

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Sep 2026

### Assessing the effectiveness of Health Complex interventional model in comparison with routine health system on comprehensive health management performance indicators in East Azerbaijan: Field Trial

#### Protocol summary

##### Summary

(1) Objectives: Assessing the effectiveness of Health Complex on performance indicators of health system (2) Design: Intervention and control groups 300 clusters of 20 households Multi center No Randomization and No Blinding (3) Setting and conduct: Data will gathered with specific questionnaires before and 2 years after intervention (4) Participants including major eligibility criteria: Households will be selected and in households the persons greater than 18 years will be studied. (5) Intervention: Foundation of Health Complex (6) Main outcome measures (primary and secondary outcome variables): Health services utilization Trust to health system Responsiveness Self-care Customer satisfaction

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201402112150N3**

Registration date: **2016-01-10, 1394/10/20**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-01-10, 1394/10/20

##### Registrant information

###### Name

Homayoun Sadeghi Bazargani

###### Name of organization / entity

Tabriz University of medical sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 3337 3741

##### Email address

homayoun.sadeghi@arums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Research Vice Chancellor of Tabriz University of Medical Sciences

##### Expected recruitment start date

2014-05-22, 1393/03/01

##### 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

Assessing the effectiveness of Health Complex interventional model in comparison with routine health system on comprehensive health management performance indicators in East Azerbaijan: Field Trial

##### Public title

Assessing the effectiveness of Health Complex on performance indicators of health system

##### Purpose

Health service research

##### Inclusion/Exclusion criteria

Inclusion Criteria : 1.Marginalized Population of Tabriz  
2.greater than 18 years  
Exclusion Criteria : 1. Lack of consent

##### Age

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

##### Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 6000

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

##### Street address

Golgasht Ave

##### City

Tabriz

##### Postal code

#### Approval date

2015-04-27, 1394/02/07

#### Ethics committee reference number

TBZMED.REC.1394.35

## Health conditions studied

### 1

#### Description of health condition studied

Diabetes Type 2

#### ICD-10 code

E11

#### ICD-10 code description

Non-insulin-dependent diabetes mellitus

### 2

#### Description of health condition studied

Depression

#### ICD-10 code

F32

#### ICD-10 code description

Depressive episode

### 3

#### Description of health condition studied

Hypertension

#### ICD-10 code

I10

#### ICD-10 code description

Essential (primary) hypertension

## Primary outcomes

### 1

#### Description

self care

#### Timepoint

before intervention , 2 years after intervention

#### Method of measurement

General Selfcare Questionnaire

### 2

#### Description

Responsiveness

#### Timepoint

before intervention , 2 years after intervention

#### Method of measurement

Questionnaire

### 3

#### Description

Health Services Utilization

#### Timepoint

before intervention , 2 years after intervention

#### Method of measurement

Questionnaire

### 4

#### Description

Trust to Health System

#### Timepoint

before intervention , 2 years after intervention

#### Method of measurement

Questionnaire

## Secondary outcomes

### 1

#### Description

Customer Satisfaction

#### Timepoint

before intervention,2 years after intervention

#### Method of measurement

Questionnaire

### 2

#### Description

Staff Satisfaction

#### Timepoint

before intervention, 2 years after intervention  
**Method of measurement**  
Questionnaire

## Intervention groups

### 1

#### Description

foundation of health complex : Health Complex is an accountable and responsive health care organization to deliver an integrated care services to people in a defined catchment area against identified per capita payment, under district health center policies and regulations .

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Chamran Health Center

##### Full name of responsible person

Dr Oroumchi

##### Street address

Tabriz-Akhmagayeh

##### City

Tabriz

### 2

#### Recruitment center

##### Name of recruitment center

Azadi Health Center

##### Full name of responsible person

Mr Alizadeh

##### Street address

Tabriz - Mofatteh Ave

##### City

Tabriz

### 3

#### Recruitment center

##### Name of recruitment center

Emamyeh Health Center

##### Full name of responsible person

Dr Vahdati

##### Street address

Tabriz - Emamyeh

##### City

Tabriz

### 4

#### Recruitment center

##### Name of recruitment center

Sahand Chamran Health Center

##### Full name of responsible person

Mrs Safari

#### Street address

Tabriz - Sahand

#### City

Oskou

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

##### Full name of responsible person

Dr Mohammad Reza Rashidi

##### Street address

Golghasht Ave

##### City

Tabriz

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Vice chancellor for research, Tabriz 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

Tabriz University of Medical Sciences

##### Full name of responsible person

Mostafa Farahbakhsh

##### Position

Psychiatrist

##### Other areas of specialty/work

##### Street address

Seghat ol Eslam Ave

##### City

Tabriz

##### Postal code

##### Phone

+98 41 3233 0147

##### Fax

+98 41 3233 0196

##### Email

mfarahbakhsh@gmail.com

##### Web page address

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

health faculty

**Full name of responsible person**

Homayoun Sadeghi Bazargani

**Position**

epidemiologist

**Other areas of specialty/work**

**Street address**

Attar Nishaboori Ave

**City**

Tabriz

**Postal code**

**Phone**

+98 41 3334 0308

**Fax**

**Email**

homayoun.sadeghi@gmail.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mostafa Farahbakhsh

**Position**

Psychiatrist

**Other areas of specialty/work**

**Street address**

Seghat ol Eslam Ave

**City**

Tabriz

**Postal code**

**Phone**

+98 41 3233 0147

**Fax**

+98 41 3233 0196

**Email**

mfarahbakhsh@gmail.com

**Web page address**

## 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*