

University of Groningen

## Self-regulation and weight reduction in patients with type 2 diabetes

Huisman, S.; de Gucht, V.; Maes, S.; Schroevers, M.; Chatrou, M.; Haak, H.

*Published in:*  
Patient Education and Counseling

**IMPORTANT NOTE: You are advised to consult the publisher's version (publisher's PDF) if you wish to cite from it. Please check the document version below.**

*Document Version*  
Publisher's PDF, also known as Version of record

*Publication date:*  
2009

[Link to publication in University of Groningen/UMCG research database](#)

*Citation for published version (APA):*

Huisman, S., de Gucht, V., Maes, S., Schroevers, M., Chatrou, M., & Haak, H. (2009). Self-regulation and weight reduction in patients with type 2 diabetes: A pilot intervention study. *Patient Education and Counseling*, 75(1), 84-90.

### Copyright

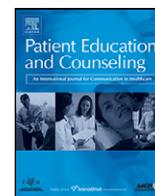
Other than for strictly personal use, it is not permitted to download or to forward/distribute the text or part of it without the consent of the author(s) and/or copyright holder(s), unless the work is under an open content license (like Creative Commons).

The publication may also be distributed here under the terms of Article 25fa of the Dutch Copyright Act, indicated by the "Taverne" license. More information can be found on the University of Groningen website: <https://www.rug.nl/library/open-access/self-archiving-pure/taverne-amendment>.

### Take-down policy

If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

*Downloaded from the University of Groningen/UMCG research database (Pure): <http://www.rug.nl/research/portal>. For technical reasons the number of authors shown on this cover page is limited to 10 maximum.*



## Intervention

## Self-regulation and weight reduction in patients with type 2 diabetes: A pilot intervention study

Sasja Huisman<sup>a,\*</sup>, Véronique de Gucht<sup>a</sup>, Stan Maes<sup>a</sup>, Maya Schroevers<sup>a</sup>, Marlène Chatrou<sup>b</sup>, Harm Haak<sup>b</sup>

<sup>a</sup> Leiden University, The Netherlands

<sup>b</sup> Máxima Medical Centre, Eindhoven, The Netherlands

## ARTICLE INFO

## Article history:

Received 30 November 2007

Received in revised form 5 September 2008

Accepted 7 September 2008

## Keywords:

Diabetes

Weight

Intervention

Self-regulation

## ABSTRACT

**Objective:** To evaluate the efficacy of a self-regulation (SR) weight reduction intervention on weight, body mass index (BMI), glycosylated hemoglobin (HbA1c) (primary outcomes), exercise, nutrition and quality of life (secondary outcomes).

**Methods:** A pilot intervention ( $n = 53$ ) based on SR-principles consisted of a motivational interview, group sessions and a workbook and was evaluated against standard care with ( $n = 38$ ) and without a self-help manual ( $n = 38$ ). Subjects were overweight ( $BMI > 27$ ) patients with type 2 diabetes (52% female) from a Dutch hospital (mean age 58.14, S.D. = 8.86).

**Results:** No differences in the outcomes were found between the intervention and control groups at 3 (T2) or 6 (T3) months. However, results at T2 and T3 revealed that patients with higher SR-skills scores had lower HbA1c levels than patients with lower scores.

**Conclusion:** The SR-intervention did not significantly influence the outcomes. This apparent lack of effect might, however, partly be due to high attrition rates in all treatment groups. SR-skills were positively related to changes in HbA1c-levels.

**Practice implications:** Improving SR-skills of overweight diabetes type 2 patients may improve their glycemic control. Patients who are 'external regulators' may however profit more from directive than from SR-interventions.

© 2008 Elsevier Ireland Ltd. All rights reserved.

### 1. Introduction

Overweight and obesity increase the chances of diabetes complications, especially if body fat is found in the abdominal region [1,2]. Weight reduction can decrease HbA1c-levels of patients with type 2 diabetes and therefore prevent serious complications [3,4]. In the past decade a number of reviews and meta-analyses have shown that weight reduction programs for patients with type 2 diabetes have only small, temporary effects on HbA1c and weight [5–8]. In a review on self-regulation and physical health and illness [9], however, Maes and Karoly state that the efficacy of health interventions increases if interventions make use of self-regulation principles.

Self-regulation can be defined as 'a sequence of actions and/or steering processes intended to attain a personal goal'. Three

phases can be distinguished in this process: a phase of (1) goal selection, (2) active goal pursuit, and (3) goal attainment, maintenance or disengagement [9]. During goal selection, goal ownership plays a key role. Persons who strive for goals which are personally relevant and important are more likely to attain those goals [10–12]. In active goal pursuit, both affective and cognitive processes are involved [9], including feedback mechanisms, feedforward mechanisms and activation of control processes. Feedback mechanisms, such as the self-monitoring of behavior and goal progress have proven to be effective intervention components of self-management programs for chronic patients [13,14]. Feedforward mechanisms, such as self-efficacy have also been frequently shown to relate to behavior change and disease management in various chronic conditions [15–17], including diabetes [18]. Less research has been conducted on the importance of emotion and attention control during goal pursuit.

