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Finding Balance : self-regulation in overweight patients with type 2 diabetes: from theory to a pilot intervention study

Huisman, S.D.

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Finding Balance

Self-regulation in overweight patients with type 2 diabetes:
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Finding Balance

Self-regulation in overweight patients with type 2 diabetes:
from theory to a pilot intervention study

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Overige leden Dr. V. J. De Gucht
 Prof. dr. W. Heiser
 Prof. dr. A.A. Kaptein
 Prof. dr. H. Pijl
 Prof. dr. F. Snoek

Voor mijn ouders

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1

General Introduction

Diabetes: an Introduction

Diabetes mellitus is the common term for various conditions that are characterized by high blood glucose levels (*hyperglycemia*). The hyperglycemia is caused by malfunctioning of the hormone insulin that is responsible for the transport and storage of glucose (blood sugar) in the body. Although there is only a thin line between the various types of diabetes, in general four types are distinguished: Diabetes Type 1, Diabetes Type 2, Gestational Diabetes and Diabetes secondary to other conditions ¹. Diabetes Type 1 and 2 are the most frequently diagnosed types of diabetes.

Diabetes Type 1 is defined as an auto-immune response which is characterized by a lack of insulin production in the pancreas ²⁻³. This lack of insulin production is caused by an autoimmune-mediated destruction of the insulin producing cells (β -cells of the islets of Langerhans) in the pancreas. The exact cause of this destruction is unknown. Since concordance for Type 1 diabetes in monozygotic twins is only around 30% ⁴, other than genetic factors are believed to play a significant role in the incidence of diabetes.

When the insulin production in the pancreas is too low relative to available glucose in the blood, blood glucose levels increase and hyperglycemia occurs. Having no or little endogenous insulin production confronts most diabetes Type 1 patients with a lifelong dependence on exogenous insulin to decrease high blood glucose levels ⁵. The exogenous insulin replacements are injected subcutaneously by the patient one to multiple times a day or enter the body by means of an insulin pump. Diagnosis of diabetes Type 1 may occur at any age, but generally occurs during childhood or in adolescence. The onset of Type 1 diabetes is characterized by classic symptoms, such as *polyuria* (increased urinary frequency), *polydipsia* (frequent thirst), weight loss, fatigue and *ketonuria/albuminuria* ⁶⁻⁷.

In patients with Diabetes Type 2 the pancreas usually still produces some insulin, but the production or uptake of insulin in the body is disturbed. Initially, many Type 2 diabetes patients show insulin resistance and no destruction of the beta cells, but beta cell failure may occur years after diagnosis ⁸⁻¹⁰. Sometimes diabetes Type 2 is defined as non-insulin-dependent-diabetes-mellitus (NIDDM) because most patients with Diabetes Type 2 do not instantly need exogenous insulin replacements after diagnosis. However, this definition might be misleading because the insulin production in the pancreas of many diabetes Type 2 patients decreases throughout the years and makes the body increasingly dependent on exogenous insulin ⁸⁻¹⁰. Furthermore, many diabetes type 2 patients eventually need exogenous insulin to keep their blood glucose levels within a normal range.

Because of the gradual decrease in insulin production by the pancreas, diabetes type 2 usually is diagnosed in mid-late adulthood (> 45 years of age). In contrast to diabetes Type 1, the diagnosis of diabetes Type 2 generally is not preceded by classic symptoms or health complaints and often occurs coincidentally with the diagnosis of a secondary condition. Concordance rates for diabetes Type 2 are much higher than for diabetes Type 1, approaching 100% in monozygotic twins ¹¹. However, diabetes type 2 is believed to be caused by an interplay of genetic and environmental (lifestyle) factors. People with a genetic predisposition for diabetes type 2 who have a healthy lifestyle and a normal weight might never develop diabetes. However, people with a genetic predisposition for diabetes type 2 who are overweight and/or have an unhealthy lifestyle are most likely to develop diabetes at some point in their lives. Eighty to ninety percent of diabetes Type 2 patients is overweight (BMI > 25) or obese (BMI > 30) ¹¹. The increasing number of people who are overweight is seen as an important factor in the increasing incidence of diabetes Type 2 ¹²⁻¹⁴.

