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A self regulatory weight reduction intervention in diabetes type II patients

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19/12/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/12/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
22/10/2008	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
0451; NTR381

Study information

Scientific Title

Acronym
Leiden Study

Study objectives
Self regulatory weight reduction interventions offer a good environment for overweight diabetic type II patients to lose weight and lower their HbA1c. Based on the literature, the following hypotheses are formulated:
1. Patients who engage in their disease management actively (condition b, c) generate better results concerning losing weight and lowering HbA1c than patients who are not actively engaged in their disease management
2. Patients who have set their own health goal(s) (condition b) achieve health goal(s) more easily and quicker than patients who have not set their own health goal(s)
3. Patients who have made a specific 'action plan' of how to achieve their health goal(s) (condition b) achieve the health goal(s) more easily and quicker than patients who have no action plan
4. Patients who have recognised and discussed the barriers to health goal achievement (condition b) overcome these barriers more easily and quicker than patients who have not recognised and discussed the barriers to health goal achievement
5. Patients who are able to recognise and solve conflict between their health goal(s) (condition b) and other important goals achieve their health goal(s) more easily and quicker than patients who are not able to recognise and solve goal conflict
6. Patients who are able to recognise and solve conflict between their health goal(s) (condition b) and important goals of their partner or important other achieve their health goal(s) more easily and quicker than patients who are not able to recognise and solve conflict between their and their partners' (health) goals
7. Patients who are able to regulate their health goal(s) related emotions (condition b) achieve their health goal(s) more easily and quicker than patients who are not able to regulate their health goal(s) related emotions
8. Patients who are taught maintenance skills (condition b) maintain their healthy behaviour more easily and longer than patients who are not taught maintenance skills
9. Patients who feel supported by the group meetings (condition b) achieve their health goal(s) more easily and quicker than patients who do not feel supported by the group meetings
10. Patients who receive tailored information with regard to disease management (condition b) manage their disease better than patients who do not receive tailored information about disease management

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Randomised active controlled parallel group trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Diabetes mellitus type II (DM type II)

Interventions
The three treatment conditions in this study are:

a. Standard care condition by an internist, including: individualised diet instructions by a dietician, individualised self-injection and blood glucose level monitoring instructions by a diabetic-nurse, and advice on exercise training by internists

b. Condition a + goal setting + psychological treatment by means of a tailored self-help manual and group meetings. In a motivational interview at baseline (1 hour) patients are motivated for weight management, through an active lifestyle and modified eating patterns, and are motivated to set a personal relevant health and social goal which relates to weight loss. Trained health psychologists will help patients set these goals by means of a goal setting procedure similar to those developed by Williams and colleagues. Most relevant health goals related to weight reduction are eating healthily and exercise.

One week after the motivational interview, patients will be sent a brief summary of their stated goals. Patients are given the opportunity to specify or modify the goals that were formulated in the interview. Patients will be asked to bring the summary of their goals to the first group meeting two weeks after the motivational interview.

The group meetings (10 patients per group) involve self regulatory strategies directed at achieving the personal relevant health and social goal related to weight loss. In group meetings and home assignments self regulatory processes are discussed and applied to personal relevant barriers in the achievement of the weight loss goals. The summary of the patients' formulated goals in the motivational interview will serve as a basis for the group meetings. During the group meetings (and the home assignments) this summary will be worked out to a goal scheme in which processes and steps are formulated that facilitate achievement of patients' health and social goal.

In the first part of the group meetings there is time to discuss patients' experiences and feelings with regard to goal progress and barriers to goal progress. This part will also facilitate patients' skills to ensure social support from the environment (partner, buddy system, family members and friends).

All group sessions are offered by a psychologist. Group sessions will be offered during the daytime as well as during the evenings. Psychologists will provide an additional telephone structure after the first two months of the intervention (1 x 10 minute phone call every month).

A diabetes manual, based on principles for self regulatory interventions will help the diabetes patients regulate their behaviour at home and continue the programme in the absence of a group meeting. The manual consists of an information part with information regarding exercise, healthy eating, stress induced eating, medication and self-testing and an assignment part in which patients are challenged and motivated to apply self regulatory principles of behaviour change to themselves.