The importance of facilitating maintenance of change has been frequently demonstrated. Relapse prevention techniques proved, e.g. to be effective for the maintenance of health behavior change regarding exercise [19] and diet [20].

\* Corresponding author at: Leiden University, Section of Clinical and Health Psychology, Wassenaarseweg 52, PO Box 9555, 2300 RB Leiden, The Netherlands. Tel.: +31 71 5273952; fax: +31 71 5274678.

E-mail address: [shuisman@fsw.leidenuniv.nl](mailto:shuisman@fsw.leidenuniv.nl) (S. Huisman).

In summary, self-regulation mechanisms are thought to play a key role in the attainment and maintenance of health goals. For the purpose of interventions, Maes and Karoly [9] formulated a set of guiding self-regulation principles. The present article concerns the evaluation of a pilot weight reduction intervention for patients with type 2 diabetes based on these self-regulation principles. This self-regulation intervention was evaluated at 3 months (T2) and 6 months (T3) after completion of the intervention by comparison with standard care with and without a diabetes self-help manual. Furthermore patients' satisfaction with the self-regulation intervention was assessed. Data were collected between September 2004 and June 2005 in a Dutch general hospital (Máxima Medical Centre in Eindhoven/Veldhoven). The study was approved by the medical ethics committee of this hospital.

The following research questions were formulated:

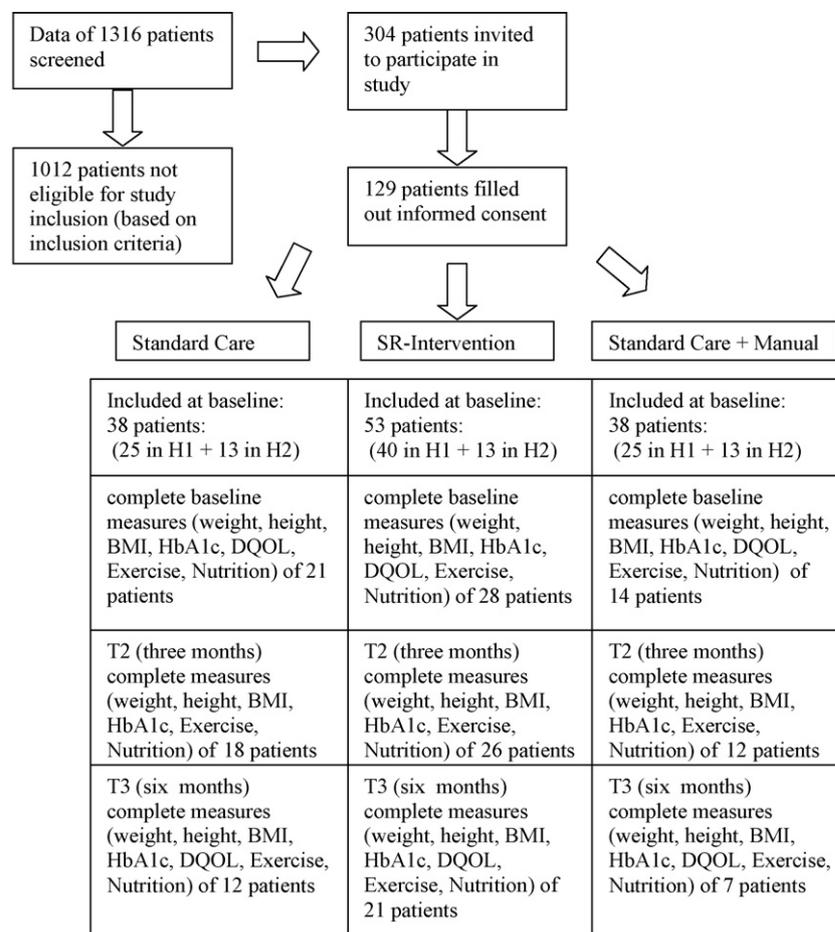
1. Does this self-regulation intervention show a greater reduction in BMI or HbA1c (primary outcomes) than standard care, with or without a diabetes self-help manual?
2. Does the self-regulation intervention influence diabetes quality of life, exercise and nutrition behavior (secondary outcomes)?
3. Are self-regulation skills related to changes in weight, BMI, HbA1c, diabetes quality of life, exercise or nutrition behavior?
4. How do overweight patients with type 2 diabetes evaluate this self-regulation weight reduction intervention?

## 2. Methods

### 2.1. Study sample and randomization procedure

The study sample consisted of 96 overweight patients with type 2 diabetes from a Dutch general hospital (2 locations: H1 and H2). Randomization occurred throughout the process of patient inclusion. Fig. 1 represents a flow chart of the inclusion and allocation of patients to the three treatment groups. Fig. 1 also shows the attrition rates in all treatment groups over time. Unfortunately, not all patients provided complete data at all measurement points. Since measurement of HbA1c, weight and height involved extra hospital visits for patients, most missing data concerned these primary outcomes. Prior to data analyses all data were checked for quality and completeness. Missing values were excluded from all analyses.

