Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Nov 2026

The Comparison of Self-care Status in Type Two Diabetic Patients Receiving versus not Receiving the Web-based Iranian Diabetic Personal Health Record System

Protocol summary

Summary

This study is a randomized control trial which will be conducted aiming at examining the impact of web-based Diabetic Personal Health Record system on self-care status of diabetic patients compared with control arm. Inclusion criteria are type two diabetic patients aged between 20-70 who live in the Mashhad city and undergo at least one year of the disease. Also, they must be computer literate and have access to the internet and must provide informed consent. The patients will be randomly sampled from one private practice unit. In this study, the trial phase and blinding are not applicable. The sample size is 66 people that randomly will be assigned to control and intervention groups. The patients in intervention group will be allowed access to the web-based Diabetic Personal Health Record system while those in the control group will receive no intervention for four months. The study outcome measures include self-care status of patients, visit adherence, and drug adherence.

General information

Acronym

DPHR=Diabetic Personal Health Record

IRCT registration information

IRCT registration number: **IRCT2013082914522N1**
Registration date: **2015-10-10, 1394/07/18**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-10-10, 1394/07/18

Registrant information

Name

Amirabbas Azizi

Name of organization / entity

Mashhad University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

This study is the PhD dissertation in which has been supported by a grant from vice chancellor for research, Mashhad University of Medical Sciences [grant # 921835]

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of Self-care Status in Type Two Diabetic Patients Receiving versus not Receiving the Web-based Iranian Diabetic Personal Health Record System

Public title

The Study on the Effect of Web-based Iranian Diabetic Personal Health Record System

Purpose

Health service research

Inclusion/Exclusion criteria

The inclusion criteria: Patient can be a male or female with type two diabetes; presence of diabetes type two at least for one year; aged between 20-70 years; be able to understand the consent content; must live in the city of Mashhad; must be computer literate and have access to the internet; must be in perfect health condition at the moment; must provide informed consent The exclusion criteria: Already participating in another ongoing experimental research; pregnancy and lactation

Age
From **20 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
The randomization process will be done by the person who has no direct involvement in this trial. Also, the random allocation sequence will be done through computerized random number program.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
the Regional Ethics Committee-vice chancellor for research, Mashhad University of Medical Sciences

Street address
Daneshgah Street-Qoreshi House-Mashhad

City
Mashhad

Postal code
۳۴۵ - ۹۱۳۷۵

Approval date
2014-03-15, 1392/12/24

Ethics committee reference number
research/921835/1/787

Health conditions studied

1

Description of health condition studied
Diabetes mellitus type 2

ICD-10 code
E11

ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
Self-care status

Timepoint
Baseline-Intermediate (two months after intervention)-immediately after end of intervention

Method of measurement
Summary of Diabetes Self-care Activities Measure-revised

Secondary outcomes

1

Description
medication adherence

Timepoint
one month after intervention-two months after intervention-three months after intervention-immediately after end of intervention

Method of measurement
the Morisky Medication Adherence Scale (MMAS-8)

2

Description
Visit appointment adherence

Timepoint
one month after intervention-two months after intervention-three months after intervention-immediately after end of intervention

Method of measurement
web-based Diabetic Personal Health Record system log

Intervention groups

1

Description
Intervention 1: the type two diabetic patients, that refer to the private practice unit, randomized to intervention arm will receive the web-based Diabetic Personal Health Record System for four months.

Category
Other

2

Description
Intervention 2: the type two diabetic patients, that refer

to the private practice unit, randomized to control arm will not receive no intervention and will be followed for four months.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Private practice unit

Full name of responsible person

Street address

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Daneshgah Street-Qoreshi House-Mashhad

City

Mashhad

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, Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Saeed Eslami

Position

Assistant professor, Department of Medical Informatics/Research affairs manager

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

PhD Candidate, Department of Medical Informatics

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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