Effects of the National Diabetes Challenge with or without a self-management app for personalized lifestyle advice, self-monitoring and behavior change in people with type 2 diabetes

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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 interventions include the National Diabetes Challenge (*NDC-only group*), and a...

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

Summary

ID

NL-OMON48522

Source
ToetsingOnline

Brief title
NDC + eHealth support in T2DM

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
type 2 diabetes mellitus; sugar

Research involving

Human

Sponsors and support

Primary sponsor: TNO
Source(s) of monetary or material Support: TKI Lifesciences & Health en TNO

Intervention

Keyword: behavior change (support), lifestyle intervention, personalized advice, type 2 diabetes mellitus

Outcome measures

Primary outcome

The study parameters mainly consist of questionnaires and anthropometric data.

Clinical chemistry data will be collected subjects in the NDC+app and the

NDC-only group. For participants in the NDC+app group and NDC-only/app-only

group, data will also be collected via the IRIS-app.

* For the NDC-only and NDC+app groups, all measurements, except the use of and

user evaluation of the IRIS-app, will be performed at baseline,

post-intervention (t=20 weeks), and after the follow-up period (t=30 weeks).

* For the NDC-only/app-only group, the measurements will take place at the

Festival day (anthropomorphic data), and in the week afterwards

(questionnaires; t=20 weeks), and after the follow-up period (t=30 weeks).

All of the following questionnaires will be self-administered, and can be

filled in by participants via an online portal at home. Participants will be

asked to fill in the questionnaires at baseline (t=0), post-intervention (t=20

weeks) and follow-up (t=30 weeks).

Quality of life (F1-b)

Quality of life is measured using the WHO (Five) Well-being Index (WHO-5; Hajos et al., 2012). The participants are asked to indicate for five statements which answer best reflects how they felt the past two weeks.

Dietary behavior (F1-d)

Dietary intake will be estimated using the online tool Eetscore (Division of Human Nutrition, Wageningen University and Research, www.eetscore.nl). The Eetscore evaluates to what extent individual food consumption patterns comply with food-based dietary guidelines, i.e. Dutch Healthy Diet index 2015 (Looman et al. unpublished). For different components of the food based dietary guidelines a score will be given ranging from 1 (non-compliant) to 10 (fully compliant). In this study we both the total score and the individual components (e.g. fruits, vegetables, whole grain products, dairy, fish, fats & oils, red meat, etc.) will be used.

Physical activity behavior (F1-b)

The Short QUestionnaire to ASses Health enhancing physical activity (SQUASH) is used to evaluate change in physical activity levels (Wendel-Vos et al., 2003). This same SQUASH is used by the DIALECT cohort that will serve as control group (Jalving et al., 2018).

Secondary outcome

Parameters related to the IRIS-app (NDC+App and NDC-only/app only groups)

Participants in the NDC+app- and the NDC-only/app-only groups will also collect

data via their use of the IRIS-app. During the *onboarding* (first use of the app), data will be entered by the participant on their demography (age, gender, length, weight), their health status (HbA1c, glucose, cholesterol, blood pressure) and medication use. Also, data are collected on dietary intake, personal goals, self-efficacy, motivation, and mood.
Finally, compliance with the app will be assessed by registering the use of the app (number of data-points, duration of use, response to notifications, etc.), as well as via a self-evaluation questionnaire (see below).

Clinical parameters

As a measure of T2DM related health status, HbA1c, fasting glucose, c-peptide, cholesterol (total, HDL and LDL) and triglycerides will be measured from venous blood samples at baseline, (t=0), post-intervention (t=20 weeks) and follow-up (t=30 weeks) for participants in the NDC-only and NDC+app group.
Changes in these parameters over time, as well as differences between the two study groups and control will be assessed.

Anthropometric measurements

For participants in the NDC+app and NDC-only group length, body weight and waist and hip circumference will be measured by the GP or GP*s assistant at baseline, (t=0). Body weight and waist & hip circumference will be repeated post-intervention (t=20 weeks) and after follow-up (t=30 weeks). BMI will be calculated from length and body weight.

Subjects in the NDC-only/app-only group will undergo anthropometric

measurements during the Festival Day (t=20 weeks) by a TNO researcher, and after follow up (t=30 weeks) by a GP or GP*s assistant.
Changes in these parameters over time, as well as differences between the study groups and control will be assessed.

Questionnaires

All of the following questionnaires will be self-administered, and can be filled in by participants via an online portal at home. Participants in the NDC+app and NDC-only will be asked to fill in these questionnaires at baseline (t=0), post-intervention (t=20 weeks) and follow-up (t=30 weeks), unless indicated otherwise.
Subjects in the NDC-only/app-only group will be asked to fill in these questionnaires after the NDC challenge (t=20 weeks) and after the follow-up period (t=30 weeks), unless indicated otherwise.

Diabetes self-management (F1-b)

Level of self-management is measured with the Diabetes Self-Management Questionnaire (DSMQ; Schmitt et al., 2013).

Psychosocial factors (F1-b)

Self-efficacy is measured with the Diabetes Mellitus Self-Efficacy Scale (DMSES; Van der Bijl, Van Poelgeest-Eeltink, & Shortbridge-Baggett, 1999), which measures the efficacy expectations someone has for performing several T2DM self-management activities.