Patients were included in the study based on the following criteria: type 2 diabetes according to the WHO classification [21], BMI between 27 and 45, age between 21 and 70, Caucasian, proficient in the Dutch language. Patients with co-morbidity (except for cardiovascular diseases) or under psychological or psychiatric treatment were excluded from the study. Patients were randomly allocated to one of the three treatment conditions.



H = hospital, BMI = Body Mass Index (kg/m<sup>2</sup>), HbA1c = glycosylated hemoglobin in %, DQOL = Diabetes Quality of Life

Fig. 1. Flow chart of study inclusion, randomization and attrition.

## 2.2. Treatment conditions: the SR-intervention

The components of the self-regulation weight reduction intervention were derived from the self-regulation principles as described by Maes and Karoly [9]. The self-regulation intervention and its materials were developed by the department of Health Psychology of Leiden University. Diabetes health care professionals and patients were also actively involved in the development of the intervention materials. The self-regulatory weight reduction intervention consisted of:

- (1) a 1-h individual motivational interview with a health psychologist,
- (2) six 2-h group meetings + two 2-h booster sessions within 1 year, led by a health psychologist,
- (3) use of a workbook with homework assignments related to diabetes and overweight,
- (4) use of a pedometer.

### 2.2.1. Motivational interview

To create weight reduction goals that were of personal importance, all patients in the intervention group were invited for an individual 1-h motivational interview. In this interview important life and health goals were discussed and ranked in importance by the participants. Patients were asked to formulate a realistic and achievable weight reduction goal for the upcoming year.

### 2.2.2. Group meetings

Two weeks after the motivational interview all patients in the self-regulatory intervention group were invited to the first of six (+2 booster sessions) 2-h group meetings. Every group meeting (10–15 patients per group) started with a thematic discussion on weight change and diabetes (e.g. nutrition, exercise, medication and stress). The sometimes abstract and complex self-regulation mechanisms and stages were translated into four concrete and practical steps: (1) Look at your current behavior (goal setting and self-monitoring) (2) Choose a realistic goal (goal setting) and prepare for action (anticipatory coping and planning), (3) Act towards goal achievement (feedback, self-reinforcement, attention and emotion control and facilitate social support), (4) Evaluate results (goal progress) and (re)formulate (new) goals (goal reformulation). During the group meetings and the home work assignments, the personal weight reduction goals resulting from the motivational interview were translated into a goal scheme. This goal scheme involved the application of the four steps to each patient's personal weight reduction goal.

In one of the eight group meetings the patients' partners (or significant others) were invited. The partners were encouraged to support the patients in the following four steps, and the patients were in turn stimulated to ask for social support and to share goal progress.

### 2.2.3. Diabetes self-regulation workbook

A diabetes self-regulation workbook, based on the self-regulation principles formulated by Maes and Karoly [9] was given to the patients to help them to follow the programme in the absence of a group meeting. The workbook consisted of an information section, containing general diabetes and overweight-relevant information partly derived from the 'Diabetes Manual' [22,23], and an assignment section that contained weekly self-regulation tasks tailored to the patients' goals. Prior to the intervention, the self-regulation workbook was pretested in four overweight patients with type 2 diabetes, leading to its present version.

### 2.2.4. Pedometer

All patients in the intervention group were given a pedometer to register their physical exercise (steps taken) on a daily basis. Facilitating and inhibiting factors for exercising were discussed in several group meetings. During every meeting patients were encouraged to increase their amount of physical exercise for next week(s).

The self-regulatory intervention was compared to standard care with and without a diabetes self-help manual. All three groups received the same standard care.

Patients in the *standard care only* condition received standard care for type 2 diabetes patients, consisting of regular consultations by an internist, individualized diet instructions by a dietician, individualized self-injection and blood glucose level monitoring instructions by a diabetes nurse, and advice on exercise training by internists. Internists, diabetes nurses and dieticians focused on the regulation of blood glucose levels and weight from a multi-disciplinary perspective.

Patients who received *standard care and the diabetes self-help manual* also received a Dutch translation of the British 'Diabetes Manual' [22,23], a self-help book for patients with type 2 diabetes. The book contains a 12-week programme to enhance patients' self-efficacy through provision of information and record keeping. Information is provided on exercise, healthy eating, and coping with stress. A diabetes nurse invited patients for a half-hour intake consultation in which the Diabetes Manual was provided, together with additional information about the manual and the research procedure. After this consultation, the diabetes nurse had three follow-up telephone consultations with each patient.

All three groups received the same standard care.

### 2.2.5. Primary outcomes

The following data were collected at baseline, T2 and T3: weight (kg), height (m) and glycosylated hemoglobin (HbA1c in %). Body mass index (BMI; kg/m<sup>2</sup>) was calculated from weight and height data by dividing weight (kg) by the square of height (m). Weight, height and HbA1c were all measured according to standardized procedures in the hospital. The weight of each patient was measured on the same calibrated scale throughout the entire study. Patients' HbA1c-levels were measured by the hospital's laboratory.

