

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Sep 2026

### Effect of problem solving strategy on quality of life, self-management profile and metabolic indices among type 2 diabetic patients with cognitive impairment

#### Protocol summary

##### Summary

This study examined the impact of the implementation of problem-solving strategies by patients with diabetes Type 2 who have cognitive impairment on their quality of life, self-management profiles and metabolic parameters. In this randomly clinical trial, 100 diabetics type 2 patients with cognitive impairment participated. They were randomly divided into control and experimental groups and the degree of their metabolic parameters, self-management profiles and quality of life were examined. The problem-solving strategies in the experimental group during the six ninety-minute sessions were taught. Then the items of both groups were measured and the differences between them were analyzed

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014041517283N1**

Registration date: **2014-08-04, 1393/05/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-08-04, 1393/05/13

##### Registrant information

##### Name

Kataun Jalali

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1647 4254

##### Email address

jalali\_k@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shiraz University of Medical Sciences

##### Expected recruitment start date

2014-01-21, 1392/11/01

##### Expected recruitment end date

2014-02-20, 1392/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of problem solving strategy on quality of life, self-management profile and metabolic indices among type 2 diabetic patients with cognitive impairment

##### Public title

problem solving strategy in type 2 diabetes with cognitive impairment

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: Type 2 diabetes a year ago; Having cognitive impairment; At least six literacy classes; Age 30 to 60 years Exclusion criteria: Other diseases, such as Alzheimer's, depression, mental retardation and ...; Severe complications of diabetes

##### Age

From **30 years** old to **60 years** old

##### Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 100

## Randomization (investigator's opinion)

Randomized

## Randomization description

## 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

Shiraz University of Medical Sciences

##### Street address

Zand Street, headquarters of Medical Sciences

##### City

Shiraz

##### Postal code

71345-1978

#### Approval date

2013-10-06, 1392/07/14

#### Ethics committee reference number

92-6723

## Health conditions studied

### 1

#### Description of health condition studied

diabetes

#### ICD-10 code

E10-E14

#### ICD-10 code description

Diabetes mellitus

## Primary outcomes

### 1

#### Description

Quality of life

#### Timepoint

Before the experiment, three months after the intervention.

#### Method of measurement

Quality of life questionnaire.

### 2

#### Description

self-management

#### Timepoint

Before the experiment, three months after the intervention.

#### Method of measurement

self-management profile

### 3

#### Description

metabolic indicators

#### Timepoint

Before the experiment, three months after the intervention.

#### Method of measurement

Blood tests

## Secondary outcomes

### 1

#### Description

Blood pressure

#### Timepoint

Before the experiment, three months after the intervention.

#### Method of measurement

Sphygmomanometer

## Intervention groups

### 1

#### Description

In the intervention group, problem-based approach to empower runs. This model is a six-week sessions of 90 minutes each week and is being held as a group. Then randomly using a random number table will be divided into two groups and controls. The intervention group by the researcher to groups of ten to twelve persons to attend meetings of the divide.

#### Category

Other

### 2

#### Description

Public education in clinic patients in the control group will receive usual.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Diabetes Clinic of Shahid Motahari Infirmary of Shiraz

**Full name of responsible person**

Tahereh Pakfetrat

**Street address**

Zand street, Namazi

**City**

Shiraz

jalali\_k@sums.ac.irjalali001@yahoo.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Science

**Full name of responsible person**

DR.Camelia Torabizadeh

**Position**

PHD

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vcrdep@sums.ac.irTorabik@sums.ac.ir

**Web page address****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**Research Council of Shiraz University of Medical  
Sciences**Full name of responsible person**

Dr Gholamreza Hatam

**Street address**Zand Street, headquarters of Shiraz University of  
Medical Sciences**City**

Shiraz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Research Council of Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Kataun Jalali

**Position**

Nursing Graduate Student

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**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*