Voed je beter met diabetes type 2: The effects of personalized dietary guidance to increase the intake of fibre-rich foods on cardiometabolic risk profile in individuals with type 2 diabetes

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

Summary

ID

NL-OMON51759

Source
ToetsingOnline

Brief title
Dutch dietary guidelines for type 2 diabetes

Condition

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

Synonym
non-insulin-dependent diabetes, type 2 diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Regio Deal Foodvalley;spoor 2 werkpakket 3 (grant nr 162135)

Intervention

Keyword: diabetes type 2, dietary fibre, Dutch dietary guidelines, RCT

Outcome measures

Primary outcome

The main study parameter is the difference in change in cardiometabolic risk profile (HbA1c, LDL-cholesterol, blood pressure and body weight) from baseline until six months between the intervention and the control group.

Secondary outcome

Secondary parameters include a diet quality score for the level of adherence to the Dutch dietary guidelines, blood lipid profile, markers of glucose metabolism, kidney, and liver function, muscle quality and physical performance, patient-oriented outcomes such as medical consumption, productivity, sleep quality, food literacy, quality of life and self-efficacy. These parameters are assessed in blood and 24-hour urine, and by means of measuring body weight, blood pressure, making ultrasound of the leg, fitness tests, a dietary recall, and self-administered questionnaires. To assess whether effects remain after the active intervention period has ended, differences in change between intervention and control group will also be investigated six months after the intervention, i.e. 12 months after the start of the study.

Study description

Background summary

Type 2 diabetes has a major impact on an individual*s life and can lead to physical and psychological distress. There is need for interventions that not only improve glucose levels, but also address other health indicators such as comorbidities and mental aspects of the disease. A healthy diet is of key importance in the management of type 2 diabetes, with dietary fibres as a critical component. However, the broad health effects of an increased intake of fibre-rich foods, as recommended in the Dutch dietary guidelines, remain unclear for individuals with type 2 diabetes. Intake levels in the Dutch population are below the recommendation, and interventions using high fibre-diets are mostly conducted with dietary fibre supplements. Previous interventions with fibre supplements show promising results among individuals with type 2 diabetes, but whether these effects are similar when adhering to the dietary guidelines without the use of fibre supplements, remains unclear.

Study objective

The primary objective of this study is to investigate the effects of personalized dietary guidance to increase the intake of fibre-rich foods, as recommended in the Dutch dietary guidelines, on cardiometabolic risk profile in individuals who have type 2 diabetes, compared to usual care. Secondary objectives are to investigate the effects on the level of adherence to the Dutch dietary guidelines, diabetes related health outcomes, including markers of glucose metabolism, lipid profile, kidney function, liver function and inflammatory markers, patient-oriented outcomes, including quality of life, self-efficacy, medical consumption, productivity and sleep quality, and muscle quality and physical performance.

Study design

The study will be a parallel randomized, controlled trial over a period of twelve months, including an intervention period of six months and a follow up period of six months in which no active intervention takes place.

Intervention

Personalized dietary guidance to increase the intake of fibre-rich foods on top of usual care. The dietary guidance is implemented by dieticians and is personalized based on adherence to dietary guidelines, current dietary intake, gender and personal goals and preferences.

Study burden and risks

Participants in the intervention group will meet with a dietician, by which they will be guided to adjust their dietary intake. Over a period of twelve months, all participants will be asked to complete questionnaires and dietary recalls at four different time points. At three time points, body weight, blood pressure, blood samples, and 24hr urine samples are obtained. An ultrasound of the leg and a fitness test are performed at these three time points as well. Benefits for participants include probable improvements of cardiometabolic risk factors which favourably impacts their cardiometabolic health and quality of life. The study can be beneficial for individuals with type 2 diabetes, as the results could lead to improved dietary guidelines for this group.

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

• Diagnosis of type 2 diabetes made by a medical doctor at least 6 months prior to study enrolment
• Adult
• Willing and able to follow dietary intervention
• Willing to participate in both intervention and control group
• Living at a reasonable distance from the research center at Wageningen University & Research (WUR) (i.e. maximum of ± 1 hour away)

Exclusion criteria

• Currently treated with insulin therapy
• Recently (< 6 months) or currently being under supervision of a dietician
• Pregnant or breast-feeding
• History of bariatric surgery, including gastric banding
• Current participation in a study with an investigational drug or dietary intervention
• Excessive alcohol consumption (more than 14 units for males/7 units for females per week) or drug use
• Clinical disorders that could interfere with the intervention (e.g. gastro-intestinal disorders, auto-immune diseases, psychiatric disorders, uncontrolled heart diseases, serious neurological disorders, renal failure or cancer)
• Not able to speak and understand the Dutch language
• No general practitioner
• Working at the department of Human Nutrition and Health at Wageningen University & Research

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	10-11-2022
Enrollment:	168
Type:	Actual

Ethics review

Approved WMO Date:	17-08-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-09-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-11-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-04-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-09-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL80697.091.22
Other	Registratie volgt na besluit