### 2.2.6. Secondary outcomes

Diabetes quality of life, exercise and nutrition behavior were the secondary outcomes in this study. Diabetes quality of life was only measured at baseline and at T3. Patients' quality of life was measured by means of the 'impact' subscale (20 items) of the validated 46-item Diabetes Quality of Life Measure [24]. The Diabetes Quality of Life 'impact' scale uses a five-point Likert scale to measure the impact of diabetes treatment and management on daily life (e.g. 'How often does your diabetes interfere with your family life?'), 5 indicating high quality of life.

Nutrition behavior was assessed with a seven-item questionnaire regarding the frequency of six nutrition behaviors within the past week. Fruit consumption was assessed by the item 'On how many days in the past week did you eat (at least) two pieces of fruit?'. Vegetable consumption was assessed by the item 'On how many days in the past week did you eat (at least) 200 grams of vegetables?' Meat consumption was assessed by the item 'On how many days in the past week did you eat red meat?' Consumption of snacks was assessed by the item 'On how many days in the past week did you eat sweets, candy, cookies/cake, chocolate, chips or other salty snacks?' Fat consumption was assessed by the items "On how many days in the past week did you eat 'low fat' products?" and 'On how many days in the past week

did you control your fat consumption?'. Salt consumption was assessed by the item 'On how many days in the past week did you control your consumption of salt?' Each of the items was rated on an eight-point scale (0–7 days). The frequency of exercise within the past week was measured by the item 'On how many days within the past week did you exercise at least 30 minutes?' An eight-point scale was also used for the assessment of this item (0–7 days).

Patients' self-regulation skills were measured by means of the 41-item self-regulation skills battery (SRSB) [25]. The SRSB consists of statements. Patients indicate on a five-point Likert scale to what extent they agree with the statement (totally disagree–totally agree). The internal item consistency (Cronbach's  $\alpha$ ) of the various subscales of the SRSB was reasonable (.61) to very high (.92). The SRSB consists of the following scales: 'goal ownership' (Cronbach's  $\alpha$  = .61, 5 items, e.g. 'This is really my own goal'), 'goal efficacy' (Cronbach's  $\alpha$  = .80, 4 items, e.g. 'I have the ability to reach this goal'), 'goal planning' (Cronbach's  $\alpha$  = .81, 4 items, e.g. 'I have a detailed step-by-step plan to help me attain this goal'), 'help seeking' (Cronbach's  $\alpha$  = .74, 4 items, e.g. 'I like others to support me in attaining this goal'), 'social comparison' (Cronbach's  $\alpha$  = .92, 4 items, e.g. 'I evaluate my progress toward this goal by comparing myself to other people who are most similar to me'), 'self-monitoring' (Cronbach's  $\alpha$  = .74, 6 items, e.g. 'I keep track of my overall progress toward this goal'), 'self-criticism' (Cronbach's  $\alpha$  = .87, 5 items, e.g. 'I routinely criticize myself for unsatisfactory work on this goal'), 'self-reward' (Cronbach's  $\alpha$  = .86, 5 items, e.g. 'I reward myself when I make progress toward this goal'), 'attention control' (Cronbach's  $\alpha$  = .71, 4 items, e.g. 'I do not allow other things to distract me from this goal'), 'self-efficacy enhancement' (Cronbach's  $\alpha$  = .71, 4 items, e.g. 'I like to learn from others, who know how to attain this goal') and finally 'emotion control' (Cronbach's  $\alpha$  = .85, 4 items, e.g. 'I manage to keep my emotions in control if I fail to make progress toward this goal').

A total self-regulation score was calculated by adding the scores of the various subscales of the self-regulation skills battery. Then, this total self-regulation score was dichotomized at the median to form a high and low self-regulation group. High scores indicated better self-regulation skills than low scores.

### 2.3. Process evaluation

Patients' satisfaction with the self-regulation intervention was assessed by means of an anonymous evaluation form that was handed out in the last regular group meeting (see Table 3). Twenty-five of the thirty-four questions were answered by means of a Visual Analogue Scale (VAS).

### 2.4. Statistical analyses

All statistical analyses were performed with SPSS release 13.0. Descriptive analyses (means and frequencies) were performed for age, gender, education and employment and for the process evaluation of the self-regulation intervention. Additional ANCOVA's and  $\chi^2$  were conducted to explore differences on these demographic variables between the study groups. Separate ANCOVA's (with baseline measures as a covariate) were performed to explore differences between the intervention and the two control groups in HbA1c and diabetes quality of life at T2 and T3. Differences between the intervention and control groups in weight and BMI at T2 and T3 were explored with MANCOVA's (with baseline measures as a covariate). MANCOVA's (with baseline measures as a covariate) were also performed for (un)healthy eating and exercise.