The information part will contain general diabetes and weight relevant information partly derived from the Diabetes Manual (UK; see condition c). The assignment part will contain self-regulation based exercises which are tailored to the patients' self-chosen health and personal goals. Exercises will help patients move toward goal achievement and motivate them for

behaviour change on a weekly basis. The manuals will be piloted on readability, lay-out, and understanding.

c. (Active control group) Condition a + Diabetes Manual Programme. The Diabetes Manual consists of a 230-page booklet to be used in a twelve week behavioural programme. The manual which is based on the validated Heart Manual has been developed and piloted in the UK. The English version of the Diabetes Manual has been translated into Dutch and will be piloted on readability, lay-out, understanding and cultural influences. The twelve week programme in the booklet is divided into 6 stages which include topics such as exercise initiation and maintenance, healthy eating and coping with stress. Aim to the twelve week programme is to enhance the patients' self-efficacy for engaging in diabetes-related behaviours through mastery experiences, information provision, record keeping, responding to biomedical feedback, goal setting and achievement. An audiotape provides a question and answer session between a general practitioner and a patient and a side for partners of patients. A second tape, to promote relaxation, is included. A diabetes nurse additionally provides a telephone support structure.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. The main (biomedical) outcome measure in this intervention is GlyHb
2. The main behavioural outcome measure in this intervention is weight in kilograms. This will be measured at baseline and throughout the intervention in both the intervention and the standard care groups.
3. Dietary and exercise behaviour will be assessed throughout the intervention by means of a short diary procedure. Patients will be asked to shortly write down their nutrition and exercise behaviour from the past week.
4. Psychological outcome measures refer to various psychological factors that may facilitate or inhibit progress toward the weight reduction goals (see also secondary outcomes)

Key secondary outcome(s))
1. Diabetes Quality of Life Measure (DQOL): Patients' quality of life is measured by the subscale 'impact' (20 items) of the validated 46-item Diabetes Quality of Life Measure (DQOL). The DQOL 'impact' scale measures the impact of diabetes treatment and disease management on daily life on a 5-point Likert scale (never-all the time).
2. Problem Areas in Diabetes (PAID): Psychological distress is measured by the validated 20-item Problems Areas in Diabetes (PAID). The PAID is a brief instrument to assess diabetes-specific distress on a 5-point Likert scale (no problem at alla very serious problem).
3. Diabetes Management Self-Efficacy Scale (DMSES): Diabetes related self-efficacy will be measured by the validated Diabetes Management Self-Efficacy Scale (DMSES). The DMSES contains of 20 items on a 10-point Likert scale (absolutely not ableIm totally able).
4. Positive and Negative Affectivity Scale (PANAS): Patients' negative and positive affect will be measured by the validated 20-item Positive and Negative Affectivity Scale (PANAS). The PANAS consists of 20 mood related words for which patients can indicate on a 5-point scale (not at all applicablevery applicable) to what extent the word is applicable to their mood over the past two weeks.
5. Beck Depression Inventory II (BDI-II): Depressive thoughts and feelings will be measured by the validated 20 item Beck Depression Inventory II (BDI-II). The BDI-II consists of 21 multiple

choice questions of how patients felt within the past two weeks. Nineteen questions have 4 multiple choice options, two questions have 7 multiple choice options.
6. Self-Regulation Skills Scale and GAPI: Patients' self-regulation skills and goal processes will be measured by the 15- and 45-item Self-Regulation Skills Scale and five subscales (26 items) of the validated 71-item Goal and Processes Inventory respectively. Both the self-regulation skills scale and the GAPI consist of statements for which the patients indicate on a 5-point Likert scale to what extent they agree with the statement (totally disagreetotally agree).
7. Biomedical outcome measures are measured in the standard care procedure for all diabetes patients in the Maxima Medical Centre in Eindhoven. These measures include: GlyHb, systolic blood pressure, total cholesterol, triglyceride, LDL cholesterol and HDL cholesterol.

Completion date
01/10/2006

Eligibility

Key inclusion criteria
1. Diabetes type II according to World Health Organization (WHO) classification (1999): fasting blood glucose levels greater than 126 mg/dl (7 mmol/l) or levels greater than 200 mg/dl (11.1 mmol/l) two hours after an oral glucose tolerance test
2. Treated by an internist from the Máxima Medical Centre
3. Body mass index (BMI) 27 - 45 kg/m^2
4. Between 21 and 70 years old
5. Caucasian patients who are able to understand, read and write in Dutch

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Patients with any severe co morbidity (except for cardiovascular diseases) will be excluded
2. Patients who are currently under treatment for a psychological or psychiatric disorder will also be excluded from the study

Date of first enrolment
01/06/2005

Date of final enrolment
01/10/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
University Leiden
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Sponsor information

Organisation
Máxima Medical Center (The Netherlands)

ROR
https://ror.org/02x6rcb77

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration