

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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

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Fax

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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**

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Mostafa Farahbakhsh

Position

Psychiatrist

Other areas of specialty/work**Street address**

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City

Tabriz

Postal code**Phone**

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Fax

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Email

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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