یا درجه 3 و 4، 10%-70% سوختگی، گذشت حداقل یک ماه از سوختگی، عدم ابتلا به بیماری‌های روانی و عقب‌ماندگی ذهنی، ساکن شهر رشت - شرایط عدم ورود: شرکت همزمان در برنامه‌های روان‌درمانی دیگر، غیبت بیش از دو جلسه در کلاس‌ها، وقوع حوادث استرس‌زا نظیر فوت بستگان یا طلاق، عدم تمایل به همکاری در پژوهش

Intervention groups
گروه های مداخله: گروه درمان راه حل محور، گروه درمان پذیرش و تعهد؛ گروه کنترل

Main outcome variables
Quality of Life; Mental health

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220129053854N1**
Registration date: **2022-04-09, 1401/01/20**
Registration timing: **prospective**

Last update: **2022-04-09, 1401/01/20**
Update count: **0**

Registration date
2022-04-09, 1401/01/20

Registrant information

Name
Amir Fakhraee

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-21, 1401/02/01

Expected recruitment end date
2022-09-23, 1401/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Determining the Effectiveness of Acceptance and Commitment-Based Approach and Solution-Based Approach on Mental Health and Quality of Life of Burn Patients: A clinical trial

Public title
Determining the Effectiveness of Acceptance and Commitment-Based Approach and Solution-Based Approach on Mental Health and Quality of Life of Burn

Patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Deep second, third and fourth degree burn 10 to 70% total body surface area (TBSA) At least one month after burn injury No mental illness and mental retardation Living in Rasht

Exclusion criteria:

Simultaneous participation in other psychotherapy programs Absence in more than two sessions in classes Occurrence of stressful events such as death of relatives or divorce Unwillingness to collaborate in research

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, in order to assign patients to intervention and control groups, the limited randomization approach will be used as a block randomization method. To prevent the last allocation from being detected in the blocks under consideration, we will consider the size of the blocks to be random with a size of 6. In this study, in order to hide the allocation, the created sequences will be placed in closed envelopes. In this regard, the letter A (control group), the letter B (intervention group with an approach based on acceptance and commitment) and the letter C (Intervention group with a solution-oriented approach) will be used and to generate random numbers, we will use the Rnnif package in R software.

Blinding (investigator's opinion)

Single blinded

Blinding description

Factors that cause errors in this category of studies are: patient and researcher awareness, and researcher evaluation of the type of treatment prescribed. To prevent bias and increase credibility in this study, we will use the one-blind method in which analysts Identification of control and intervention groups will be blinded. For this purpose, the treatment method and patient groups will be coded and any evidence that leads the analyst to identify patient groups will be removed.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethic Committees of Guilan University of Medical science

Street address

Guilan University of Medical science

City

Rasht

Province

Guilan

Postal code

4144666949

Approval date

2022-02-09, 1400/11/20

Ethics committee reference number

IR.GUMS.REC.1400.575

Health conditions studied

1

Description of health condition studied

Burn

ICD-10 code

T31.1 - T3

ICD-10 code description

Burns involving 10 to 70% of body surface with deep second, third and fourth degrees

Primary outcomes

1

Description

Quality of Life

Timepoint

One month after the burn injury- At the end of treatment sessions

Method of measurement

WHOQOL-BREF Quality of Life Questionnaire

2

Description

Mental health

Timepoint

One month after the burn injury- At the end of treatment sessions

Method of measurement

Goldberg questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Acceptance and Commitment Group - Routine burn care is provided to patients after discharge. These cares include: answering smart questions, how to care for wounds and dressings, teaching the proper diet for burns, how to wash wounds at home, how to properly use medications at home, the date and time of the next visit, and the necessary guidance for referral to a psychologist or psychiatrist if needed. Routine care is also explained in the form of exercises, related to each component for the intervention groups. One month later, after obtaining consent, a questionnaire of quality of life and mental health will be administered. Then, the acceptance and commitment-based treatment group and the solution-oriented treatment group will be treated by a clinical psychologist in 9 sessions of 2 hours, and the control group will not receive treatment. During the sessions, assignments in accordance with the therapeutic goals of each approach will be presented to patients and will be evaluated in the next sessions. Finally, in each group, the quality of life and mental health questionnaire will be administered again and the research data will be analyzed using an appropriate statistical method. Therapeutic sessions for acceptance and commitment group compiled based on Harris therapeutic guidelines (2007). The summary of the sessions is as follows: * Session 1: Introduction and acquaintance and expression of research goals; *Session 2: Discussion about patients goals and giving information about quality of life and better life outcomes; * Session 3: Discussion about quality of life in patients lives and reviewing control strategies; Session 4: Discussion about uselessness of control strategies, explanation about avoiding painful experiences and its outcomes and introducing mindfulness and acceptance; *Session 5: Explaining cognitive fusion and expressing the common relationship between emotions, cognitive functions and visible behavior, teaching cognitive faults and distance from thoughts and observing thoughts without judgment and action independent of mental experiences; *Session 6: Investigating the effect of cognitive fault training, explaining the concepts of role, context and types of self and moving towards a valuable life with a self-accepting and observant; *Session 7: Discussing the effect of observing thoughts in the lives of therapists, explaining the concept of values, motivating change and empowering clients for a better life; *Session 8: Discussing values and barriers to action according to them, creating flexible behavioral patterns in accordance with values, and creating a commitment to act towards goals and values and passing obstacles; *Session 9: Discussing the consequences of action based on values, examining constructive changes during the treatment period and how to stabilize and consolidate them, providing a summary of treatment sessions and receiving feedback from therapists, conducting post-test and finishing treatment sessions.