Perceived social support is measured using the Dutch version of the Multidimensional Scale of Perceived Social Support (MSPSS; Zimet, Dahlem, Zimet, & Farley, 1988).

Community factors (F1-b)

The following parameters will be examined to assess changes in NDC membership outcomes, and to also understand variety between NDC groups.

Collective efficacy is a 5-item scale based on an adapted version of Lent, Schmidt, & Schmidt (2006).

Social capital is measured based on a shortened version of the validated question-naire of Mackenbach et al., (2016) and measures social network, social cohesion, sense of belonging. Consists of 8 items.

Sense of community is a 6-item scale based on Ladier, Reid & Reid (2018), and consists of subscales: consists of needs fulfillment (NF), group membership (MB), influence (IN), and emotional connection (EC)

Study participation and compliance (F1-c)

At the end of the intervention, the experiences and compliance of the subject with both the NDC-program and the IRIS-app (if applicable) will be assessed via an evaluation questionnaire. Questions related to compliance with the NDC-program will include the number of times a subject participated in the weekly walks, how large the walking group was, whom supervised the walks mostly, etc.

Compliance and experiences with the app will be assessed via questions like

clarity of the app, ease of use, self-perceived compliance with goals, etc.

Study description

Background summary

There is a worldwide increase in the number of people with diabetes mellitus (DM). In the Netherlands alone, over 1.2 million people have been diagnosed with DM, and yearly 60.500 new cases are discovered. 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 behavior change can increase physical activity of people with T2DM. Effective elements of such interventions where a.o. setting realistic goals, performing the intervention in a group, monitoring own behavior, graded exercise and social support . Such interventions are not only effective in achieving behavior change, but also in maintaining health behavior.
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, and that such community-based approaches led to improved quality of life and somatic health. During the yearly 20-week NDC intervention program, participants with and without T2DM weekly walk together in groups supervised by a health care professional. In 2018, the NDC program ran in 204 locations with over 4.000 participants, of whom roughly 65% had diabetes. Despite this success, there is still insufficient knowledge about the effective mechanisms of the NDC. Potentially, the NDC can be seen as a form of civil societal activity, which recognizes the capacity of communities and self-organizing strengths. Additionally, it is necessary to understand how the NDC can respond better to existing motivations and barriers to adapting a healthier lifestyle for people with T2DM, including those who were/are not accustomed to moving sufficiently. The focus should be on the individual as a source of information, in order to provide personalized lifestyle advice.
Moreover, 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 and even remission of T2DM. Combined dietary and physical activity advice with behavior change support fitting the needs of an individual can be used to further promote self-management and health status of people with T2D. eHealth tools can contribute to increasing skills and knowledge related to self-management of health problems. TNO developed such an eHealth application focused on lifestyle, the so-called *IRIS-app*. The application contains a self-learning computational model that is able to optimize personalized advices trained by users input data. This app empowers persons with T2DM self-management. The app starts with onboarding of new community participants to get to know their biology and lifestyle. Users

will get control over their own personal health data, which can contribute to better knowledge and understanding of their own health status and lifestyle. Based on the onboarding data, personalized lifestyle interventions are offered to promote health status. Personal goal-setting and self-monitoring are used to achieve behavior change. Finally, the app offers tools and support in maintaining behavior change via interventions focusing amongst others on self-efficacy, goal-setting, motivation and relapse prevention detection.
This year, we aim to investigate the effects of a combined lifestyle intervention on behavior, quality of life and health of people with T2DM, by adding the TNO lifestyle app (IRIS-app) to the NDC program.

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 interventions include the National Diabetes Challenge (*NDC-only group*), and a combined lifestyle intervention, namely the NDC with addition of a self-management application for personalized lifestyle advice, self-monitoring and behaviour change (*NDC+app group* and *NDC-only/app-only group*).
The distinction between the latter two groups, *NDC+app group* and *NDC-only/app-only group* is defined by the starting moment of app usage. In the NDC+app group participants start using the app at the start of the NDC-program, while in the NDC-only/app-only group participants start using the app only after the NDC-program has ended.

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? between the three study groups (NDC-only, NDC+app, NDC-only/app-only)?
* 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 and NDC-only/app-only group 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?
* Is there a difference in compliance between abovementioned groups, i.e. does

app use during the NDC improve compliance as compared to app use only after the NDC has ended?
* 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) and/or preventing relapse into unhealthy habits (i.e. lower physical activity and more unhealthy dietary choices) at 10-week follow-up?

Study design

This study will be designed as a three-group intervention trial.
The interventions in this study consist of the 20-weeks National Diabetes Challenge program (NDC-program) and the IRIS-app, a self-management app for people with T2DM focused on lifestyle behaviour change. The NDC program is a community-based intervention aimed at participants with (type 2)- diabetes who walk together weekly in groups supervised by a health care professional. The NDC is organized mainly through health care centers and general practices that organize and supervise the weekly walks and that recruit participants for the program. This study will make use of the existing infrastructure of the NDC, by including a selection of the NDC locations in the study (in consultation with the location coordinators).

