

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Assessment the effect of implementation of discharge plan on physiological and behavioral anxiety parameters in patients with diabetes mellitus

Protocol summary

Study aim

Determination the effect of implementation of discharge plan on physiological and behavioral anxiety parameters in patients with diabetes mellitus

Design

A clinical trial with a control group, randomized with quad blocks, parallel groups

Settings and conduct

The study is conducted in the internal diseases department of Imam Khomeini Hospital in Shirvan city. After half an hour after the patients understand the discharge order, anxiety questionnaire is completed by them and a sample of saliva is taken. Then the discharge program implement for intervention group and the control group receive the routine program. After half an hour, the questionnaire is completed and the saliva sample is taken again.

Participants/Inclusion and exclusion criteria

Patients with diabetes mellitus are admitted to the internal department of Imam Khomeini Hospital in Shirvan city. inclusion criteria: Age more than eighteen years; Ability to reading and writing; Ability to understand and speak in Farsi; Ability to self care; Ability to speech and hearing; Absence of dementia and cognitive problem; Absence of endocrine gland diseases; Not taking medications that reduce or increase cortisol; Not taking anti-anxiety and tranquilizers; There is no underlying diseases; Desire to participate in the study exclusion criteria: Not fasting; Brushing in 4-5 hours; Not having saliva (in some cases like Sjogren's syndrome); Presence of gingivitis; Unwilling to continue research; Discharge of the patient after 10 o'clock

Intervention groups

Intervention group: Implementing a complete and up-to-date discharge plan. Control group: only receive routine training.

Main outcome variables

Salivary cortisol; anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181112041627N1**

Registration date: **2018-12-24, 1397/10/03**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-24, 1397/10/03**

Update count: **0**

Registration date

2018-12-24, 1397/10/03

Registrant information

Name

Mohsen Fooladzadeh Dehghan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3622 4373

Email address

mohsen.antisemitism12@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment the effect of implementation of discharge plan on physiological and behavioral anxiety parameters in patients with diabetes mellitus

Public title

Assessment the effect of implementation of discharge plan on anxiety in patients with diabetes mellitus

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

age more than eighteen years ability to reading and writing ability to understand and speak in Farsi ability to self care ability to speech and hearing absence of dementia and cognitive problem absence of endocrine gland diseases not taking medications that reduce or increase cortisol (such as corticosteroids, anticonvulsants) not taking anti-anxiety and tranquilizers (such as propranolol, clonazepam, etc.) There is no underlying diseases desire to participate in the study

Exclusion criteria:

Not fasting Brushing during recent 4-5 hours Not having saliva (in some cases like Sjogren's syndrome) Presence of gingivitis Unwilling to continue research Discharge of the patient after 10 o'clock (due to stable salivary cortisol levels between 7 and 10 o'clock)

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomized method by quad blocks, The letter A for the intervention group and the letter B for the control group are considered. Then, all the reciprocal combinations of the letters A, A and B,B which are 6 different combinations, are written on 6 cards, and one digit of one to six digits is selected randomly. (By random number tables or from patient number one we want to choose a card randomly)

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**

Ethics committee of Tehran University of Medical Sciences

Street address

Tohid Square, Dr Mirkhani St. (Eastern Nusrat)

City

Tehran

Province

North Khorasan

Postal code

1419733171

Approval date

2018-11-06, 1397/08/15

Ethics committee reference number

IR.TUMS.FNM.REC.1397.143

Health conditions studied**1****Description of health condition studied**

Diabetes mellitus

ICD-10 code

Diabetes m

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes**1****Description**

Anxiety Score in Beck's questionnaire

Timepoint

Anxiety Measurement at the beginning of the study (before the intervention) and half an hour after the intervention

Method of measurement

Anxiety Beck's questionnaire

2**Description**

Salivary cortisol levels based on micrograms per deciliter

Timepoint

Anxiety Measurement at the beginning of the study (before the intervention) and half an hour after the intervention

Method of measurement

Saliva sample

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: implementation an educational program during discharge with the general definition of diabetes, blood glucose control, diet, exercise and activity, acute complications of diabetes and their prevention, chronic complications of diabetes and their prevention, rules of illness

Category

Lifestyle

2

Description

Control group: Routine training of ward

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital in Shirvan city

Full name of responsible person

Mozhdeh Navidhamidi

Street address

No. 7, Fourth Alley Foroughi Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Email

fooladzadeh8343@gmail.com

Web page address

http://fnm.tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohsen Fooladzadeh

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Mozhdeh Navidhamidi

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Educational content will be provided to patients in the form of a booklet

When the data will become available and for how long

From the beginning of the study, the intervention group will be delivered the educational booklet and the control group will be delivered the educational booklet after completing the study.

To whom data/document is available

Intervention group and control group will be delivered the educational booklet.

Under which criteria data/document could be used

After publishing an article, it is possible to use the results for further research.

From where data/document is obtainable

Tehran University of Medical Sciences, Faculty of Nursing and Midwifery

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

The applicant can receive the documentation after calling the listed phone number.

Comments

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohsen Fooladzadeh

Position

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Latest degree

Bachelor

Other areas of specialty/work

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