

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### The Effect of Motivational Interviewing (MI) on Adherence to Therapy in COPD patients

#### Protocol summary

##### Summary

This study is performed to determine the Effect of Motivational Interviewing (MI) on Adherence to Therapy in COPD patients. This study is a clinical trial of two groups, before and after treatment that was done in Masih Daneshvari and Baghiyatallah hospital on 60 patients that was done randomly (four-blocks) and was divided into two groups. The studies population includes the patient suffering from chronic obstructive pulmonary disease who where less than 65 and the exclusion criteria was suffering others disease. In intervention group: during hospitalization, Motivational Interviewing is done by the interviewer over two days and then instructing the disease and life style is done in the third day. In control group: during hospitalization instructing the disease and life style is received in one day. Before doing native questionnaire intervention, adherence to treatment among chronic patient and the Morisky 8-Item Medication Adherence Questionnaire will be given to the sick and then one and two months later the questionnaire will be given to them. The Motivational Interviewing session in recorded and will be shown to the expert. The fascicle of instructing the disease and life style will be confirmed by the experts.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201604128650N7**  
Registration date: **2016-07-27, 1395/05/06**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-07-27, 1395/05/06

#### Registrant information

##### Name

Abbas Ebadi

##### Name of organization / entity

Baqiyatallah University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

ebadi1347@bmsu.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Baqiyatallah University of Medical Sciences

#### Expected recruitment start date

2016-02-20, 1394/12/01

#### Expected recruitment end date

2016-08-21, 1395/05/31

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The Effect of Motivational Interviewing (MI) on Adherence to Therapy in COPD patients

#### Public title

The Effect of Motivational Interviewing (MI) on Adherence to Therapy in COPD patients

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

The inclusion criteria: diagnosed COPD by specialist or internist; the minimum age of 20 and maximum age of 65 years old; no other underlying diseases such as stroke and diabetes; speaking persian to communicate better

with patients; access and follow up for 8 weeks; no history of mental illness and Alzheimer's disease; at least reading and writing literacy to fill out the questionnaire. Exclusion criterion: physically and mentally debilitating complications during the study.

#### **Age**

From **20 years** old to **65 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **60**

#### **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**

Baqiyatallah University of Medical Sciences

##### **Street address**

4th Floor, Nursing Faculty, Baqiyatallah University of Medical Sciences, P.O.Box: 19575174

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2016-01-11, 1394/10/21

#### **Ethics committee reference number**

IR.BMSU.REC.1394.220

### **Health conditions studied**

#### **1**

#### **Description of health condition studied**

Chronic obstructive pulmonary disease

#### **ICD-10 code**

J44

#### **ICD-10 code description**

Other chronic obstructive pulmonary disease

### **Primary outcomes**

#### **1**

#### **Description**

Adherence to treatment

#### **Timepoint**

Pre intervention and one and two months after intervention

#### **Method of measurement**

Questionnaire Adherence to treatment in chronic patient and Morisky 8-Item Medication Adherence Questionnaire

### **Secondary outcomes**

#### **1**

#### **Description**

Re admission

#### **Timepoint**

One and two months after intervention

#### **Method of measurement**

Question from patient

### **Intervention groups**

#### **1**

#### **Description**

In intervention group, motivational interviewing is held in two day and in each day based on the bearing of the patients is held in 30 to 60 minutes by the interviewer and in the third day instructing to the patient by the interviewer will be done over 30 to 60 minutes based on bearing of the patient individually. motivational interviewing is in some parts of familiarity, feeling, passive and negative aspects, values and continuing the treatment or leaving the unsuitable behavior.

#### **Category**

Behavior

#### **2**

#### **Description**

In control group they receive only one day instruction about disease in 30 to 60 minutes that is based on bearing and need individually by the interviewer. the mentioned subject in instructing the disease and life style is the two groups.

#### **Category**

Behavior

### **Recruitment centers**

#### **1**

#### **Recruitment center**

##### **Name of recruitment center**

National research institute of tuberculosis and lung disease Masih Daneshvari hospital

##### **Full name of responsible person**

Hamid Naderloo

**Street address**

Masih Daneshvari hospital, Darabad

**City**

Tehran

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Baqiyatallah University of Medical Sciences

**Full name of responsible person**

afshin pakjo

**Street address**

The financial office, Nursing Faculty, Baqiyatallah University of Medical Sciences

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Baqiyatallah 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**

Baqiyatallah University of Medical Sciences

**Full name of responsible person**

Hamid Naderloo

**Position**

Master student of critical care nursing

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**

Dr. Abbas Ebadi

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PhD in Nursing

**Other areas of specialty/work**

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## Person responsible for updating data

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**Other areas of specialty/work**

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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*