Additionally, MANCOVA's (with baseline measures as a covariate) were conducted to explore differences between patients with high or low self-regulation skills in nutrition and exercise measures in the total patient sample. MANCOVA's were also performed to explore differences between patients with high or low self-regulation skills (in the total patient sample) in weight and BMI. ANCOVA's were conducted to explore differences between patients with high or low self-regulation skills (in the total patient sample) in HbA1c and diabetes quality of life. Finally, a post hoc power analysis was conducted to assess the (lack of) statistical power in relation to the small sample size.

## 3. Results

Table 1 represents the results of the descriptive analyses that were conducted for age, gender, education and employment. No differences between groups were found for any of the demographic variables.

The ANCOVA's for HbA1c and diabetes quality of life at baseline revealed no differences between the SR-intervention and other treatment groups. Neither did the MANCOVA's for weight and BMI reveal any differences between these groups. The MAN(C)OVA's for (un)healthy eating and exercise, however, revealed differences in the frequency of self-reported exercise between the two control groups. At baseline, patients in the diabetes manual group were found to report to exercise more frequently than patients in standard care (see Table 2).

Additional (M)ANCOVA's were conducted to explore differences between patients with high or low self-regulation skills in the total patient population. At T2, no differences between patients with many or few self-regulation skills were found for weight, BMI, 'diabetes quality of life', 'exercise', 'healthy eating' or 'unhealthy Eating'. Differences were, however, found for HbA1c. Patients with low self-regulation skills had significantly higher HbA1c levels than patients with high self-regulation skills [ $F(1,36) = 5.38$ ,  $p = .027$ , partial  $\eta^2 = .137$ ].

Similar to results at T2, no differences were found between patients with high or low self-regulation skills for weight, BMI, 'diabetes quality of life', 'exercise', 'healthy eating' or 'unhealthy Eating' at T3. Differences were, however, found for HbA1c. Patients with a lower self-regulation skills score had significantly higher HbA1c levels than patients with a higher self-regulation skills score [ $F(1,36) = 5.28$ ,  $p = .028$ , partial  $\eta^2 = .082$ ].

### 3.1. Process evaluation

At the end of the last group meeting, patients in the intervention group filled out an anonymous evaluation form.

**Table 1**  
Baseline characteristics.

	Standard care		SR-intervention		Standard care + manual	
	N	M (S.D.)	N	M (S.D.)	N	M (S.D.)
Age (years)	35	56.69 (9.88)	43	60.07 (6.76)	23	56.74 (10.30)
Gender	m/f %	16/19 (46/54)	m/f %	23/21 (52/48)	m/f %	10/14 (42/58)
Education	h/l %	28/7 80/20	h/l %	31/12 72/28	h/l %	21/3 87/13
Work	w/u %	17/18 (49/51)	w/u %	14/30 (32/68)	w/u %	9/15 (38/62)

m/f = male/female, h/l = high/low, w/u = work/unemployed, N = number of subjects in analysis, M = mean, S.D. = standard deviation.

**Table 2**  
Baseline characteristics and results at T2 and T3 of primary and secondary outcomes.

Variable	Standard care		SR-intervention		Standard care + manual	
	N	M (S.D.)	N	M (S.D.)	N	M (S.D.)
<i>T1 (Baseline)</i>						
Weight (kg)	32	101.18 (17.05)	37	104.05 (20.17)	23	103.08 (15.55)
BMI	32	35.01 (5.31)	37	35.97 (6.77)	23	35.73 (6.14)
HbA1c	22	7.23 (1.13)	28	7.28 (1.26)	16	7.60 (1.54)
DQOL	33	3.65 (0.38)	37	3.66 (0.41)	18	3.66 (0.49)
Exercise	35	<b>3.63 (2.64)</b>	42	4.38 (2.40)	23	<b>5.30 (2.27)*</b>
Healthy eating	35	4.75 (1.49)	43	4.84 (1.54)	23	5.33 (1.32)
Unhealthy eating	35	3.24 (1.47)	43	3.87 (1.37)	21	3.83 (1.23)
<i>T2 (3 months)</i>						
Weight (kg)	19	97.27 (18.33)	32	101.73 (20.43)	13	100.57 (15.46)
BMI	19	34.60 (5.79)	32	35.51 (6.92)	13	34.42 (6.69)
HbA1c	18	7.45 (1.10)	28	7.41 (1.04)	13	7.45 (1.31)
Exercise	20	7.85 (0.88)	31	5.03 (1.56)	14	5.07 (2.34)
Healthy eating	24	5.41 (1.10)	31	5.09 (1.35)	13	5.42 (1.19)
Unhealthy eating	24	2.32 (1.37)	30	2.48 (1.30)	13	2.96 (1.03)
<i>T3 (6 months)</i>						
Weight (kg)	12	91.50 (12.61)	24	100.73 (17.17)	7	95.11 (13.96)
BMI	12	32.18 (3.15)	24	35.88 (6.77)	7	33.10 (4.81)
HbA1c	15	7.02 (1.12)	21	7.58 (1.32)	9	7.13 (0.67)
DQOL	18	3.76 (0.76)	28	3.52 (0.89)	10	3.61 (0.82)
Exercise	21	5.24 (1.84)	30	4.60 (2.06)	10	6.60 (0.84)
Healthy eating	21	5.90 (0.76)	30	4.72 (1.55)	10	5.98 (0.72)
Unhealthy eating	21	2.19 (1.89)	30	4.72 (1.56)	10	2.55 (1.14)

N = number of subjects in analysis, M = mean, S.D. = standard deviation, BMI = body mass index (kg/m<sup>2</sup>), HbA1c = glycosylated hemoglobin in %, DQOL = diabetes quality of life.

\*  $p < .05$ .

Table 3 summarizes the results of this evaluation. Patients rated the group meetings as very useful (mean = 8.52, S.D. = 1.03), and indicated that the group meetings changed their nutrition and exercise patterns (mean = 7.10, S.D. = 1.85). Most appreciated topics within the group meetings were 'being aware of your lifestyle' (mean = 8.13, S.D. = 1.02), 'diabetes and exercise' (mean = 7.94, S.D. = 1.41), and 'emotions' (mean = 7.59, S.D. = 1.48). The least appreciated topics was 'self-reinforcement' (mean = 6.48, S.D. = 2.06). The motivational interview, held 2 weeks before the first group meeting, was seen as beneficial (mean = 7.77, S.D. = 0.99). However, it perhaps did not adequately address the unrealistic weight loss expectations held by some patients. Unrealistic expectations for weight loss could explain the only moderate appreciation of how the group meetings met patient expectations (mean = 6.41, S.D. = 1.97). Group size, and duration and quality of group meetings were all evaluated as

adequate. However, frequency of group meetings was rated as too low by more than half of the patients (54.8%).

## 4. Discussion and conclusion

### 4.1. Discussion

The present study examined the efficacy of a pilot self-regulation weight reduction intervention for patients with type 2 diabetes. Primary outcomes were weight, BMI and HbA1c and secondary outcomes consisted of diabetes quality of life, exercise and nutrition behavior. No differences between the intervention and the control groups were found on any of the primary or secondary outcomes. Decreases in weight and HbA1c were small, and were similar in all three groups. These findings correspond with those of existing meta-analyses: changes in weight and HbA1c in patients with diabetes are generally small, and are difficult to maintain [5–7]. These findings, however, are in contrast to the promising findings of another self-regulation based intervention [26] for patients with type 2 diabetes that effectively decreased HbA1c-levels in both the short (6 month) and longer (18 month) term.

A total score of self-regulation skills was included as a nesting variable in (M)ANCOVA analyses to explore whether self-regulation skills could explain differences in the primary or secondary outcomes over all groups. Patients with a higher self-regulation skills score had lower HbA1c-levels at both T2 and T3 than patients with a lower self-regulation skills score. As this effect was found for the total patient group, it can thus not be related to the self-regulation intervention.

Although the study results did not show any differences in weight or HbA1c between patients in the intervention and control groups, the process evaluation indicates that patients appreciated the intervention. Patients rated the intervention as 'highly useful' and reported to have changed their exercise and nutrition pattern because of the group meetings. These self-reported changes could

**Table 3**  
Evaluation of group meetings (N = 31).

	Mean	S.D.
How did you appreciate the motivational interview?	7.77	0.99
Did the group meetings meet your expectations?	6.41	1.97
How useful did you find the group meetings?	8.52	1.03
Did the meetings change your nutrition and exercise pattern?	7.10	1.85
How did you appreciate the location?	8.23	0.92
How useful did you find the topic: 'Motivation to lose weight'?	7.42	1.57
How useful did you find the topic: 'Setting realistic goals'?	7.32	1.45
How useful did you find the topic: 'Diabetes and weight gain'?	7.53	1.41
How useful did you find the topic: 'Diabetes and exercise'?	7.94	1.41
How useful did you find was the topic: 'Self-monitoring of eating pattern'?	7.35	1.14
How useful did you find the topic: 'Being aware of your lifestyle'?	8.13	1.02
How useful did you find the topic: 'Self-reinforcement'?	6.48	2.06
How useful did you find the topic: 'Barriers to goal achievement'?	7.16	1.53
How useful did you find the topic: 'Emotions'?	7.59	1.48
How useful did you find the topic: 'Stress and relaxation'?	7.38	1.72

S.D. = standard deviation.

however not be verified by the research team. Future interventions should provide information on the reliability of self-report of behavior change as well as on intervention fidelity of the patients.

The absence of differences in study outcomes between the intervention and control groups can be attributed to various reasons.

First of all, this article only concerns short-term effects. Since many studies point at the fact that self-regulation is especially effective producing sustained behavior changes, a long-term follow-up could show different results [27–29].

Second, previous self-regulation intervention studies [30,31] that effectively changed health behaviors and medical outcomes in patients with type 2 diabetes, focused specifically on patients who had been diagnosed 3–33 months previously. Patients with recent diagnoses are more likely to differ both from a psychological and from a medical perspective from our sample, which consisted of patients diagnosed with type 2 diabetes many years prior to this study.

