A feasibility study for an e-health blended personalised lifestyle intervention to change lifestyle behaviour and reverse the risk for type 2 diabetes in people with prediabetes.

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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-OMON56477

Source
ToetsingOnline

Brief title
ELFI Health (Empowerment by Lifestyle, Food advice and Interaction)

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
type 2 diabetes

Research involving
Human

Sponsors and support

Primary sponsor: TNO
Source(s) of monetary or material Support: Roche Diagnostics,TKI-LSH TKI-LSH: Totale vergoeding vanuit TKI-LSH is 95;500 EUR. TKI-LSH (Topconsortium voor Kennis en Innovatie Life Sciences & Health) financiert zijn activiteiten door middel van subsidies;die worden verstrekt door zowel publieke als private instanties. Deze subsidies ondersteunen onderzoeksprojecten en innovaties binnen de life sciences en gezondheidssector. TKI-LSH fungeert als een samenwerkingsverband tussen bedrijven;kennisinstellingen en overheden;waarbij subsidies een cruciale rol spelen bij het mogelijk maken van baanbrekend onderzoek en de ontwikkeling van nieuwe technologieën in de sector. De financiering via subsidies draagt bij aan het bevorderen van kennisoverdracht;het versnellen van innovaties en het versterken van de concurrentiepositie van Nederland op het gebied van life sciences en gezondheid. World Data Exchange (WDX): geen vergoeding;alleen inkind bijdrage. WDX heeft een platform/PGO dat zich specialiseert in het veilig uitwisselen van gegevens. Tijdens dit project wordt er nog geen gebruik gemaakt van een PGO;maar al wel nagedacht over hoe we dit zouden kunnen implementeren.

Intervention

Keyword: empowerment, lifestyle, personalised, prediabetes

Outcome measures

Primary outcome

HbA1c as marker for prediabetes risk

Secondary outcome

blood lipids (HDL, LDL, total cholesterol)

Blood pressure

anthropometrics

body composition

habitual food intake

compliance

Study description

Background summary

In the Netherlands about 1,2 million people are living with type 2 diabetes. This number increases weekly by an average of 1000 people. Besides, an equal number of people are living in a condition of prediabetes. In this precondition of type 2 diabetes, prevention is still possible for people by changing their lifestyle. Ideally, for every individual a personalised lifestyle intervention, adapted to the individual situation, biology and preferences is advised. A personalised lifestyle intervention is effective in preventing and delaying progression to type 2 diabetes. In this study, it will be investigated whether it is feasible to perform a personalised lifestyle intervention in combination with an online e-health platform. The e-Health for Empowerment by Lifestyle, Food advice and Interaction (ELFI) Health lifestyle intervention aims to improve the lifestyle of people with prediabetes to prevent them from developing type 2 diabetes.

Study objective

The primary objective is to execute a feasibility study of the ELFI Health lifestyle intervention for three months in people with prediabetes in primary care (based on HbA1c). The secondary objectives are assessing the impact of the ELFI health lifestyle intervention after three months on objective outcome parameters, including lipid profile, body composition, waist and hip circumference, blood pressure, and nutritional intake, as well as evaluating the lifestyle intervention and the online e-health platform used by participants and medical professionals.

Study design

This study is a feasibility study, studying the ability of a personalised lifestyle intervention and e-health platform to change lifestyle behaviour and decrease the risk for the development of type 2 diabetes in people with prediabetes.

Intervention

The intervention in this study consists of a personalised lifestyle intervention for three months. After measurements of HbA1c, blood lipids, body composition, waist and hip circumferences, blood pressure, and after assessment of food intake, a personal goal is set and participants start following the personalised lifestyle intervention. This is partly a digital intervention and partly a physical intervention (blended care). The digital part is followed via an online e-health platform, which offers different information modules. The physical part consists of different measurements of the outcome parameters and community events, where participants are in contact with their general practitioner and other peers. Besides, participants have three appointments

during the intervention period with a dietician to discuss their personalised program.

Study burden and risks

Participants are asked to visit the general practitioners office 7 times in three months for measurements and appointments. In total, these 7 visits will take up around 3 hours. At the start and after 3 months, HbA1c and a complete blood lipid profile are determined. At the start, after 1 and 3 months, body composition, waist and hip circumferences, and blood pressure are measured, and food intake is assessed. Since part of the intervention is digital, it is expected that the lifestyle intervention is less burdensome.

We do not foresee any serious health risks. The risks involved may be related to physical injuries when participants may start to become physically (more) active. However, due to coaching and monitoring by the general practitioner assistant (GPA) and dietician no serious health risks are expected when participants start to live a healthier lifestyle (eat heathier, become more physically active, sleep more, and stress less).

People with prediabetes are chosen for this study, because a healthy lifestyle is known to be effective for prevention or delay of (further development of) chronic diseases, like type 2 diabetes. Because prediabetes is a serious health risk to develop type 2 diabetes, people should be empowered to learn what they can do themselves with respect to lifestyle to prevent further worsening.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

To be eligible to participate in this study, a subject must meet all the following criteria:
1. During the information session, health is assessed by the:
a. Screening questionnaire (P9885 F02; in Dutch)
2. During the health check, blood measurements are assessed by the point-of-care tool:
a. HbA1c: 39 - 53 mmol/mol (= 5.7 - 7.0%)
3. Age between 18 - 70 years
4. Stable BMI of 25 - 35 kg/m2
5. Informed consent signed
6. Willing to comply with the study procedures during the study
7. Being able to become more physically active, as assessed by the screening questionnaire (P9885 F02; in Dutch).
8. Being digitally competent
9. Willing to accept the use of all nameless data, including publication, and the confidential use and storage of all data for at least 15 years

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
1. Being diagnosed with diabetes type 1 or 2
2. Use of insulin, corticosteroids (systemic), or beta-blockers in past month
3. Use of oral diabetes medication in past year
4. (Having a history of a) medical condition that might significantly affect the study outcome as judged by the general practitioner and health and lifestyle questionnaire. This includes gastrointestinal dysfunction, diseases related to inflammation or allergy, or a psychiatric disorder

5. Being abroad or on vacation for longer than a week.
6. Alcohol consumption > 21 (women) - 28 (men) units/week
7. Reported unexplained weight loss or gain of > 2 kg in the month prior to the pre-study screening
8. Recent blood donation (<1 month prior to the start of the study)
9. Not willing to give up blood donation during the study
10. Not willing to accept information-transfer concerning participation in the study, or information regarding his health, like laboratory results, findings at anamnesis or physical examination and eventual adverse events to and from his general practitioner.
11. Pregnant or lactating women
12. Involved in another GLI or weight loss program
13. On GLP-1 analogues to stimulate weight loss

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	07-02-2024
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	05-01-2024
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL85760.028.23

Study results

Date completed: 08-08-2024

Results posted: 19-11-2024

First publication
15-07-2024

URL result
URL
Type
int
Naam
M2.2 Samenvatting voor de leek
URL

Internal documents
File