Diabetes and WELLbeing the Netherlands 2

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A relationship can be identified between HbA1c levels and self-management and quality of life. It appears better self-management skills result in a larger improvement of HbA1c levels, and the other way around, getting control over HbA1c levels is a...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Interventional

Summary

ID

NL-OMON50665

Source
ToetsingOnline

Brief title
DWELL-NL 2

Condition

- Diabetic complications

Synonym
diabetes mellitus, Type 2 diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Kinetic Analysis
Source(s) of monetary or material Support: Interreg 2 Zeeën en Kinetic Analysis

Intervention

Keyword: Activity monitoring, Diabetes, Motivational Interviewing, Quality of Life

Outcome measures

Primary outcome

The aim of this study is to decrease HbA1c levels through the use of motivational interviewing and a combined lifestyle intervention. Therefore, the change in HbA1c levels will be the main study parameter.

Secondary outcome

The effect of the interventions on physical activity will be investigated using the International Physical Activity Questionnaire (IPAQ).

The effect of the interventions on eating behaviour will be investigated using the Dutch version of the Dutch Eating Behaviour Questionnaire (NVE).

The effect of the interventions on health status will be investigated using the Short Form Health Survey (SF-12).

The effect of the interventions on quality of life will be investigated using the European Quality of Life (EQ5D) questionnaire.

The effect of the interventions on well-being will be investigated using the abbreviated version of the Illness Perception Questionnaire (IPQ-BR).

The effect of the interventions on psychosocial self-efficacy will be investigated using the Diabetes Empowerment Scale-Short Form (DES-SF)

Study description

Background summary

Diabetes is a long term non-communicable disease with high costs to patients, health services and society, and for which there is currently no standardised approach to self-management. Diabetes is an increasing problem, even more so it is starting to become an worldwide epidemic. This emphasizes that type 2 diabetes is an ever increasing problem, and this has led to a cross-border initiative (United Kingdom, Belgium, France and the Netherlands) under the name of the DWELL project (Diabetes WELLbeing).
An overall aim has been set, that every country will use to set up their own mono-centre intervention, of which all data will be combined when the study is completed. Data analyses will then be performed on the data derived from each country.
This research protocol will therefore be restricted to the Amphia hospital, the centre of interest for the Netherlands.

Healthy diet, regular physical activity, and maintaining a normal body weight are ways to prevent or delay the onset of diabetes type 2. Based on this fact, it seems necessary to evaluate physical (in)activity in diabetes patients. Physical inactivity has been identified as the fourth leading risk factor for global mortality, meaning extreme sedentary behaviour can actually be deadly. This emphasizes the importance of physical activity in the entire health care system. In the DWELL project physical activity levels will be identified using the International Physical Activity Questionnaire (IPAQ). This is questionnaire designed to investigate people*s activity levels.

Motivational interviewing is a directive, patient-centred form of counselling designed to evoke changes in behaviour by assisting people to explore, clarify and resolve ambivalence regarding behaviour change. Using motivational interviewing the advantages and disadvantages of the current and intended behaviour can be identified, thereby motivating the patient to take control of the situation and identify barriers that keep the patient from changing his behaviour. From this point onwards, the patient will be assisted in setting realistic goals regarding behaviour change, which can be used to increase intrinsic-motivation, which will ultimately positively affect lifestyle changes long term. Previous studies have shown controverting results towards the effect of motivational interviewing, and it appears the frequency, intensity and timing of the sessions are of great importance for its effect.

In conclusion, we believe it is in the best interest of diabetes patients worldwide to create a holistic innovative treatment programme, which involves a combination of lifestyle interventions such as monitoring physical activity and offering motivational interviewing, to create the most personal and specified support for patients, that could increase the success-rate of self-management.

Study objective

A relationship can be identified between HbA1c levels and self-management and quality of life. It appears better self-management skills result in a larger

improvement of HbA1c levels, and the other way around, getting control over HbA1c levels is a necessity to be able to effectively manage and control diabetes. Therefore, HbA1c levels could be used as an objective parameter to identify whether physical activity coaching and motivational interviewing leads to increased self-management skills. Furthermore, improved HbA1c levels seem to correlate with an improved quality of life. The main objective of this study is to investigate changes in HbA1c levels of type 2 diabetes patients, as a result of an intervention involving motivational interviewing and a combined lifestyle intervention.