Third, our self-regulation intervention apparently did not increase self-regulation skills in patients who lacked them, which points at the importance of trait aspects of self-regulation [10,32,33]. We speculate that an important subgroup of patients in our study is strongly externally regulated, and will not easily be transformed into autonomous regulators [34]. It is hypothesized that 'external regulators' may thus not profit from self-regulation interventions, but rather from more directive, externally regulated interventions where the patient has less input in his or her course of treatment.

The fact that half of the patients in our study wanted more group meetings, while the other half did not may further illustrate patients' differing needs and orientation. Screening patients' self-regulation skills prior to an intervention could help to match patients to suitable interventions.

Finally, the limited number of subjects in this pilot study could also have played an important role in the lack of findings between the intervention and control groups with regard to weight or HbA1c. For this pilot intervention study we included 129 patients. Due to attrition, this number dropped to 64 patients at T3 (6 months). Based on the attrition rate in this study (51%), we calculated that a future randomized controlled trial would need to include a total number of 390 patients (130 per condition) to be able to predict significant differences in outcomes after 6 months. Since no specific drop-out data were collected in this study, it is not possible to pinpoint the main reasons for the high attrition rates. However, patients who actively withdrew from the study were asked to list reasons for their withdrawal. Frequently mentioned reasons for withdrawal were: work obligations, family issues and conflicting health problems.

#### 4.2. Conclusions

A pilot self-regulation weight reduction intervention did not appear to reduce weight or HbA1c in overweight patients with type 2 diabetes. No differences between the self-regulation intervention and the two control groups were found on any of the primary (weight, BMI and HbA1c) or secondary (diabetes quality of life, exercise and nutrition) outcomes. The lack of differences in any of the outcomes might have been a result of our small sample size or the high attrition rates in all treatment groups.

In the total patient group, self-regulation skills were associated with significantly lower HbA1c-levels at both T2 and T3. This finding indicates that it might be important to enhance self-regulation skills in patients with low glycemic control. Whether a self-regulation intervention is able to enhance self-regulation skills in this population needs to be further examined.

#### 4.3. Practice implications

Overall, the results suggest that self-regulation skills might be important determinants of glycemic control in patients with type 2 diabetes. Improving patients' self-regulation skills might therefore improve glycemic control in this patient group. However, self-regulation interventions may be more profitable for internally motivated patients than for patients who are more externally motivated. Screening patients for self-regulation skills prior to an intervention might distinguish 'self-regulators' from 'external regulators'. Self-regulation interventions can then be offered to 'self-regulators' and more directive interventions to 'external regulators' in order to increase the effect of weight loss interventions in diabetes patients. Future research should explore this and also examine the long-term effects of a self-regulation intervention including a larger patient sample.

'I confirm all patient/personal identifiers have been removed or disguised so the patient/person(s) described are not identifiable and cannot be identified through the details of the story.'

#### References

- [1] Ohlson LO, Larsson B, Svärdsudd K, Welin L, Eriksson H, Wilhelmsen L, Bjorntorp P, Tibblin G. The influence of body fat distribution on the incidence of diabetes mellitus: 5 years of follow-up of the participants in the study of men born in. *Diabetes* 1985;34:1055–8.
- [2] Després JP, Lemieux I. Abdominal obesity and metabolic syndrome. *Nature* 2006;444:881–7.
- [3] Campbell L, Rössner S. Management of obesity in patients with type 2 diabetes. *Diabetic Med* 2001;18:345–54.
- [4] Hart CL, Hole DJ, Lawlor DA, Davey Smith G. How many cases of type 2 diabetes mellitus are due to being overweight in middle age? Evidence from the Midspan prospective cohort studies using mention of diabetes mellitus on hospital discharge or death records. *Diabetic Med* 2006;24:73–80.
- [5] Brown SA, Upchurch S, Anding R, Winter M, Ramirez G. Promoting weight loss in type II diabetes. *Diabetes Care* 1996;19:613–24.
- [6] Ismail K, Winkley K. Systematic review and meta-analysis of randomized controlled trials of psychological interventions to improve glycaemic control in patients with type 2 diabetes. *Lancet* 2004;363:1589–97.
- [7] Gary TL, Genkinger JM, Gualler E, Peyrot M, Brancati FL. Meta-analysis of randomized educational and behavioral interventions in type 2 diabetes. *Diabetes Educator* 2003;29:488–501.
- [8] Norris SL, Zhang X, Avenell A, Gregg E, Bowman B, Schmid CH, Lau J. Long-term effectiveness of weight-loss interventions in adults with pre-diabetes. A review. *Am J Prev Med* 2004;28:126–39.
- [9] Maes S, Karoly P. Self-regulation assessment and intervention in physical health and illness: a review. *Appl Psychol* 2005;54:267–99.
- [10] Williams GC, Freedman ZR, Deci EL. Supporting autonomy to motivate patients with diabetes for glucose control. *Diabetes Care* 1998;21:1644–51.
- [11] Williams GC, McGregor HA, Zeldman A, Freedman ZR, Deci EL. Testing a self-determination theory process model for promoting glycemic control through diabetes self-management. *Health Psychol* 2004;23:58–66.
- [12] Williams GC, McGregor HA, Sharp D, Levesque C, Kouides RW, Ryan RM, Deci EL. Testing a self-determination theory intervention for motivating tobacco cessation: supporting autonomy and competence in a clinical trial. *Health Psychol* 2006;25:91–101.
- [13] Teach SJ, Crain EF, Quint DM, Hylan ML, Joseph JG. Improved asthma outcomes in a high-morbidity pediatric population – results of an emergency department-based randomized clinical trial. *Arch Pediatr Adol Med* 2006;160:535–41.
- [14] Jansen JP. Self-monitoring of glucose in type 2 diabetes mellitus: a Bayesian meta-analysis of direct and indirect comparisons. *Curr Med Res Opin* 2006;22:671–81.
- [15] Scholz U, Sniehotta FF, Schwarzer R. Predicting physical exercise in cardiac rehabilitation: the role of phase-specific self-efficacy beliefs. *J Sport Exercise Psychol* 2005;27:135–51.
- [16] Sol BGM, van der Graaf Y, van der Bijl JJ, Goessens NGB, Visseren FJL. Self-efficacy in patients with clinical manifestations of vascular diseases. *Patient Educ Couns* 2006;61:443–8.
- [17] Mancuso CA, Sayles W, Robbins L, Phillips EG, Ravenell K, Duffy C, Wenderoth S, Charlson ME. Barriers and facilitators to healthy physical activity in asthma patients. *J Asthma* 2006;43:137–43.
- [18] Ianotti RJ, Schneider S, Nansel TR, Haynie DL. Self-efficacy, outcome expectancies, and diabetes self-management in adolescents with type 1 diabetes. *J Dev Behav Pediatr* 2006;27:98–105.
- [19] Fogelholm M, Kukkonen-Harjula K, Nenonen A, Pasanen MT. Effects of walking training on weight maintenance after a very-low-energy diet in premeno-

