

De effecten van de Nationale Diabetes Challenge en een zelf-management app voor leefstijl op gezondheidsgedrag en kwaliteit van leven bij mensen met diabetes type 2

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22632

Source

NTR

Brief title

NDC + eHealth support in T2DM

Health condition

Type 2 diabetes

Sponsors and support

Primary sponsor: TNO, Bas van de Goor Foundation, Reinier Haga Medical Center, Saltro, LUMC

Source(s) of monetary or material Support: TKI Life Sciences and Health

Intervention

Outcome measures

Primary outcome

Quality of Life
Dietary behavior
Physical activity behavior

Secondary outcome

Clinical parameters (HbA1c, glucose, cholesterol, etc.)
Anthropometric parameters (weight, waist circumference, hip circumference)
Compliance and experiences with the self-management app for lifestyle
Questionnaires (diabetes self-management, psychosocial factors, community factors, study participation)

Study description

Background summary

Rationale: Despite the well-known beneficial health effects of lifestyle, a large proportion of people with T2DM fails to change their lifestyle. Research has shown that several lifestyle interventions focused on behaviour change can increase physical activity of people with T2DM. Recently, it has been shown that people with T2DM could be activated in being physically active via a community-based intervention program: the “National Diabetes Challenge” (NDC) program. During the yearly 20-week NDC intervention program, participants with and without T2DM weekly walk together in groups supervised by a health care professional. Up to now the NDC has only focused on physical activity in improving lifestyle of people with T2D, while also a healthy dietary pattern can contribute to improved health status with T2DM. Combined dietary and physical activity advice with behaviour change support fitting the needs of an individual can be used to further promote self-management and health status of people with T2D. TNO developed an eHealth application focused on self-management and lifestyle behaviour change for people with T2DM, the so-called “IRIS-app”.

Objective: to compare the effects of two interventions on lifestyle behaviour (food intake and physical activity) and quality of life in people with T2DM: the NDC and a combined lifestyle intervention, namely the NDC with addition of a self-management application for personalized lifestyle advice, self-monitoring and behaviour change.

Study design: This study will be designed as a two-group intervention trial. One arm will only participate in the National Diabetes Challenge, the other arm will also be supported by an eHealth application.

Study population: The study population will consist of 300 people with T2DM that participate in the National Diabetes Challenge program in 2019 at selected locations.

Intervention: the intervention consists of an eHealth application focused on lifestyle, the so-

called “IRIS-app”. This app empowers persons with T2DM self-management. Users will get control over their own health data, be provided with personalized lifestyle interventions, and can set personal goals and self-monitor their goals to achieve behaviour change. Finally, the app offers tools and support in maintaining behaviour change via interventions.

Main study parameters/endpoints: The main study parameters are Quality of Life (WHO-5), physical activity (SQUASH), and dietary intake (Eetscore). These will all be assessed via online questionnaires at baseline (t=0), post-intervention (t=20 weeks) and follow-up (t=30 weeks).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: In this study, people with type 2 diabetes are motivated to change their lifestyle, which could result in a small risk for hypoglycaemia. This risk is mitigated by the involvement of the GP and/or GPA of the patient in the program, which can closely monitor the health status of the patients, and make necessary changes in medication. For subjects that undergo blood withdrawal, there is a small risk for bruises.

Study objective

Primary Objective: to compare the effects of two interventions on lifestyle behaviour (food intake and physical activity) and quality of life in people with T2DM: the NDC and a combined lifestyle intervention, namely the NDC with addition of a self-management application for personalized lifestyle advice, self-monitoring and behaviour change.

Secondary Objective(s):

- What are the effects of the combined lifestyle intervention, with and without the app on metabolic, physiological and psychological markers of health in people with T2DM?
- Is there a change in psychosocial factors (self-efficacy, knowledge, social support, attitude) after the intervention between the two intervention groups, and what is their influence on the effects of the intervention (with and without the lifestyle app) on the change in health behaviour (physical activity and nutrition)?
- Does participation in the NDC result in increased perceived collective efficacy, sense of community, and social capital?
- Can changes in primary and secondary outcomes be explained by the community mechanisms and/or app acceptance and usage?

For the NDC+app group only also the following two research questions will be investigated:

- What is the compliance with the app in terms of use of the app, as well as adherence to the individually set goals?
- What is the potential of the app in maintaining the lifestyle results at the end of the existing National Diabetes Challenge intervention (i.e. post-intervention t=20-weeks) or preventing relapse into unhealthy habits (i.e. lower physical activity and more unhealthy dietary choices) at 10-week follow-up?

Study design

Start of intervention (April / May 2019)

End of National Diabetes Challenge intervention (September / October 2019)

Intervention

Subjects in the intervention groups (both NDC-only and NDC+app) will take part in the NDC intervention program, a 20-week community-based walking event in which weekly group walks are organized under professional guidance of a health care provider or local sports coach. This intervention program will start in May 2019 and end with a (facultative) festival day end of September in the Hague. Subjects are recruited amongst people that already signed up to participate in the NDC-program. As such, the NDC-program itself is not considered an intervention in this study.

The NDC+app group will, on top off the weekly walks organized by the NDC, also get access to a Smartphone application developed by TNO for personalized lifestyle support for people with type 2 diabetes.

The app includes functionality to:

- Assess current health status;
- Generate a personalized recommendation for lifestyle (e.g. a dietary pattern);
- Assess current food and diet related habits;
- Advice the user in achieving the recommended lifestyle, tuned to the individual health data and current dietary behaviour of the user;
- Set personal lifestyle goals as first step towards achieving a healthy diet and physical activity;
- Monitor the achievements in lifestyle change;
- Notifications for reminding the participants of entering their data;
- Provide support via evidence-based behaviour change interventions.

Subjects in the NDC+App group are asked to use this smartphone application during the National Diabetes Challenge program, as well as during the follow-up period (October - December 2019).

Contacts

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Eligibility criteria

Inclusion criteria

- Diagnosed with type 2 diabetes mellitus
- Digitally skilled (able to work with computers for filling in questionnaires)
- Proficient in Dutch
- Willing to complete the National Diabetes Challenge program
- Willing to comply with all study procedures
- Able and willing to sign the informed consent form

Only for the people in the NDC+app-group, the following inclusion criterion also applies:

- In possession of an Android (v.4.4 or higher) or iOS (v.9 or higher) smartphone

Exclusion criteria

- On holidays for more than three weeks during the NDC program
- Planned surgery during the entire study period (including follow-up)
- Pregnant or lactating women

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	13-04-2019
Enrollment:	300
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description

n/a

Ethics review

Positive opinion

Date: 16-04-2019

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48522

Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7678
CCMO	NL68915.028.19
OMON	NL-OMON48522

Study results

Summary results

n/a