Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of sexual counseling based on the Good Enough Sex model versus control group on sexual quality of life and satisfaction with appearance in women after burn trauma: a randomized clinical trial

Protocol summary

Study aim
To assess the effect of sexual counseling based on the Good Enough Sex model versus control group on sexual quality of life and satisfaction with appearance in women after burn trauma

Design
This is a randomized clinical trial with a control group with parallel groups without blinding, in which 42 eligible patients will be randomly assigned to the intervention and control groups using block randomization.

Settings and conduct
This study will be conducted at the Sina Hospital in Tabriz, involving 42 eligible women affected with burn. The patients will be randomly assigned to the intervention and control groups using block randomization. This trial will not be blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 49 years, Whole body burn between 10 to 40 percent, Married, Educated, Exclusion criteria: Psychiatric disorders Sexual disorders

Intervention groups
Intervention group: Routine treatment and care of burn plus sexual counseling based on the Good Enough Sex model for 90 to 120 minutes, one session per week for 4 weeks Control group: Routine treatment and care of burn

Main outcome variables
Primary outcome: Average quality of sextual life score; Average score of satisfaction with appearance; Average score of sexual dysfunctions

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N598**
Registration date: **2026-04-08, 1405/01/19**
Registration timing: **prospective**

Last update: **2026-04-08, 1405/01/19**
Update count: **0**

Registration date
2026-04-08, 1405/01/19

Registrant information

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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-05-05, 1405/02/15

Expected recruitment end date
2026-08-06, 1405/05/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of sexual counseling based on the Good Enough Sex model versus control group on sexual quality of life and satisfaction with appearance in women after burn

trauma: a randomized clinical trial

Public title
Effect of sexual counseling based on the Good Enough Sex model versus control group on sexual quality of life and satisfaction with appearance in women after burn trauma
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 49 years, Whole body burn between 10 to 40 percent, Married, Educated,
Exclusion criteria:
Psychiatric disorders Sexual disorders
Age
From **18 years** old to **49 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **42**
Randomization (investigator's opinion)
Randomized
Randomization description
Routine treatment and care of burn plus sexual counseling based on the Good Enough Sex model for 90 to 120 minutes, one session per week for 4 weeks (including definition of enough not perfect sextual relationship, effect of burn on body, physiologic changes after burn, acceptance of body appearance in sextual satisfaction, methods of self-care after burn, softening scars, safe massage with moistening cream, selecting carefree cloths for positive touching of body, flexibility in sextual experience, relaxation rather than idealism, skills of producing intimacy, reconstruction of body confidence, persistency of good relationship)
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 Committee of Urmia University of Medical Sciences
Street address
Vice-chancellor for Research and Technology, Urmia University of Medical Sciences, Pardis Nazlo Road
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Urmia
Province
West Azarbaijan
Postal code
5714783734
Approval date
2026-04-06, 1405/01/17
Ethics committee reference number
IR.UMSU.REC.1405.005

Health conditions studied

1

Description of health condition studied
Whole body burn
ICD-10 code
T30
ICD-10 code description
Burn and corrosion, body region unspecified

Primary outcomes

1

Description
Average quality of sextual life score
Timepoint
Before intervention and one month later
Method of measurement
Using Symonds Sexual Quality-of-Life for Female Questionnaire

2

Description
Average score of satisfaction with appearance
Timepoint
Before intervention and one month later
Method of measurement
Using the Satisfaction with Appearance Scale

3

Description
Average score of sexual dysfunctions
Timepoint
Before intervention and one month later
Method of measurement
Using the Female Sexual Dysfunction Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Routine treatment and care of burn plus sexual counseling based on the Good Enough Sex model for 90 to 120 minutes, one session per week for 4 weeks (including definition of enough not perfect sextual relationship, effect of burn on body, physiologic changes after burn, acceptance of body appearance in sextual satisfaction, methods of self-care after burn, softening scars, safe massage with moistening cream, selecting carefree cloths for positive touching of body, flexibility in sextual experience, relaxation rather than idealism, skills of producing intimacy, reconstruction of body confidence, persistency of good relationship)
Category
Other

2

Description
Control group: Routine treatment and care of burn
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital in Tabriz
Full name of responsible person
Zeynab Vahidi
Street address
Sina Hospital, Azadi Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Urmia University of Medical Sciences
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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
Urmia 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
Urmia University of Medical Sciences
Full name of responsible person
Zeynab Vahidi
Position
Midwifery Student
Latest degree
Master
Other areas of specialty/work
Midwifery
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Position

Reproductive Health Specialist

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Professor of Epidemiology

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