- pausal obese women – a randomized controlled trial. *Arch Internal Med* 2000;160:2177–84.
- [20] Dornelas EA, Wylie-Rosett J, Swencionis C. The DIET study: long-term outcomes of a cognitive-behavioral weight-control intervention in independent-living elders. *J Am Dietetic Assoc* 1998;98:1276–81.
- [21] World Health Organization. Obesity and overweight. Factsheet No 311. September 2006, Retrieved September 12, 2007 from <http://www.who.int/mediacentre/factsheets/fs311/en/index.html>.
- [22] Sturt J, Taylor H, Dale J, Doherty A, Taylor L. A psychological approach to providing self-management education for people with type 2 diabetes: the Diabetes Manual. *BMC Family Practice* 2006;7:70.
- [23] Sturt J, Hearnshaw H, Farmer A, Dale J, Eldridge S. The Diabetes Manual trial protocol: a cluster randomized controlled trial of a self-management intervention for type 2 diabetes [ISRCTN06315411]. *BMC Family Practice* 2006;7:45.
- [24] Jacobson AM, DCCT Research Group. Diabetes quality of life measure. Boston, USA: Joslin Diabetes Center; 1987.
- [25] Maes S, Karoly P, de Gucht V, Ruhlman LS, Heiser W. The self regulation skills battery (SRSB). Leiden/Phoenix (AZ): Leiden University/Arizona State University; 2006.
- [26] Lorig K, Ritter PL, Villa F, Piette JD. Spanish Diabetes Self-Management with and without automated telephone reinforcement. *Diabetes Care* 2008;31:408–14.
- [27] Williams GC, Grow VM, Freedman ZR, Ryan RM, Deci EL. Motivational predictors of weight loss and weight-loss maintenance. *J Pers Soc Psychol* 1996;70:115–26.
- [28] Bellg AJ. Maintenance of health behavior change in preventive cardiology. *Behav Modif* 2003;27:103–31.
- [29] Rothman AJ. Toward a theory-based analysis of behavioural maintenance. *Health Psychol* 2000;19:64–9.
- [30] Thoolen B, De Ridder D, Bensing J, Gorter K, Rutten G. Beyond good intentions. The development and evaluation of a proactive self-management course for patients recently diagnosed with type 2 diabetes. *Health Educ Res* 2008;23:53–61.
- [31] Thoolen B, De Ridder D, Bensing J, Maas C, Griffin S, Gorter K, Rutten G. The effectiveness of a self-management intervention in patients with screen-detected type 2 diabetes. *Diabetes Care* 2007;30:2832–7.
- [32] Baumeister RF, Gailliot M, DeWall Cn, Oaten M. Self-regulation and personality: how interventions increase regulatory success, and how depletion moderates the effects of traits on behavior. *J Pers* 2006;74:1773–801.
- [33] Hoyle RH. Personality and self-regulation: trait and information-processing perspectives. *J Pers* 2006;74:1507–25.
- [34] Deci EL, Ryan RM. The 'what' and 'why' of goal pursuits: human need and the self-determination of behavior. *Psychol Inquiry* 2000;11:227–68.