Study design

The study will be set up as a randomized controlled trial, consisting of 3 groups, one control group that will receive standard care and two intervention groups. It has been chosen to make the control group slightly smaller, to be able to receive significant results, but at the same time provide as many participants as possible with the intervention. The participants of both intervention groups will be given a personalized combination of lifestyle interventions based on the IPAQ. The participants in one of the intervention groups will receive motivational interviews (for 12 weeks) in addition to the personalized combination of lifestyle interventions. The appointment to each group will be blinded as CASTOR will be used to randomly assign participants to either of the groups. A long-term check-up will be performed after 9- and 15 months, which falls in line with usual care check-ups.

Intervention

Patients in the intervention groups, will be asked to fill in the IPAQ questionnaire, as a means of getting information on physical activity. Participants will be asked to fill out this questionnaire at baseline, after the 12-week intervention, and at 9- and 15-month follow-up. The questionnaires, Short Form Health Survey (SF-12), Nederlandse Vragenlijst voor eetgewoonten (NVE), European Quality of Life (EQ5D) and brief version of the Illness Perception Questionnaire (IPQ-BR), Diabetes Empowerment Scale-Short Form (DES-SF), will be conducted at baseline, at the end of the 12 week intervention and at 9- and 15 months follow-up as well. Blood values are measured as form of standard care, and will be analysed for this study as well.

The motivational interviewing will be used as an extra form of support in the process to decreasing HbA1c in one of the intervention groups. Motivational interviews will be conducted more frequently, namely 2 to 8 times in the 12-week intervention period. The first meeting will take place in the first week, the second meeting will be initiated by the patients themselves. During this meeting it will be estimated how many meetings are desirable based on the individual needs and characteristics of the patient. By complying to the patient*s needs, the motivational interviewing will increase motivation and

coherence to treatment. Its effect will be measured through the change in HbA1c levels.

Patients in the control group will receive the standard diabetes care, and will be asked to complete all questionnaires, IPAQ, SF-12, NVE, EQ5D, IPQ-BR, DES-SF at baseline, after the 12 week intervention period and at 9-, and 15 months follow-up and their bloodwork will be analyzed as well. The quality of care questionnaire will be completed after 12 weeks intervention period.

Study burden and risks

It is the aim of the DWELL project to involve patients in the development of several modules that can be added to the intervention. Building on that, the DWELL project is hoping to get some motivated participants and train them to become patient ambassadors. They will then receive training as well and will become a factor of support for new patients. Since they have been through the process themselves, it is expected that these patient ambassadors have a better understanding of the patients and will be able to provide support from experience and create group relatedness, which can be beneficial for both old and new patients. The old patients will form a beacon of information and support for the new patients, whereas the new patients will provide a constant flow of motivation for the old patients.

All tests will be performed by educated and specifically trained personnel in controlled environments, using standardised protocols that guarantee patient safety. Therefore, it is expected that significant risks will not occur.
In addition, a risk classification has been performed, using the NFU risk classification list and table. Based on these tables, it is safe to conclude that the participants in this study are at no risk.

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

Type 2 diabetes
Over the age of 18
Able to walk independently for 4 meters, walking aids allowed
Cognitively able to follow instructions and able to understand the Dutch or English questionnaires.
Able to get up from a chair without assistence

Exclusion criteria

Suffering from psychiatric problems, or have memory problems
Below the age of 18
Not able to walk independently for 4 meters
Not able to get up form a chair without assistence

Study design

Design

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

Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-11-2018
Enrollment:	270
Type:	Actual

Ethics review

Approved WMO Date:	23-08-2017
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	11-10-2017
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	15-03-2018
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	26-03-2018
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	31-10-2018
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	29-04-2020
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: 23619
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL62544.028.17
OMON	NL-OMON23619