DWELL, a 12-week self-management support programme to improve blood glucose levels, quality of life and overall wellbeing.

No registrations found.

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

Summary

ID

NL-OMON23619

Source
NTR

Brief title
DWELL-NL 2

Health condition

Type 2 Diabetes Mellitus
MESH terms: Diabetes Mellitus, Adult-Onset; Diabetes Mellitus, Ketosis-Resistant; Diabetes Mellitus, Maturity-Onset; Diabetes Mellitus, Non Insulin Dependent; Diabetes Mellitus, Non-Insulin-Dependent; Diabetes Mellitus, Noninsulin Dependent; Diabetes Mellitus, Noninsulin-Dependent; Diabetes Mellitus, Slow-Onset; Diabetes Mellitus, Stable; Diabetes Mellitus, Type II; MODY; Maturity-Onset Diabetes; Maturity-Onset Diabetes Mellitus; NIDDM; Noninsulin-Dependent Diabetes Mellitus; Type 2 Diabetes; Type 2 Diabetes Mellitus

Keywords: Diabetes; Quality of Life; Motivational Interviewing; Activity Tracking

Sponsors and support

Primary sponsor: Maarten Gijssel, Kinetic Analysis
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Source(s) of monetary or material Support: 60% Interreg 2 Seas

Intervention

Outcome measures

Primary outcome

HbA1c: Blood glucose levels over the past 3 months

Time frame: Baseline, 3, 6, 9, 12 month follow-up.

Secondary outcome

- Physical activity: type; frequency; duration; intensity; (International Physical Activity Questionnaire) score

- Physical performance: SPPB (Short Physical Performance Battery) score

- Eating behaviour: NVE (Dutch version of the Dutch Eating Behaviour Questionnaire) score
- Health Status: SF-12 (Short Form Health Survey) score

- Quality of life: EQ5D (European Quality of Life questionnaire) score

- Wellbeing: IPQ-BR (abbreviated version of the Illness Perception Questionnaire) score

- Systolic blood pressure

- Diastolic blood pressure

- Blood lipids: HDL/LDL/Cholesterol

- Bodyweight

- Height

- BMI

- Year of birth

- Gender

- SIMMS level

- Medication: Amount, type and dosage

Study description

Background summary

The Diabetes and Wellbeing project is an international initiative to assist diabetics in dealing with their disease in daily life. The DWELL (Diabetes and WELLbeing) project is a cross-border collaboration between 8 parties in the United Kingdom, Belgium, the Netherlands and France. Kinetic Analysis will lead the project in the Netherlands and the project will be implemented in collaboration with the Amphia Hospital, in Breda.

People with diabetes benefit from a healthier lifestyle, including an increase in physical activity. However, it appears to be difficult to actually engage in physical activity, and remain active. The aim of this study is to stimulate diabetics to keep making healthy choices and reach personally set goals. By doing so, the project strives to enhance physical health and quality of life in the diabetes population. Positive health is an important pillar within the DWELL project.

The project takes an individual holistic approach, with one-on-one conversations at the base. The goal is to motivate people to change their lifestyle on the longer term, instead of focussing on treating their current (medical) condition, which often seems to be the standard form of practice.

As described before, the project will be executed in collaboration with the Amphia hospital in Breda. This is where the diabetes patients, currently treated in the clinic at Amphia, will be invited to partake in the DWELL project. These patients will partake in a 12 week programme. In addition they will be given access to an additional pallet of ‘pick & mix’ options in the region, that will assist them in making healthier lifestyle choices. By adding the ‘pick & mix’ pallet DWELL focusses on a personalised approach, to enable behavioural changes in each participant. All participants will be followed and monitored by the Amphia hospital.
A pallet of available activities, aimed at promoting physical activity, healthier nutrition and lifestyle changes will be made available to those participating in the programme. These activities will be gathered on an online platform.
After 12 weeks, blood glucose levels will be measured and analysed, to determine the impact of the 12 week programme. It is expected that the blood glucose levels will improve. Blood glucose levels are an important measure, since they can provide an indication to which extend the participants have control over their diabetes. Due to the 12 week programme, the personalised approach and specific and individual advise, it is expected the participants will have improved their self-management skills, thereby improving control over their diabetes.

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 wearing a move monitor and motivational interviewing.

Study design

Baseline, 3 mo follow-up, 6 mo follow-up; 9 mo follow-up; 1 year follow-up

Intervention

- McRoberts Move Monitor: personalised physical activity advice based on the output of the McRoberts Move Monitor

- Motivational Interviews: a patient-centred, behaviour-changing strategy to be used to emphasize the importance of behavioural changes to increase quality of life and set personalised goals

Contacts

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Eligibility criteria

Inclusion criteria

o Type 2 diabetes

o Over the age of 18

o Able to walk independently for 4 meters, walking aids allowed

o Cognitively able to follow instructions and able to understand the Dutch or English questionnaires.

o Able to get up from a chair without assistance

Exclusion criteria

o Suffering from psychiatric problems, or have memory problems

o Below the age of 18

o Not able to walk independently for 4 meters

o Not able to get up form a chair without assistance

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2018
Enrollment:	270
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-11-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50665
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6681
NTR-old	NTR6851
CCMO	NL62544.028.17
OMON	NL-OMON50665

Study results

Summary results
Not applicable yet