Prevalence of Diabetes

Diabetes is reaching epidemic proportions throughout the world. It is estimated that more than 180 million people worldwide suffer from diabetes ¹⁵. Approximately 90-95% of these people are diagnosed with diabetes Type 2. Because of the increasing incidence of unhealthy lifestyles and overweight the number of 180 million diabetes patients worldwide is expected to have doubled by the year 2030 ¹⁵. Although Type 2 diabetes generally was diagnosed in mid-late adulthood and therefore was known as maturity-onset diabetes, due to the increase in people with unhealthy lifestyles and overweight an increasing number of young adults and even children are diagnosed with diabetes Type 2 ¹⁶.

Compared to other European or non-European countries the prevalence of diabetes in the Netherlands is relatively low ¹⁷⁻¹⁸. The number of diabetes patients in the Netherlands is estimated to be round 600.000 which represents about 3% of the total Dutch population. This number, however, is still increasing. About ninety percent of these people suffer from diabetes type 2. The prevalence of diabetes in the Netherlands is highest among people living in urban areas and the non-Caucasians.

Short and Long Term Consequences of Diabetes

When the pancreas does not produce (sufficient) insulin or when the body is not able to effectively use the insulin, blood glucose levels rise and hyperglycemia occurs. Without computerized monitoring of their blood glucose levels, most patients are unaware of their

hyperglycemia in the short term and do not experience any symptoms or health complaints. However, some patients report symptoms of hyperglycemia such as dryness of the mouth, fatigue or blurry vision. In the long term (> 15 years), hyperglycemia manifests itself through serious diabetes complications such as neuropathy (nerve damage), retinopathy (eye problems), nephropathy (renal damage/kidney failure), joint problems and cardiovascular damage ⁵. In extreme cases hyperglycemia can result in coma, seizures or death through ketoacidosis (acidified tissue and organs) ¹⁹. However, most diabetes patients die of cardiovascular complications ²⁰.

When the exogenous insulin replacement is too high relative to available glucose levels in the blood hypoglycemia occurs. Hypoglycemia often occurs as a consequence of insufficient dietary intake or excessive physical exercise relative to exogenous insulin replacement. Some patients are 'hypo-unaware' and do not experience any symptoms of hypoglycemia. However, most patients report symptoms of hypoglycemia ranging from hunger, perspiration, sleepiness, dizziness, confusion or nervousness to difficulty speaking ¹⁹. Hypoglycemia can be treated by the intake of fast-acting carbohydrates to prevent a further decrease of blood glucose levels. Left untreated, severe hypoglycemia can lead to coma or death.

Treatment and Self-Management of Diabetes

In general, treatment of both diabetes Type 1 and Type 2 patients focuses on decreasing and stabilizing blood glucose levels. For accurate feedback about patients' blood glucose levels physicians generally rely on patients' feedback provided by the computerized monitoring of blood glucose levels and on their glycosylated hemoglobin assay (HbA1c). HbA1c provides an estimate of a patient's average blood glucose levels in the preceding six to eight weeks.

For Type 1 diabetes patients the medical treatment of diabetes usually comprises injections with exogenous insulin or the use of an insulin pump. For Type 2 patients the medical treatment usually starts with oral anti-diabetics (e.g. Biguanides, Sulphonylurea or Thiazolidinediones) and often gradually changes into an insulin based treatment over the years ²¹. Next to the medical treatment with anti-diabetics and/or insulin, great emphasis in the treatment of diabetes is put on diabetes self-care behaviors. The most important diabetes self-care behaviors are the self-monitoring of blood glucose levels (self-control) and management of food intake.

Because blood glucose levels fluctuate throughout the day, diabetes patients (who use insulin therapy) are instructed to monitor their blood glucose levels multiple times a day. Regular self-control gives patients an important tool to adjust insulin injections to the level of blood glucose in

the blood. Adjusting insulin to the glucose levels in the blood prevents patients from injecting too much or too little insulin, which in turn prevents hypo- and hyperglycemia.

Furthermore patients are advised to monitor their intake of carbohydrates and to adjust their medication/insulin to their intake of carbohydrates. Controlling dietary intake and alcohol consumption immediately influences the balance between available glucose levels in the blood (from foods or alcohol) and the uptake of glucose by insulin present in the body.

