The Effect of an Online Plant-Based Dietary Program on Cardiovascular Risk Factors in Persons with Type 2 Diabetes Mellitus: A Randomized Controlled Trial

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Primary Objective:• To evaluate the effect of an online 12 week plant-based dietary program compared to usual diet on change in glycated hemoglobin and estimated relative CVD risk in persons with type 2 diabetes. Secondary Objective(s): • To...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON51514

Source
ToetsingOnline

Brief title
Plate-DM

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Lipid metabolism disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
diabetes, diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Regiodeal Foodvalley

Intervention

Keyword: cardiovascular, diabetes, plant-based

Outcome measures

Primary outcome

A blinded intention-to-treat analysis of the endpoint will be conducted. The primary outcomes of this study are change in HbA1c and change in estimated relative CVD risk (based on change in LDL-c, SBP and HbA1c) after 12 weeks of intervention.

Secondary outcome

Secondary outcomes of will be measures of glycemic control (HOMA2-IR, HOMA2-B%, TyG-index, NAFLD Score), lipoprotein profile (LDL cholesterol, apolipoprotein B, non-HDL cholesterol, HDL cholesterol), inflammation, blood pressure, quality of life, anthropometric measurements (BMI, hip/waist ratio) and adherence to the dietary intervention will be assessed using a dietary index. Lastly, the effect of the adherence and diabetes subtype (e.g. insulin-resistant or insulin deficient) on these outcomes will be quantified and barriers and factors supporting adherence will be identified.

Study description

Background summary

References are indicated with a number. The relevant source can be found in the

reference list of the protocol

Persons with Type 2 Diabetes (T2D) are at an increased risk of cardiovascular disease (CVD) and mortality1. Dietary changes are recommended by guidelines to treat T2D and reduce risk of CVD2-4. Plant-based diets eliminate certain (i.e. vegetarian diet) or eliminate all animal based products (i.e. vegan diet)5. Clinical trials with plant-based diets have not looked at incidence of CVD as a (primary) outcome, but at intermediate outcomes of cardiovascular risk. A meta-analysis of 8 trials including 369 persons with T2D found an effect of a plant-based diet on glycated hemoglobin (HbA1c) of -0.29% [95% CI: -0.45, -0.12%]6 relative to mostly (omnivorous) low-fat diets or usual diet. The 95%CI ranged from what the authors had defined as clinically trivial to clinically relevant. For lipids, a network meta-analysis in persons with T2D compared the effect of a plant-based diet to a (omnivorous) low fat diet (274 patients allocated to a plant-based diet vs 2047 patients allocated to low fat diets). Compared to omnivorous low fat diets, the mean effect of plant-based diets on LDL-Cholesterol was -0.33 mmol/L [95%CI:* 0.55, * 0.12]. However, the quality of the evidence for this estimate was graded as low, mainly due to imprecision and within-study-bias7. Furthermore, plant-based diets might reduce blood pressure (BP). However, while vegetarian diets reduce BP in patients with and without hypertension8, for vegan diets the effect was only significant in patients with a systolic BP>130mmHgz (see section 1.4.3). Additionally, the effect of plant-based diets on inflammation, which might also be causally related9 to CVD risk in persons with T2D10,11, has not been reported in trials with persons with T2D. Furthermore, most clinical trials of plant-based diets in persons with T2D have used resource intensive interventions, like weekly group meetings12-14 and cooking sessions13. The effect of an online plant-based dietary intervention, which is more scalable, has not been reported in clinical trials. Lastly, factors influencing adherence in these trials have not been reported15.
In summary, plant-based diets likely lower CVD risk by lowering HbA1c, LDL cholesterol and potentially blood pressure in persons with T2D. However, estimated effect sizes are imprecise and the effect on inflammation is still unknown. Furthermore, trials to date have used resource intensive interventions. Thus, the present trial aims to study the effect of a primarily online plant-based dietary program on (cardio)vascular risk factors in persons with T2D. Additionally, adherence and factors influencing adherence will be investigated.

Study objective

Primary Objective:
• To evaluate the effect of an online 12 week plant-based dietary program compared to usual diet on change in glycated hemoglobin and estimated relative CVD risk in persons with type 2 diabetes.

Secondary Objective(s):

• To evaluate the effect of an online 12 week plant-based dietary program compared to usual diet in persons with type 2 diabetes on
o estimated absolute CVD risk reduction;
o glycemic control, lipid profile, blood pressure and inflammation;
o medication use, quality of life and stress in persons;
o incidence of hypoglycemia or other adverse events;
o body weight, BMI and waist circumference.
• To evaluate to which extent the effect of an online 12 week online plant-based dietary program on glycemic control, lipid profile, chronic inflammation and blood pressure is modified by
o adherence to the plant-based diet.;
o T2D subtype;
o change in body weight.
• To evaluate the effect of an online 12 week plant-based dietary platform without arranged support groups in the control group on estimated relative CVD risk reduction in persons with type 2 diabetes.
• To identify barriers to and factors supporting adherence to a plant-based diet in patient with type 2 diabetes.
• To identify the effect of providing access to an online learning environment (without support groups and with self-arranged care from a dietician) on glycemic control, lipid profile, blood pressure and medication usage in persons with type 2 diabetes.

Study design

a single center, randomized, investigator blinded, parallel, 12-week controlled trial. One group will receive the online plant-based dietary program, the other group will receive (dietary) care as usual. The trials starts with a one week run-in period, after which baseline measures are collected. The measurements of primary end-point are collected in week 12 and additional follow-up measurements are collected in week 24.

Intervention

a 12-week plant-based dietary program consisting of information via an online platform, guidance by dieticians and peer support groups. Patients will aim to maximize their intake of plant-based products while reducing their of animal products as much as possible. The control group will be offered access to the online platform at the end of the study.

Study burden and risks

The hypothesized beneficial insulin sensitizing effect of the dietary intervention may increase the risk of occurrence of mild hypoglycemia and may lead to a reduced need of glucose-lowering drugs and insulin13,14,16-21. In the present trial multiple measures have been taken to ensure that patients receive

standard of care during the trial (see section 5.2). Thus, while some episodes of mild hypoglycemia may occur, given the measures in place, the risk of severe hypoglycemia is deemed small. Another potential risk of a strictly plant based diet are deficiencies in vitamin B12. For this reason, patients in the intervention group will take a vitamin B12 supplement. The burden for patients consists of 4 visits to the hospital for measurements for the intervention group and 5 for the control group. During the visits, patients need to be fasted, will have their blood drawn and a physical exam will be performed. Patients will also fill-out seven questionnaires and a dietary record. The burden of the intervention made up of the online program, sessions with the dietician and the group sessions. Completing all sessions is expected to take about 40 hours.
Expected benefits of the intervention for patients are weight loss, improved glycemic control and improved cardiovascular risk profile. Whether these effects last, is probably largely dependent on long term adherence

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Diagnosis of Type 2 Diabetes sinds at least 1 year and using oral glucose-lowering medication
2. If using lipid-lowering and/or blood pressure-lowering medication than on a stable dose for at least 2 months before the screening.
3. Age of 18 years or older on the day of signing the informed consent form.

Exclusion criteria

1. Hypoglycemia unawareness
2. 2 or more episodes of severe hypoglycemia during last 3 months
3. uncontrolled hypertension or diabetes
4. vitamin B12 or iron deficiency

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-11-2022
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO Date:	21-09-2022
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	08-11-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	28-03-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	05-07-2023
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCTnummervolgt
CCMO	NL80378.041.22