Monitoring of package 1 and 2 of the Beweegkuur for overweight and obese people

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Diabetic complications
Study type	Observational invasive

Summary

ID

NL-OMON36486

Source
ToetsingOnline

Brief title
Monitoring Beweegkuur package 1 and 2

Condition

- Diabetic complications
- Lifestyle issues

Synonym
overweight; physical inactivity

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: health outcome, life style intervention, physical activity, process evaluation

Outcome measures

Primary outcome

The primary study outcome indicators are:

- dietary behavior and physical activity level, both measured by self reportage through a short version of the Vet-lijst and the International Physical Activity Questionnaire (IPAQ)

- participation, attrition and compliance, measured with the digital registration file of the LSA. To yield a more detailed view on compliance, it will additionally be measured with a number of questions in the proces evaluation questionnaire. The researchers will visit teh articiapting practices on a regular basis to observe helath care professionals in their compliance to the protocol.

Secondary outcome

Secundary study outcome indicators are:

- Motivation to maintain a healthier dietary behavior and a higher level of of physical activity

- Participants' experiences with the Beweegkuur

- Quality of life (QoL)

- Physical fitness

- Health risk related factors:

o Antropometry: physical height, body weight, fat percentage, waist

circumference

o Bloodvalues: bloodpressure, HbA1c

Motivation is measured with a set of validated questionnaires. Experiences will be measured with an adjusted version of the questionnaire that has been used in the pilotstudy of the Beweegkuur. QoL i smeasured with the Euroqol 6d. These questionnaires wil be presented to the participants together with the previously mentioned questionnaires.
Physical fitness of package 1 and 2 participans is assessed by the physical therapist with the Astrand test. This is a submaximal aerobic capacity test that belongs to the routine protocol of the Beweegkuur. If necessary (suspicion for cardiac diseaese), the participant will be referred to the GP.
The participant will only be included after permission of the GP.
Measurements of health risk related factors belong to the routine protocol of the Beweegkuur. They are performed by the LSA. Test results are recorded in the digital registration file.

Study description

Background summary

The BeweegKuur has been developed by NISB (Dutch Institute for Sports and Physical Activity) to help people with an increased, lifestyle related health risk to adapt a healthier lifestyle. Within the BeweegKuur three lifestyle intervention programs exist that differ with respect to the intensity of the support provided to adapt physical activity. For people with relative minor limitations, package 1 or 2 will be offered. A study by RIVM has proven effectiveness and cost effectiveness of these two packages for the populations that they have been developed for. However, little is known about the extent of

application of the Beweegkuur for the target group of people with overweight and obesity, about the number of participants that follow the complete program and about the extent of compliance to the Beweegkuur protocol by the health care professionals as well as by the participants. It is also unclear if this compliance is related to a shift towards a more favorable motivation to engage in and maintain a healthier dietary behavior (lower energy and fat intake) and a higher level of physical activity, and to a reduction of body weight..

Study objective

The main objectives of this monitoring study are: To asses 1) the number of potential participants, selected by the health care professionals, that are actually included in the Beweegkuur; 2) the number of participants that follow the complete program; 3) the extent to which health care professionals apply the Beweegkuur protocol as intended, and participants comply to the recommendations and advice, and 4) explore the effectiviness of the Beweegkuur concerning a change towards a more favorable motivation for healthier dietary behavior and a higher level of physical activity, towards the actual change in and maintenance of these behaviors.

Study design

The monitoring study is a prospective cohortstudy without control condition. The complete study covers a time episode of 39 months. Measurments wil be performed at baseline (T0: the moment the participant is included in the study), within one week after a participant in package 2 has ended the physiotherapy intevention (T2 - about 12 weeks after T0) at the end of the Beweegkuur (T3: 12 months after T0) and at follow up (T4: 24 months after T0). measuremnts mainly consist of self reportage through questionnaires; monitoring the digital registration file of the LSA and observations on location. In the registration file the LSA records the results of the routine measurements of the Beweegkuur (e.g. physical height, body weight, Body Mass Index; blood sugar, HbA1c; submaximal aerobic capacity test). Participants will be recruited form 29 GP practices who are familiar with a former version of the Beweegkuur for DM2 patients.

Study burden and risks

Measurements will elicit a limited burden to the participant Part of the data gathered for this study are part of the routine Beweegkuur protocol, and will consequently be performed in all Beweegkuur participants at T0 and T3, irrespective of their participation in the study. Extra measurements for the study at T1 and T3 are:
- a short version of the Vet-lijst
- the IPAQ activity quetsionnaire
- the questionnaire for motivational factors

- the Euroqol 6d
- the process-evaluation questionnaire
The estimated completion time for the quetionnaires is one hour per measurement moment . No risks are associated with these measurements. Participants in the study have no benefits compared to those who follow the Beweegkuur without participation in the study. The extra consultation of the LSA after 24 months can be seen as a smal burden for the patient, since only the regular measurements are executed.

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

The inclusioncriteria for participation in the distinct packages of the Beweegkuur match the categorization of the Partnership Overgewicht Nederland (PON) and the Nederlands

Huisartsen Genootschap (NHG).
Package 1:
• BMI 25-30 and a too large waist circumference (>= 88 cm for women; >= 102 cm for men)
• BMI 30-35 and a normal or too large waist circumference
Package 2:
• BMI 25-35 with an enhanced risk for DM2 or Cardio-Vascular Diseases (CVD)
Package 3:
• BMI 25-35 with comorbidity such as sleepapneu, arthrosis deformans, DM and/or CVD
• BMI 35-40 and a normal or too large waist circumference and an enhanced risk for DM2 or (CVD);For the monitoring study only participants of package 1 and 2 are included;Additional inclusion criteria, irrespective of the package are:
1. being motivated to change their behavior
2. inactive lifestyle (not meeting the Nederlandse Norm Gezond Bewegen)

Exclusion criteria

Counterindications:
- DM2 with 3 or more complications limiting routine functioning (CVS, nephropathy, retinopathy, neuropathy, diabetic ulceration)
- DM2 with severe polyfarmacy (> 5 therapeutic categories)
- DM2 with hypertension level 3 (RR >180/110 mmHG)
- Severe limitations for physical exercize (< 70% of the expected exercize capacity)
- Limitations for participation in the Beweegkuur, assessed by the GP
- BMI < 25 with DM2
- BMI > 35 with comorbidity

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2010

Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	30-07-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	24-11-2011
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)

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	NL32615.068.10