Apart from the self-monitoring of blood glucose and the management of food intake, all patients are advised to live a generally healthy lifestyle. The increased chances of diabetes patients for developing a cardiovascular disease underline the importance of maintaining a healthy diet, engaging in regular physical exercise and quitting smoking.

For most diabetes Type 2 patients, the initial medical treatment with oral anti-diabetics is usually combined with treatment strategies for weight loss. Weight loss can increase insulin sensitivity, most especially when weight loss occurs in abdominal fat deposits ²³⁻²⁵. Treatment of diabetes type 2 patients, therefore, mostly focuses on changes in food consumption and an increase in physical activity.

The increasing awareness of the importance of lifestyle and health behaviors in the management of diabetes has changed perspectives in diabetes treatment throughout the years. Whereas the treatment of diabetes previously focused on adherence to medical and pharmacological regimes ²⁶, current diabetes treatment generally focuses on the interplay between medical, pharmacological, lifestyle and psychosocial factors in diabetes ²⁷. The high and immediate impact of lifestyle behaviors and self-control on blood glucose levels creates major opportunities for diabetes management without invasive medical procedures. Patients' self-regulation skills with regard to these lifestyle behaviors and self-control techniques are the most important tools in the management of high or low blood glucose levels ²⁸.

Acknowledging the importance of lifestyle and health behaviors in diabetes management has led to an increased awareness of the important role of psychology in diabetes care. Psychological theories about patient education and how to motivate/teach patients to change behavior have been increasingly applied to diabetes care throughout the years ²⁹. The previous assumption that provision of medical information would automatically lead to behavior change has been abandoned and has been replaced by the idea that psychological strategies are needed to motivate patients for behavior change. Understanding why patients do or don't perform self-management behaviors has become increasingly important.

Self-regulation Theory and Diabetes Self-Care

One of the modern theoretical perspectives of looking at self-management behaviors is the self-regulation perspective. Self-regulation theory provides a theory-based framework from which practical guidelines for interventions and specific working mechanisms for behavior change can be derived ³⁰.

Self-regulation can be defined as 'a sequence of actions and/or steering processes intended to attain a personal goal' ³⁰. These actions and/or steering processes, also referred to as change and maintenance mechanisms, can be divided into three phases: a) a phase of goal selection, goal setting and goal representation, b) a phase of active goal pursuit, and c) a phase of goal attainment and maintenance or goal disengagement.

In the phase of goal selection, goal setting and goal representation, goal autonomy plays a key role. Intervention health goals such as weight loss, quitting smoking or engaging in physical exercise are often set for, and not by, the individual and are often defined without relating them to the individual's pre-existing personal goals. As a consequence, the individual is confronted with other goals in his personal life which are conflicting with the achievement of the coerced health goal. Disengagement with the health goal often is the result. Deci and Ryan ³¹ have repeatedly demonstrated that 'autonomous regulation', that is setting and pursuing self-formulated goals, produces notable effects in terms of life-style changes, medication adherence and diabetes management outcomes ³²⁻³⁵. Goal selection is also highly influenced by illness perceptions such as experienced illness symptoms, perceived causes for the illness, perceived control over the treatment and cure, the expected timeline of the illness, and experienced daily consequences of the illness ³⁶. These five dimensions have been proven to relate to the self-management of various chronic conditions ³⁷ including diabetes ³⁸⁻³⁹. In a study by Griva, Myers and Newman ⁴⁰ beliefs of control over diabetes were consistently associated with treatment adherence. Broadbent, Petrie, Main and Weinman ⁴¹ demonstrated that higher personal control over diabetes was associated with lower HbA1c whereas experiencing more diabetes symptoms was associated with higher HbA1c-levels.

The transition from goal selection and goal setting to active goal pursuit is facilitated by both cognitive and affective processes ³⁰. Positive and negative affect function as emotional reinforcements of goal facilitating and goal inhibiting behaviors respectively ⁴². The cognitive processes which facilitate goal achievement are categorized into three types: (a) feedback mechanisms, which refer to the ability to evaluate and monitor goal progress on the basis of results, (b), feed forward mechanisms, which consist of expectations with regard to the outcome of goal pursuit as well as efficacy expectations, and (c), activation of control processes, such as

control over distracting emotions, being able to focus on goal-related information, being able to motivate oneself and using failure as an opportunity for learning ⁴².

