

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

The effect of self management training based on Pender's health promotion model on clinical findings of patients with brucellosis

Protocol summary

Study aim

The effect of self management education based on Pender's health promotion model on clinical findings of patients with brucellosis

Design

Patients will be divided into two groups of test and control each of them 4 patients will be divided using 4 permutation blocks method and in both groups the valid and reliable questionnaire will be filled and clinical findings will be recorded and the control group will receive routine care in the self management training group based on Pender's model and then again the questionnaire and clinical findings will be measured after the intervention and the information will be analyzed.

Settings and conduct

Randomized clinical trial and research community of all patients with brucellosis will have inclusion criteria under the cover of community health centers in Gonabad city.

Participants/Inclusion and exclusion criteria

The patient with a diagnosis of brucellosis and in the acute stage and in the first two weeks of drug treatment. All or a number of clinical signs and symptoms of fever and pain, fatigue, sweating and anorexia have a burn or kom 1.80 burn or 2ME test equal to or greater than 1.40.40. Have access to a phone or internet at home and be literate about women not breastfeeding and pregnancy Exclusion criteria: Not participating in online or in person training group. Stop taking medication for medical reasons Dissatisfaction with cooperation in the continuation of the study inpatient. hospitalization during the study simultaneous. participation in similar educational groups

Intervention groups

Self management training is based on Pender's model by lecture method and based on the pre-organizer model. The control group does not receive training

Main outcome variables

Self-management education based on Pender's health promotion model

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220205053940N1**

Registration date: **2022-02-16, 1400/11/27**

Registration timing: **prospective**

Last update: **2022-02-16, 1400/11/27**

Update count: **0**

Registration date

2022-02-16, 1400/11/27

Registrant information

Name

Maryam Tavazoi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3768 2606

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tavazoim1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-01, 1400/12/10

Expected recruitment end date

2022-08-08, 1401/05/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of self management training based on Pender's health promotion model on clinical findings of patients with brucellosis

Public title

The effect of self management training based on Pender's model on clinical findings of patients with brucellosis

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

The patient has brucellosis according to the diagnosis and in the acute stage (less than 3 months from the onset of symptoms) be at most in the first two weeks of drug treatment All or a number of clinical signs and symptoms have fever and pain, fatigue, sweating and anorexia The headline of Wright or Coombs Wright is equal to or greater than 1/80, or the 2ME test is equal to or greater than 1/40 Be under drug treatment in accordance with the national guidelines for controlling brucellosis Lack of mental illnesses according to the client's history and ability to self care Willingness to participate in this study. Capable of speaking, being able to hear and communicate He has not previously attended self management training on brucellosis. Have access to the phone and preferably the Internet at home (if the program is implemented online) and have read and write literacy Not about women in breastfeeding and pregnancy

Exclusion criteria:

Not participating in online or in person training group (absence of more than one session) Discontinuation of drug use for medical reasons Dissatisfaction with cooperation in the continuation of the study Client's hospitalization during study Simultaneous participation in similar educational groups

Age

From **16 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **94**

Randomization (investigator's opinion)

Randomized

Randomization description

The selection of the sample begins in an access to the study by preparing a list of patients with the conditions of participation in the study, and then random allocation of the subjects to the experimental and control groups will be done using the four point permutation block method.

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

Research Ethics Committee of Gonabad University of Medical Sciences

Street address

Mahdi zadeh Next to the Asian Road, Deputy for Research, Gonabad University of Medical Sciences, Gonabad, Iran

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Approval date

2022-01-30, 1400/11/10

Ethics committee reference number

IR.GMU.REC.1400.187

Health conditions studied

1

Description of health condition studied

brucellosis

ICD-10 code

A23

ICD-10 code description

Brucellosis

Primary outcomes

1

Description

Fever, pain, fatigue, appetite

Timepoint

At the beginning of work in both experimental and control groups, measurement of fever, pain, fatigue, appetite, Sweating and 8 weeks later and after the end of drug treatment, reassessment.

Method of measurement

Fever with thermometer, Appetite from the first 3 questions of the questionnaire (ADTA), Sweating with the patient's self expression, Pain with visual analog scale (VAS), Fatigue with visual fatigue intensity scale (VAFS)

Secondary outcomes

empty

Intervention groups

1

Description

We have an intervention group. Intervention Group Self management training based on Pender's model, which first determines how self management behavior and its deficiencies before the intervention, then using the constructs of personal factors, perceived benefits, perceived barriers, perceived self efficacy, and interpersonal influencers to why self management behavior in patients with brucellosis will be achieved and then the training program will be performed in 4 sessions for the intervention group.

Category

Other

2

Description

Control group: According to the instructions of the health deputy of patients with brucellosis, routine and routine care of visits and treatment of medication and self care is done by the physician.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Deputy of Health, Gonabab University of Medical Sciences of Medical Sciences

Full name of responsible person

Dr. Javad Sadeghi Nasab

Street address

Gonabab University of Medical Sciences , Deputy of Health, Corner of Nasir Khusraw 15, Gonabab, Nasir Khusraw, Street Khorasan Razavi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Gonabab 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

Gonabab University of Medical Sciences

Full name of responsible person

Dr. Shahla Khosravan

Position

Vice Chancellor for Research, Gonabab University of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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