Category

Rehabilitation

2

Description

Intervention group: solution-based Group - Routine burn care is provided to patients after discharge. These cares include: answering smart questions, how to care for wounds and dressings, teaching the proper diet for burns, how to wash wounds at home, how to properly use medications at home, the date and time of the next visit, and the necessary guidance for referral to a psychologist or psychiatrist if needed. Routine care is also explained in the form of exercises, related to each component for the intervention groups. One month later, after obtaining consent, a questionnaire of quality of life and mental health will be administered. Then, the acceptance and commitment-based treatment group and the solution-oriented treatment group will be treated by a clinical psychologist in 9 sessions of 2 hours, and the control group will not receive treatment. During the sessions, assignments in accordance with the therapeutic goals of each approach will be presented to patients and will be evaluated in the next sessions. Finally, in each group, the quality of life and mental health questionnaire will be administered again and the research data will be analyzed using an appropriate statistical method. Solution-based therapy sessions were developed according to resources related to this therapeutic approach, including Walter and Peller (1992), Maud (2000), Lipchik (2002) and Nelson and Thomas (2007).The summary of the sessions is as follows: *The first session: introduction, the expression of research objectives and how the research process, the number of meetings and rules and regulations of the department, the implementation of the pre-test, *Session 2: discussing the positive things in the life of the therapists, encouraging the therapists to express what they want instead of focusing on the problem, setting tangible, objective, positive and practical goals; * Session 3: Discussing the goals of therapists, developing solutions by examining the changes that will happen if problems are solved in the lives of the therapists; *Session 4: Using scaling to assess people's commitment and hope for solving the problem, *Session 5: Discussing how to make changes, helping therapists find exceptions to better function in life, creating hope for change and tackling the problem; *Session 6: Discussing exceptions and highlighting appropriate solutions, asking miracle questions and encouraging therapists to express their abilities and strengthening them; *Session 7: Discussing the respondents' responses to the miracle question, emphasizing on implementing solutions using the word "instead" and replacing appropriate thoughts, feelings and behaviors instead of problematic thoughts, feelings and behaviors; *Session 8: Highlighting the capabilities and capabilities of therapists, discussing how to stabilize the changes made, *Session 9: providing a summary of treatment sessions, discussing the positive points and weaknesses of the therapist and the treatment plan, and receiving feedback from the therapists, performing post-test and finishing treatment sessions.

Category

Rehabilitation

3

Description
Control group: Routine burn care is provided to patients after discharge. These cares include: answering smart questions, how to care for wounds and dressings, teaching the proper diet for burns, how to wash wounds at home, how to properly use medications at home, the date and time of the next visit, and the necessary guidance for referral to a psychologist or psychiatrist if needed. Routine care is also explained in the form of exercises, related to each component for the intervention groups. One month later, after obtaining consent, a questionnaire of quality of life and mental health will be administered. Then, the acceptance and commitment-based treatment group and the solution-oriented treatment group will be treated by a clinical psychologist in 9 sessions of 2 hours, and the control group will not receive treatment. During the sessions, assignments in accordance with the therapeutic goals of each approach will be presented to patients and will be evaluated in the next sessions. Finally, in each group, the quality of life and mental health questionnaire will be administered again and the research data will be analyzed using an appropriate statistical method.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Velayat hospital
Full name of responsible person
Dr. Mohammad Reza Mobayen
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
Dr. Mohammad Reza Mobayen
Position
Director of the Department of Surgery, Head of the Burn and Plastic Surgery Hospital, Head of the Bu
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
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
Undecided - It is not yet known if there will be a plan to make this available