

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effect of pharmacotherapy and hypnotherapy with pharmacotherapy on quality of life and symptoms of irritable bowel syndrome patients

Protocol summary

Summary

The aim of the present study is to determine the impact of hypnotherapy alongside pharmacotherapy with pharmacotherapy alone on quality of life and symptoms of irritable bowel syndrome patients. This is a clinical trial study in which 34 patients will select using Rome-III criteria. Inclusion criteria will include of diagnostic irritable bowel syndrome base on Rome-III criteria and participate of volunteere in the project and exclusion criteria will include history of receiving psychotherapy during 6 mounts ago and irritable bowel syndrome with constipation and mix predominance. ptients will randomly divided into two groups of 17 patients. The first group underwent hypnotherapy alongside pharmacotherapy. The second group receive pharmacotherapy alone. The quality of life (QOL-IBS) and Bowel Symptom Severity and Frequency (BSS-FS) will assessment for both groups befor and after therapeutic intervention. Patients will follow-up for a peiod of 6 month after the intervention.

General information

Acronym

Efficacy of hypnotherapy with pharmacotherapy and pharmacotherapy on quality of life and symptoms

IRCT registration information

IRCT registration number: **IRCT201210268253N2**
Registration date: **2012-12-09, 1391/09/19**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-12-09, 1391/09/19

Registrant information

Name

Sayed Kamal Solati

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38133338157

Email address

kamal_solati@yahoo.com

Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Sciences

Expected recruitment start date

2012-07-05, 1391/04/15

Expected recruitment end date

2012-09-05, 1391/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of pharmacotherapy and hypnotherapy with pharmacotherapy on quality of life and symptoms of irritable bowel syndrome patients

Public title

The effecacy hypnotherapy on treatment of irritable bowel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The presence of diagnostic irritable bowel syndrome base on Rome-III criteria; Participate of

volunteered in the project;The minimum level of literacy in primary. Exclusion criteria: The presence of organic damage and cognitive dysfunctions such as dementia and mental retardation;The presence of history of receiving psychotherapy during 6 months ago;Irritable bowel syndrome with constipation and mix predominance.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 34

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

Shahrekord University of Medical Sciences

Street address

Shahrekord University of Medical Sciences,Kashani street,Shahrekord

City

Shahrekord

Postal code

8815713471

Approval date

2012-05-21, 1391/03/01

Ethics committee reference number

91-3-1

2

Ethics committee

Name of ethics committee

Shahrekord University of Medical Sciences

Street address

Shahrekord University of Medical Sciences,Kashani street,Shahrekord

City

Shahrekord

Postal code

8815713471

Approval date

2012-08-20, 1391/05/30

Ethics committee reference number

1-3-91

Health conditions studied

1

Description of health condition studied

سندرم روده تحریک پذیر

ICD-10 code

K58

ICD-10 code description

Irritable bowel syndrome

Primary outcomes

1

Description

Quality of Life

Timepoint

before of intervention,after of intervention and after 6 intervention (follow-up)

Method of measurement

Quality of life test

2

Description

Bowel symptoms of severity and frequency

Timepoint

before of intervention,after of intervention and after 6 intervention (follow-up)

Method of measurement

Bowel symptoms of severity and frequency scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Hypnotherapy with Pharmacotherapy. In this group,patients will underwent for 5 hypnotherapy session,in addition to current pharmacotherapy.

Category

Treatment - Other

2

Description

Control group: Pharmacotherapy. This group will underwent current pharmacotherapy alone.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Psychiatry ward,Hajar hospital,Parastar
Street,Shahrekord,Iran

Full name of responsible person

Sayed Kamal Solati

Street address

Psychiatry ward,Hajar hospital,Parastar
Street,Shahrekord,Iran

City

Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahrekord University of Medical Sciences

Full name of responsible person

Sayed Kamal Solati

Street address

Psychiatry Ward,Hajar Hospital,Parastar
Street,Shahrekord,Iran

City

Shahrekord

Grant name

91-3-1

Grant code / Reference number

91-3-1

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

Yes

Title of funding source

Shahrekord 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

Shahrekord University of Medical Sciences

Full name of responsible person

Sayed Kamal Solati

Position

PhD in Psychology,Assistant Professor

Other areas of specialty/work

Street address

Psychiatry Ward,Hajar hospital,Parastar
Street,Shahrekord,Iran

City

Shahrekord

Postal code

8815713471

Phone

+98 38 1222 0016

Fax

+98 38 1224 3715

Email

kamal_solati@yahoo.com

Web page address

www.skums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahrekord University of Medical Sciences

Full name of responsible person

Sayed Kamal Solati

Position

PhD in Psychology,Assistant Professor

Other areas of specialty/work

Street address

Psychiatry Ward,Hajar Hospital,Parastar
Street,Shahrekord,Iran

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Phone

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Email

kamal_solati@yahoo.com

Web page address

www.skums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahrekord University of Medical Sciences

Full name of responsible person

Sayed Kamal Solati

Position

PhD in Psychology,Assistant Professor

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Street address

Psychiatry Ward,Hajar hospital,Parastar
Street,Shahrekord,Iran

City

Shahrekord

Postal code

00983812220016

Phone

+98 38 1222 0016

Fax

+98 22 43715

Email

kamal_solati@yahoo.com

Web page address

www.skums.ac.ir

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