Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effectiveness of Mindfulness Based Stress Reduction (MBSR) Therapy on Psychological Distress among Patients with Oral Lichen Planus

Protocol summary

Study aim
This Study Purpose is determine the effectiveness of mindfulness based stress reduction Treatment on psychological disturbance, intensity of pain and burning, Pain Catastrophizing and Quality of Life of Patients with Oral Lichen Planus.

Design
Clinical Trial with Control Group, with Parallel Group, Single Blind, Randomized, on 50 Patients

Settings and conduct
Dental clinics affiliated with Kashan University of Medical Sciences and Department of Oral and Dental Diseases of Tehran University of Medical Sciences, Patient who have the Inclusion Criteria are Selected And after Obtaining Informed Consent, they will be Randomly Placed in Experimental and Control Groups Also, before the Implementation of the Intervention, Questionnaires will be Provided to them. The Participants are not Given Information about which of the Groups is the Experimental and which of them is Control Group.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Oral Lichen Planus Patients whose Disease has been Diagnosed through Biopsy and Histopathology Results and who are in the symptomatic phase of the disease. Non Inclusion Criteria: Absence of Pain and Burning or Mild Pain and Burning (Score Lower than 4 on the VAS), Age younger than 18 and older than 60, Degree less than middle School degree

Intervention groups
Experimental Group: Mindfulness Based Stress Reduction is implemented for them. Control Group: Training Sessions about Some Topics of Developmental Psychology or Personality will be Provided that are not Related to the Main Intervention.

Main outcome variables
Psychological Disturbance Score in DASS-21, Pain Catastrophizing Score in Pain Catastrophizing Scale

General information

Reason for update
Change in sampling time range due to lack of collaboration of patients

Acronym
MBSR

IRCT registration information
IRCT registration number: **IRCT20221204056709N1**
Registration date: **2022-12-31, 1401/10/10**
Registration timing: **prospective**

Last update: **2024-07-12, 1403/04/22**
Update count: **1**

Registration date
2022-12-31, 1401/10/10

Registrant information

Name
Fatemeh Sarebannezhad

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2245 3511

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-05, 1401/10/15

Expected recruitment end date
2023-09-06, 1402/06/15

Actual recruitment start date
2023-01-30, 1401/11/10

Actual recruitment end date
2024-02-09, 1402/11/20

Trial completion date

2024-06-13, 1403/03/24

Scientific title
The Effectiveness of Mindfulness Based Stress Reduction (MBSR) Therapy on Psychological Distress among Patients with Oral Lichen Planus

Public title
The Effect of Mindfulness Based Stress Reduction Therapy in Improving Oral Lichen Planus Disease

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Oral Lichen Planus Patients whose Disease has been Diagnosed through Biopsy and Histopathology Results. Patients who are in the Symptomatic Phase of the Disease.

Exclusion criteria:
Absence of Pain and Burning or Mild Pain and Burning (Score Lower than 4 on the VAS). Age younger than 18 and older than 60 Degree less than middle School degree

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **50**
Actual sample size reached: **34**

Randomization (investigator's opinion)
Randomized

Randomization description
According to the Inclusion Criteria, 50 patients with oral lichen planus were purposefully selected and placed in the intervention group and the control group through random assignment using a table of random numbers. In this method, the first selected number (randomly) is placed in the intervention group and the next number is placed in the control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
The blindness of the participants in the treatment is that they do not know that there is another group, but after the end, they will be informed about the existence of another group, and if they wish, the treatment will be done for them. The researcher is aware of the existence of the intervention and control groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kashan University of Medical Sciences

Street address
5th kilometer of Qutb Rawandi Blvd., Kashan University of Medical Sciences

City
Kashan

Province
Isfehan

Postal code
8715988141

Approval date
2022-10-23, 1401/08/01

Ethics committee reference number
IR.KAUMS.MEDNT.REC.1401.137

Health conditions studied

1

Description of health condition studied
Oral Lichen Planus

ICD-10 code
L43

ICD-10 code description
Lichen planus

Primary outcomes

1

Description
Psychological Disturbance Score in DASS-21

Timepoint
Before the Intervention, After the Intervention

Method of measurement
DASS-21

2

Description
Pain Catastrophizing

Timepoint
Before the Intervention, After the Intervention

Method of measurement
Pain Catastrophizing Scale

Secondary outcomes

1

Description

Severity of Pain and Burning

Timepoint

Before the Intervention, After the Intervention

Method of measurement

Visual Analouge Scale

2

Description

Shape and Size of the Lesions

Timepoint

Before the Intervention, After the Intervention

Method of measurement

Thongprasom Scale

3

Description

Quality of Life Related to Oral Health

Timepoint

Before the Intervention, After the Intervention

Method of measurement

Oral Health Impact Profile-14 (OHIP-14)

Intervention groups

1

Description

Intervention group: Mindfulness Based Stress Reduction was created by Kabat-Zinn (1990), This Treatment is an Eight Week Evidence based Program. The Main Contents of the Treatment are: a) Relaxation Training, Meditation and Mind-Body Connection. b) Teaching Meditation and Yoga Exercises inside and outside the Treatment Session and during the Day c) Removing Barriers to Successful Education, Providing Brochures Related to the Instructions of each Session that were given to the Clients and Daily Homework Exercises

Category

Lifestyle

2

Description

Control group: The control group does not receive any other treatment except its drug treatment.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashan University of Medical Sciences

Full name of responsible person

Dr. Elaheh Ghasemzadeh

Street address

Ketabachi Special Dentistry Clinic, First of Shahid Bahonar Blvd, Moalem Square

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2

Recruitment center

Name of recruitment center

Tehran University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Gholam Ali Hamidi

Street address

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research@kaums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan 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
Kashan University of Medical Sciences

Full name of responsible person
Fatemeh Sarebannezhad

Position
Masters student

Latest degree
Bachelor

Other areas of specialty/work
Psychology

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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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