Effect evaluation of Reverse diabetes type 2 program by Voeding Leeft

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To evaluate the effectiveness of a multidisciplinary outpatient group-based nutrition and lifestyle intervention program *Reverse diabetes type 2* executed by Voeding Leeft on self-reported haemoglobin A1c (Hb1Ac) as measure of glucose regulation...

Ethical review	Not approved
Status	Will not start
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational non invasive

Summary

ID

NL-OMON45893

Source
ToetsingOnline

Brief title
Evaluation *Reverse diabetes type 2 program*

Condition

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

Synonym
Diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Louis Bolk Instituut
Source(s) of monetary or material Support: VGZ via Voeding Leeft and Ekhaga Foundation (een Zweedse stichting die het onderzoek financieel ondersteunt: http://www.ekhagastiftelsen.se/eng/)

Intervention

Keyword: Diabetes type 2, Evaluation, Lifestyle program

Outcome measures

Primary outcome

Self-reported HbA1c values and medication use assessed via online

questionnaires.

Secondary outcome

Other than HbA1c self-reported T2D biomarkers, subjective health parameters,

sleep, dietary intake, physical activity and program adherence.

Study description

Background summary

Prevalence of type 2 diabetes (T2D) is increasing rapidly and lifestyle interventions to reverse diabetes are seen as a possible solution to stop this trend. Long-term practice-based evidence is needed to gain more insight in the actual, and above all scientific, basis for these claims.

Study objective

To evaluate the effectiveness of a multidisciplinary outpatient group-based nutrition and lifestyle intervention program *Reverse diabetes type 2* executed by Voeding Leeft on self-reported haemoglobin A1c (Hb1Ac) as measure of glucose regulation and medication use. Secondary outcomes include other self-reported T2D biomarkers, subjective health parameters, sleep, dietary intake, physical activity and program adherence.

Study design

An observational study with a quasi-experimental design and stepped-wedge inclusion of participants.

Study burden and risks

Participants of this observational evaluation study complete online questionnaires on T2D biomarkers, medication use, general well-being, sleep, lifestyle and socio-demographics at 7 time points, each lasting 30-45 minutes (baseline, 1, 3, 6, 12, 18 and 24 months). A subset of participants is asked to complete 3 web-based 24h recalls at 4 time points, each estimating to take 30 min.

Risk-benefit analysis: The risks in this observational evaluation study are minimal as partakers are participants of a lifestyle intervention program executed by Voeding Leeft and this evaluation study by the Louis Bolk Institute only involves completing a number of online questionnaires. Questionnaires assess T2D biomarkers if available and which are mostly already collected as part of their standard medical care according to the Dutch NHG Standard for T2D for insulin users; for non-insulin users this requires up to 3 additional measurements of T2D biomarkers requested through their GP or nurse practitioner which in practice already happens for the majority of T2D patients not taking insulin.
The potential benefits are huge as this research provides information on the effectiveness of this lifestyle intervention program, when shown effective and in line with the pilot study, could benefit those with T2D which is an increasing public health problem.

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

All participants of the Voeding Leeft program can participate in this evaluation study.

Exclusion criteria

None.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	300
Type:	Anticipated

Ethics review

Not approved

Date:	20-11-2018
Application type:	First submission

Review commission: METC Wageningen Universiteit (Wageningen)

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	NL67513.081.18