

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Effectiveness of an educational program on knowledge of patients with diabetes mellitus about prevention of late complications

#### Protocol summary

2024-01-04, 1402/10/14

#### Study aim

To assess knowledge of diabetic patients regarding late complications. To evaluate effectiveness of educational program regarding late complications. To find out relationship between knowledge of diabetic patients regarding late complication of diabetic and there demographic characteristics.

#### Design

quasi experimental design

#### Settings and conduct

at alkarama teaching hospital in alkut city in iraq

#### Participants/Inclusion and exclusion criteria

1. Diabetes mellitus type I& type II patients, Both male and female. 2. Adult patients 18-70 years of age. 3. Patients who were agree to participate in the present study. 4.Level of education for these patients at least read and write. 3.4.4. Exclusion Criteria 1.patients with neurological disorder 2. Diagnosis patients with diabetes mellitus more than 20 years.

#### Intervention groups

this group that recieved educational program from 20/1/2024 to 10/2/2024

#### Main outcome variables

increase patients knowledge to prevent late complications of diabetic

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20231225060523N1**

Registration date: **2024-01-04, 1402/10/14**

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

Last update: **2024-01-04, 1402/10/14**

Update count: **0**

##### Registration date

#### Registrant information

##### Name

Raissan Rahi

##### Name of organization / entity

Baghdad University/ Collage of Nursing

##### Country

Iraq

##### Phone

+964 783 055 3929

##### Email address

raissan.rahi2202m@conursing.uobaghdad.edu.iq

#### Recruitment status

##### Recruitment complete

#### Funding source

#### Expected recruitment start date

2024-01-04, 1402/10/14

#### Expected recruitment end date

2024-04-02, 1403/01/14

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effectiveness of an educational program on knowledge of patients with diabetes mellitus about prevention of late complications

#### Public title

Effectiveness of an educational program on knowledge of patients with diabetes mellitus about prevention of late complications

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

**Inclusion criteria:**

1. Diabetes mellitus type I & type II patients, Both male and female. 2. Adult patients 18-70 years of age. 3. Patients who were agree to participate in the present study. 4. Level of education for these patients at least read and write.

**Exclusion criteria:**

1. patients with neurological disorder 2. Diagnosis patients with diabetes mellitus more than 20 years.

**Age**

From **18 years** old to **70 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description**

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

used control and study groups.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

quasi experimental

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethic committee in collage of nursing at university of Baghdad

**Street address**

Bab-AL-muadhim street

**City**

Baghdad city

**Postal code**

code N/A

**Approval date**

2023-11-22, 1402/09/01

**Ethics committee reference number**

1510

**Health conditions studied**

1

**Description of health condition studied**

diabetic type I & type II

**ICD-10 code**

of patient

**ICD-10 code description**

E11.69

**Primary outcomes**

1

**Description**

primary outcomes prevention of late complications

**Timepoint**

timepoint before intervention and 2 weeks after intervention

**Method of measurement**

self-report questioner

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group: group that receive program

**Category**

Prevention

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

alkarama teaching hospital

**Full name of responsible person**

Raisan Rahi Helal

**Street address**

ALANWAR STREET

**City**

Alkut city

**Postal code**

code N/A

**Phone**

+964 783 055 3929

**Fax**

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**Email**

raissan.rahi2202m@conursing.uobaghdad.edu.iq

**Web page address**

[https://www.irct.ir/user/trial/74788/update/recruitmen t\\_center](https://www.irct.ir/user/trial/74788/update/recruitmen t_center)

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

university of Baghdad /college of nursing

**Full name of responsible person**

Raisan Rahi Helal

**Street address**

Bab-AL-muadhim street

**City**

Baghdad city

**Postal code**

code N/A

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**Email**

raissan.rahi2202m@conursing.uobaghdad.edu.iq

**Web page address**

<https://www.irct.ir/user/trial/74788/update/sponsor>

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

Yes

**Title of funding source**

university of Baghdad /college of nursing

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

Persons

**Person responsible for general inquiries****Contact****Name of organization / entity**

university of Baghdad /college of nursing

**Full name of responsible person**

Raisan Rahi Helal

**Position**

wasit

**Latest degree**

Master

**Other areas of specialty/work**

Emergency Medicine

**Street address**

Bab-AL-muadhim street

**City**

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**Province**

Baghdad

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**Email**

raissan.rahi2202m@conursing.uobaghdad.edu.iq

**Web page address**

[https://www.irct.ir/user/trial/74788/update/public\\_queries\\_contact](https://www.irct.ir/user/trial/74788/update/public_queries_contact)

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

university of Baghdad /college of nursing

**Full name of responsible person**

Raisan Rahi Helal

**Position**

wasit

**Latest degree**

Master

**Other areas of specialty/work**

nursing

**Street address**

Bab-AL-muadhim street

**City**

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**Person responsible for updating data****Contact****Name of organization / entity**

university of Baghdad /college of nursing

**Full name of responsible person**

Raisan Rahi Helal

**Position**

wasit

**Latest degree**

Master

**Other areas of specialty/work**

nursing

**Street address**

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**Web page address**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

The data will be the results of ESRD-AQ that measure adherence to hemodialysis and associated factors among patients with end stage renal failure after applying instruction program for intervention group and compare

the result with the control group

**When the data will become available and for how long**

once the process of data collection, analysis, and successful publishing of manuscript, all the related files will become available

**To whom data/document is available**

available for academic nursing and any researcher who is interested in the data

**Under which criteria data/document could be used**

the data could be used after getting the permission via email. also, users need to acknowledge the owner

**From where data/document is obtainable**

users can ask for the data and permission via email at Raissan.Rahi2202m@conursing.uobaghdad.edu.iq

**What processes are involved for a request to access data/document**

preparing a summary report of the research findings, highlighting the key outcomes, conclusions, and recommendations. This document will be shared electronically as a PDF file. The process to request access to this document involves: a. Request Submission: Interested individuals can submit a formal request for the research findings. b. Review and Approval: The requests will be reviewed to ensure they comply with ethical guidelines and any applicable data protection regulations. c. Access Provision: If approved, the research findings report will be shared electronically with the applicant.

**Comments**