All 200 (T2DM) subjects included in the intervention will follow the NDC-program. Part of these subjects (n=75) will - on top of, and during the NDC-program - get access to an eHealth application for self-management and lifestyle behaviour change, the IRIS-app (*NDC+app-group*), while the other group (n=50) does not (*NDC-only-group*). A third group (n=75) will be enrolled in the study after the NDC-program has ended, and get access to the application after finishing the NDC program (*NDC-only/app-only group*). The IRIS-app contains functionalities for data ownership, personalized lifestyle advice, goal-setting, monitoring and feedback, and behavioural change support.

All participants will fill out questionnaires and undergo anthropometric measurements (standard measurements).
In participants in the NDC-only group and the NDC+app-group clinical parameters will be measured via venous blood sampling at local medical diagnostic centres (MDC). Due to logistic difficulties of offering blood collection after the NDC-program has ended (subjects are not recruited via NDC locations, so NDC locations cannot facilitate this), clinical parameters will not be measured in the NDC-only/app-only group.

After the NDC-program has ended (September 2019), the subjects assigned to the NDC+app-group will continue to use the eHealth app for 10 more weeks to assess the added value of the app for maintenance of behaviour change. The NDC-only-group will not have any intervention during these 10 weeks of follow-up. The NDC-only/app-only group will be enrolled in the study at the end of the NDC-program and start using the application from this time onwards

during the 10 weeks follow-up period. This group will consist of participants of the NDC that did not use the IRIS app during the NDC challenge. The results of this group will be used to assess the added value of the app for maintenance of behaviour change, independent of active NDC participation.
This group will be compared to the NDC-only group (to assess the beneficial effects on an application during follow-up), as well as the NDC+app group (to assess whether the usage period of the application affects compliance and maintenance of behaviour change).

Cohort data from a comparable population with T2DM will be used as a control group. For this purpose, data from the "DIAbetes and LifEstyle Cohort Twente" (DIALECT) will be used, which is a T2DM cohort running from the ZGT (hospital group Twente) in the Netherlands (Gant et al., 2017; Jalving et al., 2018). From this cohort lifestyle behaviour (physical activity via SQUASH questionnaire and dietary intake via FFQ), clinical parameters (HbA1c, glucose, lipid profile), anthropometry (weight, waist circumference, BMI) and demographic data (age, gender, SES, etc.) can be extracted. These cohort data reflect care as usual in people with T2DM. As for this cohort no quality of life data are available, the participating health care centres (NDC locations) will be asked to distribute the link to an online quality of life questionnaire to their patients that are not participating in the NDC program. These data can then serve as a control situation for the psychosocial parameters.

Intervention

Subjects in the study groups (NDC-only, NDC+app, and NDC-only/app-only) 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.

The NDC+app and the NDC-only/app-only group will, on top off the weekly walks organized by the NDC, get access to the IRIS-app. This is a Smartphone application developed by TNO for personalized systems-based lifestyle support for people with type 2 diabetes.
The app includes functionality to:
* Assess current health status, using the main T2D-related health markers (glucose, in-sulin, body weight, BMI) as well as medication use;
* Generate a personalized recommendation for lifestyle (e.g. a dietary pattern). Sub-jects may be recommended one or more of these dietary pattern based on their T2DM pathophysiology and medication use. If more than one dietary pattern is rec-ommended, the subject can choose which diet fits their preferences;
* 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
* Monitor the achievements in lifestyle change;
* Notifications for reminding the participants of entering their data (reaching goals, moti-vation, self-efficacy, mood);
* Provide support via evidence-based behaviour change interventions, including motiva-tion enhancement, planning interventions and relapse prevention detection.
Subjects in the NDC+app group are asked to use this smartphone application during the Na-tional Diabetes Challenge program, as well as during the follow-up period (October -December 2019).
Subjects in the NDC-only/app-only group will be asked to start using this smartphone applica-tion at the end of the NDC-program, thus during the follow-up period only (October-December 2019).
Use of the application will cost participants maximum a few minutes per day, mostly for self-monitoring their personal goals.

Study burden and risks

In this study, people with type 2 diabetes are included. All of the subjects will participate in the NDC-program, which means they will be physically active. Half of the study population will also get lifestyle advice via an app. By changing their lifestyle, people with type 2 diabetes could improve their diabetes-related health markers, including glucose and insulin. If changes in these parameters occur, changes in medication might also be necessary. 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. Additionally, the intensity of the lifestyle interventions is not very high, due to the focus on long-term behaviour change and empowerment, and thus no very extreme or sudden changes in biomarkers are expected.
For subjects that undergo blood withdrawal, there is a small risk for bruises.

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 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 and the NDC-only/app-only group, the following inclusion criterion also applies:
* In possession of an Android (v.4.4 or higher) or iOS (v.9 or higher) smartphone
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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:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2019
Enrollment:	200
Type:	Anticipated

Ethics review

Approved WMO Date:	12-04-2019
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	22-05-2019
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	11-09-2019
Application type:	Amendment
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

ID: 22632
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL68915.028.19
OMON	NL-OMON22632