

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Impact of therapeutic writing on quality of life and psychological distress in patients with vitiligo

Protocol summary

2009-08-12, 1388/05/21

Summary

A randomized trial will be performed to determine the effect of written emotional disclosure on psychological distress and quality of life in patients with vitiligo. PATIENTS AND METHODS: 72 vitiligo patients completing medical treatment will be assigned randomly to intervention and control groups. Intervention group will write about their deepest thoughts and feelings during four weeks but control group will take only routine medical treatment. Psychological distress and Quality of life outcomes will be assessed before and 1 month after intervention. Instruments: 1) Dermatologic Quality of life Index: It is a simple 10-question validated questionnaire which has been used in 33 different skin conditions in 32 countries. At present the DLQI is the most frequently used instrument in randomized controlled trials in dermatology. 2) The GHQ is used to detect psychiatric disorder in general patients and out-patients. It assesses the respondent's current state and asks if that differs from his or her usual state. It is therefore sensitive to short-term psychiatric disorders but not long-standing attributes of the respondent. The four sub-scales, each containing seven items, are as follows: A- somatic symptoms (items 1-7) B- anxiety/insomnia (items 8-14) C- social dysfunction (items 15-21) D- severe depression (items 22-28).

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Iran university of medical sciences and health Services

Expected recruitment start date

2009-04-21, 1388/02/01

Expected recruitment end date

2009-08-23, 1388/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138801161788N1**

Registration date: **2009-08-12, 1388/05/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

Scientific title

Impact of therapeutic writing on quality of life and psychological distress in patients with vitiligo

Public title

Impact of therapeutic writing on quality of life and psychological distress in patients with vitiligo

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Age>18 years, lasting more than 6 month after diagnosis, literacy at least primary school

Exclusion Criteria: psychosis, systemic and chronic illness, no consent to participate in study

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Nursing and Midwifery School, Iran University of Medical Sciences

Street address

Nursing and Midwifery School, Yasemi street, Vanak SQ

City

Tehran

Postal code

Approval date

2009-02-17, 1387/11/29

Ethics committee reference number

1156087

Health conditions studied

1

Description of health condition studied

Vitiligo

ICD-10 code

L80

ICD-10 code description

Vitiligo

Primary outcomes

1

Description

Psychological distress and quality of life

Timepoint

1 month

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: education of writing therapy in 60 minute session individually and writing by pateients daily for 4 weeks + current treatment

Category

Other

2

Description

Control Group: current treatment

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital, Tehran University of Medical Sciences

Full name of responsible person

Dr. Mortazavi

Street address

Vahadat eslami street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Fourough Rafiee

Street address

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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

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Iran university of Medical Sciences, Nursing and Midwifery School

Full name of responsible person

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Position

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Web page address**Person responsible for updating data****Contact****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty