

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Effect of high protein versus high carbohydrate intake at evening meal on quality of life, sleep quality and inflammation in patients with type 2 diabetes

Protocol summary

Study aim

The aim of this study was to compare the effect of high protein versus high carbohydrate intake at evening meal on quality of life, sleep quality and inflammation in patients with type 2 diabetes.

Design

This is a 10-week single blinded, randomized controlled trial. Applying block randomization, the participants were randomly assigned to either of the following three groups: Standard evening meal, High carbohydrate evening meal and High protein evening meal. Sample size was calculated to be 30 in each group with attrition rate of 20%.

Settings and conduct

The Participants were followed for 10 weeks, during which they visited the specially designated clinic in Shiraz city at weeks 2, 5 and 10. Anthropometric measurements and blood pressure were monitored at weeks 0, 5 and 10. Inflammatory marker hs-CRP was measured at the beginning and at the end of the study. Quality of life and sleep quality questionnaires were filled by the participants at weeks 0, 5 and 10. Participants were unaware of random allocation into different groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria were type 2 diabetes; hemoglobin A1c equal or less than 8%; body mass index equal or greater than 22 and less than 35 kilograms per square meter; not taking insulin or α glucosidase inhibitors; not having heart, liver, kidney, thyroid, gastrointestinal and respiratory disorders or malignancies; not being pregnant or lactating.

Intervention groups

In Standard evening group, protein and carbohydrate were rather evenly distributed among meals. In High carbohydrate evening meal group, 40-45% of total carbohydrate intake was provided at dinner and evening snack. In High protein evening meal group, 40-45% of

total protein intake was at dinner and evening snack.

Main outcome variables

Main outcome of current study was change in quality of life of study participants.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170427033666N2**

Registration date: **2018-11-22, 1397/09/01**

Registration timing: **retrospective**

Last update: **2020-10-19, 1399/07/28**

Update count: **2**

Registration date

2018-11-22, 1397/09/01

Registrant information

Name

Fatemeh Nouripour

Name of organization / entity

Shiraz Univesity of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3725 1007

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-05, 1397/02/15

Expected recruitment end date

2018-05-20, 1397/02/30

Actual recruitment start date

2018-04-29, 1397/02/09

Actual recruitment end date

2018-05-05, 1397/02/15

Trial completion date

2018-08-06, 1397/05/15

Scientific title

Effect of high protein versus high carbohydrate intake at evening meal on quality of life, sleep quality and inflammation in patients with type 2 diabetes

Public title

The effect of diet on quality of life and sleep quality of patients with diabetes

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having type 2 diabetes mellitus according to American Diabetes Association criteria Diabetes duration of 1-15 years Age range of 30-65 years old Hemoglobin A1c (HbA1c) less than or equal to 8% Body mass index (BMI) 22- 35 kilograms per square meter Weight maintenance (\pm 3 kg) during past 3 month Stable medications during at least past two month Willingness to participate in study

Exclusion criteria:

Not taking insulin or α glucosidase inhibitors Not having heart, liver, kidney, thyroid, gastrointestinal and respiratory disorders or malignancies Not consuming alcohol Not being on special diets like gluten free or vegan; Not being pregnant or lactating

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **90**

Actual sample size reached: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants were randomly assigned into three groups using block randomization. Block size of 3 was used. To do this, first participant was assigned into the first group, second participant into the second group and third participant into the third group and the process was continued.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants were not aware of random allocation to different groups. Statistics specialist is also unaware of intervention each group received.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Central building of Shiraz University of Medical Sciences, Zand st

City

Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2018-04-29, 1397/02/09

Ethics committee reference number

IR.SUMS.REC.1397.101

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

Type 2 diabetes

ICD-10 code

E 11

ICD-10 code description

Type 2 diabetes mellitus

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

Quality of life

Timepoint

The beginning, middle and the end of the study

Method of measurement

Questionnaire

Secondary outcomes**1****Description**

Sleep quality

Timepoint

The beginning, middle and the end of the study

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: A 10-week diet in which 40-45% of total carbohydrate intake was provided at dinner and evening snack.

Category

Lifestyle

2

Description

Intervention group: A 10-weeks diet in which 40-45% of total protein intake was at dinner and evening snack.

Category

Lifestyle

3

Description

Control group: A 10-weeks diet in which protein and carbohydrate were rather evenly distributed among meals.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahhari Diabetes Clinic

Full name of responsible person

Fatemeh Nouripour

Street address

Namazi square

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2

Recruitment center

Name of recruitment center

Hakim Diabetes Clinic

Full name of responsible person

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3

Recruitment center

Name of recruitment center

AliAsghar Diabetes Clinic

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Recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Fatemeh Nouripour

Position

کارشناس ارشد تغذیه

Latest degree

Master

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Zohreh Mazloom

Position

Professor

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Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

I have no plan to share it.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable