Effect of Mediterranean diet combined with healthy food boxes on blood glucose levels of people with type 2 diabetes and low socioeconomic status: a randomized controlled trial

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Primary Objective: What is the difference in the effectiveness of the Food Pharmacy Program in glycaemic regulation compared to nutrition coaching performed by dieticians after three months in overweight adults with type 2 diabetes? Secondary...

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

Summary

ID

NL-OMON57037

Source
ToetsingOnline

Brief title
Food Pharmacy trial

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Diabetes mellitus type 2, Non-insulin dependent diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: HarvestCare,Rotterdam De Boer Op,Stichting De Verre Bergen,Stichting Goeie Grutten,subsidies

Intervention

Keyword: Diet, Food pharmacy, Mediterranean, Type 2 diabetes

Outcome measures

Primary outcome

Between-group difference in HbA1c (mmol/mol) from baseline to three months.

HbA1c will be measured using routine clinical lab procedures.

Secondary outcome

- Anthropometry: Body weight and waist circumference

- Cardiovascular risk factors: LDL cholesterol, total cholesterol, HDL

cholesterol, triglycerides, fasting blood glucose and blood pressure, measured

with routine lab procedures

- Quality of life

- Work productivity

- Demographic variables, drug use, smoking and drinking habits, exercise and

(diabetes) medication use

- Food intake and adherence to the diet intervention (% used products of food

boxes)

- Patient satisfaction

- Number of participants that drop out

Study description

Background summary

The prevalence of type 2 diabetes (T2D) continues to rise. In the Netherlands, it is estimated that 1,2 million people are currently affected by T2D, which is expected to grow to 1,4 million by 2040. In the European region, approximately 60 million people live with diabetes, making it one of the leading causes of death and disability.

Unhealthy diets and physical inactivity can lead to an increase in overweight and obesity, especially among socioeconomically disadvantaged communities. In addition, people with low socio-economic status (SES) are more likely to develop T2D. One reason for this could be the financial aspect of food. Research done in the Netherlands found an inverse association between energy density and the costs of food items. Energy-dense, nutritionally depleted food products, such as refined grains, added sugar, and fats, cost significantly less than nutrient-dense foods.

Nowadays, several dietary interventions have been shown to be effective for patients with T2D, including the Mediterranean diet. This diet is characterized by a high intake of vegetables, fruits, legumes, whole grains, nuts, fish, and olive oil, which has been associated with several health benefits. Intake of products rich in fibers, mono- and poly-saturated fatty acids, vitamins, probiotics, antioxidants, and low-glycaemic foods can decrease inflammation and insulin resistance and improve glycaemic control in diabetes patients. For dietary treatment to be successful in people with T2D, individual responsibility and intrinsic motivation for change are critical enablers. However, increasing costs of healthy products, such as those recommended in the Mediterranean diet, pose a barrier to maintaining healthy dietary patterns, especially among patients experiencing food or financial insecurity. To support patients in overcoming these barriers, a growing body of evidence is examining the use of food as a medical prescription to improve access to fresh produce.

Several product interventions have shown a positive association between providing food via incentives such as food vouchers or boxes and positive health outcomes. A systematic review and meta-analysis by Haslam et al. (2023) lists HbA1c improvement, weight reduction, reduction of systolic blood pressure, increased health index scores, and increased vegetables and fruit servings as the primary outcomes. Bhat et al. (2021) point out that despite possible positive outcomes such as increased fruit and vegetable consumption, decreased BMI and HbA1c, most of the studies were designed in quasi-experimental (pre/post) interventions without a control group. Randomized control trials investigating the effect of healthy food prescriptions on diet quality and cardiovascular risk factors among T2D patients are lacking,

especially in Europe.

Study objective

Primary Objective: What is the difference in the effectiveness of the Food Pharmacy Program in glycaemic regulation compared to nutrition coaching performed by dieticians after three months in overweight adults with type 2 diabetes?

Secondary Objectives:
1. What is the difference in weight loss, waist circumference, cardiovascular risk factors, and diabetic medication usage between FPP and nutrition coaching after three months in overweight adults with type 2 diabetes?
2. What is the difference in fruit and vegetable consumption between the intervention and control groups?
3. What is the difference in the quality of life, treatment satisfaction, compliance, and adherence between the intervention and control groups?

Study design

The above-presented objectives will be answered by conducting a randomized controlled pilot study in which eligible T2D patients will be randomized to either the control or intervention group.

Intervention

Both groups will be recommended to follow the Mediterranean diet. Participants in the intervention group will receive weekly whole plant-based food boxes supplied from local farms in the South Holland region for 12 weeks. Additionally, during the intervention, patients will be asked to participate in two health facilitated by a dietician and two culinary medicine workshops facilitated by a trained chef. Additionally, at baseline, week 4 and week 12 of the intervention, patients will receive coaching sessions with a dietician.

The control group participants will receive three coaching sessions with a dietician (usual care) at baseline, week 4 and week 12, provided under the reimbursement scheme of the basic insurance package in the Netherlands.

Study burden and risks

The burden and risks associated with participation in the study are considered to be low. The participants will benefit from the intervention by receiving food boxes and professional support to help them improve their health. All participants will be asked to attend the standard visits at the doctor's office to collect the cardiovascular risk factors and perform anthropometric measurements at the dietician's office. Participants of the intervention group

are asked to pick up weekly boxes in Rotterdam South and attend health and cooking workshops, which will require time investment.

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

- Diagnosed T2D
- BMI > 25 kg/m2
- Aged 18 - 75 years
- Be living in Rotterdam South
- Yearly income below 25.000 euro

Exclusion criteria

- Pregnancy or lactation during the trial
- Severe psychiatric disorders, use of antipsychotic drugs
- Serious heart conditions such as: significant heart arrhythmia, unstable angina pectoris, decompensated congestive heart failure
- Organ failure
- Untreated hypothyroidism
- End-stage renal failure
- Carcinomas
- Transplants, myocardial infarct, cerebrovascular accident, or any large-scale surgery within the last 3 months
- Corticosteroid-induced diabetes (in patients still using corticosteroids)
- Food allergies for the products delivered in the food boxes

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	22-01-2025
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Date:	08-10-2024
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-01-2025
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL87221.078.24