Diabetes and WELLbeing

Published: 05-04-2017
Last updated: 12-04-2024

Decrease disease-burden in the diabetes type 2 population, by improving quality of life, physical activity levels, physical performance and the overall quality of diabetes care. Thereby empowering the diabetes population to better self-manage their...

Ethical review	Not approved
Status	Will not start
Health condition type	Diabetic complications
Study type	Interventional

Summary

ID

NL-OMON45399

Source
ToetsingOnline

Brief title
DWELL-NL

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 Zeeen en Kinetic Analysis

Intervention

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

Outcome measures

Primary outcome

Decrease disease burden by increasing physical activity levels, increasing quality of life and improve the overall quality of diabetes care. This is directly translated into the use of move monitors and motivational interviewing as forms of intervention. The effect of the move monitor and motivational interviewing will be the main study parameters.

Secondary outcome

The relationship between physical performance and disease-burden will be investigated using the iSPPB (instrumented Short Physical Performance Battery), which consists of: a balance test, the sit-to-stand test and a 4-metre-walk-test.

The effect of the interventions on physical activity will be investigated using the IPAQ and the move monitor.

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). The overall aim of DWELL is to enhance self-management of type 2 diabetes through a co-produced 12 week educational programme, and improve health and wellbeing measures. The co-production entails using input from current patients and health care staff

in order to create a programme that will appeal to all diabetics. In addition a specific staff training programme will be produced, to ensure all staff can be of the best service to participants, and, even more importantly, staff will be able to prolong the DWELL education programme after the project ends. The ultimate goal of the DWELL project is to create a programme with elements that apply to everyone, which will allow participants to pick the elements that best suit their needs, and will provide a solid support system to ensure the best results for each individual. In addition to a certain set of elements that will be identical in all delivery countries, each country will add additional elements based on their expertise.
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. The importance of improving physical activity and physical performance in diabetes patients is clear, however how this can be accomplished is another story. There are several interventions possible, and multiple interventions have been proven effective in the past, however their effects were only short term. Each country contributing to the DWELL project will find his own way in delivering the intervention. However, what they all have in common is the emphasis on self-management. Patients must be motivated to take matters into their own hands.
Motivational interviewing is a directive, patient-centred form of counselling designed to evoke changes in behaviour by assisting people 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 that have implemented motivational interviewing in the diabetes population have shown some positive results. Given the fact that motivational interviewing increases intrinsic motivation, combined with the successes in previous studies, it is hypothesized that motivational interviewing can have a massive effect on the ability to self-manage diabetes.
In conclusion, we believe it is in the best interest of diabetes patients worldwide to create a new innovative treatment programme, which involves monitoring movement and offering motivational interviewing, to create the most personal and specified support for patients, that should and could massively increase the success-rate of self-management.

Study objective

Decrease disease-burden in the diabetes type 2 population, by improving quality

of life, physical activity levels, physical performance and the overall quality of diabetes care. Thereby empowering the diabetes population to better self-manage their condition, through the use of movement monitors and motivational interviewing.

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 receive a move monitor, which they will wear for a week at baseline and at the end of the 12 week intervention period. A long term check-up will be performed after 6 and 12 months, which falls in line with usual care check-ups, at the one year follow-up point the participants will be asked to wear the move monitor again for a week. The participants in one of the intervention groups will receive motivational interviews (for 12 weeks) in addition to wearing the move monitor, the appointment to each group will be blinded as CASTOR will be used to randomly assign participants to either of the groups.

Intervention

Patients in the intervention groups, will be asked to wear a McRoberts movement monitor for 24 hours on 7 consecutive days. The movement monitor will be worn for a week at baseline and at the end of the 12 week intervention period. To be able to investigate the long term effects, the move monitor will be worn for one week at one year follow-up again. In addition the IPAQ questionnaire will be used, as a simple means of getting additional information on physical activity. Participants will be asked to fill out this questionnaire at baseline, after the 12 week intervention, and at 6 and 12 month follow-up. To gain insight in the physical performance levels, the iSPPB will be conducted at baseline, after the 12 week intervention and at 6-, 9-, and 12 months follow-up. The questionnaires, EQ5D and IPQ-R, will be conducted at baseline, at the end of the 12 week intervention and at 6-, 9- and 12 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 disease burden in one of the intervention groups. Motivational interviews will be conducted more frequently, namely 3 to 12 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 using physical parameters, wellbeing and quality of life (QoL) questionnaires and blood values.

Patients in the control group will receive the standard diabetes care, and will be asked to complete all questionnaires, IPAQ, EQ5D, IPQ-R and the quality of care questionnaire at baseline, after the 12 week intervention period and at 6-, 9-, and 12 months follow-up. They will also be asked to complete the iSPPB at baseline, after the 12 week intervention and at 6-, 9-, and 12 months follow-up, and their bloodwork will be analyzed.

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 is 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, walking aids allowed
Cognitively able to follow instructions and able to understand the Dutch or English questionnaires.

Exclusion criteria

Suffering from psychiatric problems, or have memory problems
Below the age of 18
Not able to walk independently

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:	Will not start
Enrollment:	270
Type:	Anticipated

Ethics review

Not approved

Date:	05-04-2017
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	NL60708.028.17