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Cost-effectiveness of package 3 versus package 2 of the BeweegKuur in the prevention and treatment of overweight

Submission date	Recruitment status	[ ] Prospectively registered
23/12/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/02/2011	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
31/01/2018	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
50-51100-98-001

Study information

Scientific Title
Cost-effectiveness of package 3 (a supervised physical training and nutrition program) versus package 2 of the BeweegKuur a combined lifestyle intervention in the prevention and treatment of overweight

Study objectives
The more structured and more intense supervised intervention offered in package 3 is more effective and cost-effective in assisting people with overweight and obesity to adopt a healthier lifestyle than package 2 of the BeweegKuur.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee of Maastricht University Medical Centre, 09/07/2010, ref: 31990.068.10

Study design
Single-blind multicentre cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Overweight and obesity

Interventions
Experimental program is package 3 of the BeweegKuur consisting of a physical activity and dietary program. Control program is package 2 of the BeweegKuur consisting of a physical activity and dietary program.

The physical activity program takes place in the standard, local activity facilities or (temporarily) with support of a physical therapist. The characteristics of the physical activity program depend on the BeweegKuur package followed. Package 2 and 3 differ in the amount of supervision /support provided by the physical therapist. In package 2 participants receive three sessions in

which barriers for being physically active are identified and participants are supported to cope with these barriers in a plan to become physical active autonomously. The physical therapist will stimulate self-initiated activities and/or visiting local movement facilities. The physical activity program of package 3 starts with intensive support from the physical therapist. Participants will exercise under supervision of the physical therapist for 12 weeks. Goal is outflow to local facilities or independent activities following these 12 weeks, if this goal is not reached, the supervision period can be extended once with 4 weeks.

The dietary program consists of (a combination of) individual tailored advice of a nutritionist and group meetings at the nutritionist with other participants. The dietary advice is based on several Dutch guidelines (dietary guidelines diabetes [NDF, 2006], guidelines good diet [Health Council, 2006], guidlines obesity diagnosis and treatment in adults and children [CBO, 2008]). The content of the dietary advice is independent from the physical activity program.

The duration of the BeweegKuur intervention is one year for both packages. Independent of the package, the participants have five meetings with their Life Style Advisor (LSA).

Intervention Type
Behavioural

Primary outcome measure
Moderate to vigorous physical activity (MVPA) in minutes per week. This is measured by means of:
1. Activity monitor at baseline, and at one year and two years after the start of the intervention
2. Self administered questionnaire International Physical Activity Questionnaire (IPAQ) at baseline, six months, twelve months, 18 months and 24 months

Secondary outcome measures
1. Dietary habits (short version of the ENVET) at baseline, six months, twelve months, 18 months and 24 months
2. Quality of life (EQ6-D), medication, side effects, direct and indirect costs, at baseline and every three months from baseline until 2 years of follow-up
3. Health risk, e.g. waist circumference (cm), body composition (body mass in kg, fat and fat free mass in %), diastolic blood pressure (DPB) (mmHg), systolic blood pressure (SBP) (mmHg), resting heart rate, blood values, i.e. fasting glucose (mmol/L), HbA1c (% or mmol/L), total cholesterol (mmol/L), HDL (mmol/L), triglycerides (mmol/L) and creatinin (micromol/L) and physical fitness (Astrand test, Valk neuropathy test, Timed Up and Go Test) at baseline, at one year and two years after start of the program

Overall study start date
01/08/2010

Completion date
31/07/2013

Eligibility

Key inclusion criteria
1. Adults with a weight-related health risk
2. Have an inactive lifestyle (Dutch norm Healthy Exercise: 30 minutes moderate physical activity for at least 5 days per week)

3. Motivated for behavioral change
4. Willing to participate after having read the informed consent information
5. Body mass index (BMI) between 25 - 30 kg/m2 combined with a large waist circumference (men greater than 102 cm, women greater than 88 cm) with comorbidity (cardiovascular disease and/or diabetes mellitus II, arthrosis and sleep apnoea)
6. BMI between 30 - 35 kg/m2 combined with a normal or large waist circumference with comorbidity
7. BMI between 35 - 40 kg/m2 combined with a normal or large waist circumference with risk factors for cardiovascular disease or diabetes mellitus II and without other comorbidity

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
600

Key exclusion criteria
1. BMI less than 25 kg/m2
2. BMI of 25 - 30 kg/m2 combined with normal waist circumference
3. BMI of 35 - 40 kg/m2 combined with comorbidity (cardiovascular disease and/or diabetes mellitus II, arthrosis and sleep apnoea)
4. BMI of greater than 40 kg/m2
5. Impairments that prevent from participating in the BeweegKuur (according to the GP)

Date of first enrolment
01/08/2010

Date of final enrolment
31/07/2013

Locations

Countries of recruitment
Netherlands

Study participating centre
Maastricht University
Maastricht
Netherlands
6200 MD

Sponsor information

Organisation
The Netherlands Organization for Health Research and Development (ZonMw) (Netherlands)

Sponsor details
Laan van Nieuw Oost Indië 334
PO Box 93245
The Hague
Netherlands
2509 AE

Sponsor type
Research organisation

Website
http://www.zonmw.nl/

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type
Research organisation

Funder Name
ZonMw (ref: 50-51100-98-001)

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Funder Name
Nutrition and Toxicology Research Institute Maastricht (NUTRIM) (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/03/2015		Yes	No
Results article	results	01/12/2016		Yes	No