Feedback mechanisms, such as the self-monitoring of nutrition and exercise behavior prove to be effective intervention components in many diabetes interventions. Moreover, for most insulin-dependent diabetes patients the self-monitoring of blood glucose levels has become a daily routine.

The inclusion of feed forward mechanisms in health interventions is usually represented by the inclusion of self-efficacy components. Self-efficacy has been frequently shown to relate to behavior change and disease management in various chronic conditions, including diabetes ⁴⁹⁻⁵¹.

To the best of our knowledge, the activation of control processes as such have not been examined within a diabetes context. Motivations to perform diabetes (self-care) behaviors have been frequently assessed as part of a self-determination intervention ⁵² however; motivation in this context is usually defined as prior-to-treatment motivation, rather than motivation in the action phase of goal pursuit.

Maintenance of (new) health behaviors is one of the biggest challenges for both patients and health care providers. Numerous interventions have shown the relative simplicity of changing health behaviors in the short term and the extreme difficulty of maintaining those behaviors in the longer term ⁵³, also in the context of diabetes self-care ⁵⁴. To increase chances of maintenance, various diabetes interventions have included relapse prevention techniques ⁵⁵⁻⁵⁶.

All of the above-mentioned interventions indicate that self-regulation theory has found its way into the field of diabetes self-care. However, a systematic use of important mechanisms from all three phases of self-regulation to facilitate goal achievement was not yet found within the field of diabetes research. It is therefore that this thesis will use the orienting principles for self-regulation interventions ³⁰ to evaluate the effect of existing diabetes weight loss interventions and to conduct a self-regulation weight reduction intervention for diabetes type 2 patients.

Research questions and Outline of the Thesis

The central focus of this thesis is to explore the role of self-regulation in overweight diabetes type 2 patients. The general research questions in this thesis are:

- 1) What is the role of self-regulation principles in diabetes weight loss interventions? (CH 2)?
- 2) Do self-regulation cognitions relate to diabetes self-efficacy and weight regulating behavior in overweight diabetes type 2 patients? (CH 3)
- 3) What are the effects of a pilot self-regulation weight reduction intervention for type 2 diabetes patients? (CH 4)
- 4) Can self-regulation cognitions predict drop-out from a weight reduction intervention for type 2 diabetes patients? (CH 5)

Overview of Chapters in Thesis

This thesis consists of six chapters, four of which are empirical. Chapter one briefly introduces the topic of diabetes and self-regulation theory. The meta-analysis in chapter two describes the general effect of diabetes weight loss interventions as well as self-regulatory moderators of these effects.

Chapter three uses the baseline data of the self-regulation pilot intervention. Cross-sectional relationships between self-regulatory cognitions, diabetes self-efficacy and weight regulating behavior are examined.

Chapter four presents the three and six month results of the self-regulation pilot intervention. The effect of the self-regulation intervention on weight, HbA1c, self-regulation and quality of life is examined in the intervention and control groups.

Chapter five briefly describes predictors of six month drop-out of the intervention study. Univariate and multivariate differences between drop-outs and stay-ins are examined. Furthermore, logistic regression analyses were conducted to find the best psychosocial predictors of drop-out.

In chapter six an attempt is made to integrate and discuss the main findings from this thesis from a theoretical, methodological and clinical point of view. A discussion of the results, limitations of the study, implications of the results and suggestions for future research are made.

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2

The Effect of Weight Reduction Interventions for Patients with Type II Diabetes: A Meta-Analysis from a Self-Regulation Perspective

A version of this chapter was submitted for publication (Huisman, De Gucht, Dusseldorp, Maes)

Abstract

The purpose of this study was to evaluate the general effect of weight loss interventions in diabetes patients. In a meta-analysis of 34 studies, effect sizes were calculated for weight and HbA1c. In addition, moderating effects of specific self-regulation principles and intervention characteristics were explored.

The overall effect sizes (d) for weight loss in the short term (<6 months) were low and even lower in the longer (> 6 months) term. The overall effect sizes for HbA1c-outcomes were higher and remained stable in the longer term. The total amount of self-regulation present in interventions increased the effect on both weight and HbA1c outcomes. Furthermore 'goal reformulation' increased the effect on weight outcomes and 'emotion regulation' increased the effect on HbA1c. Another moderator for the effect on weight was the 'inclusion of a patient's partner or relative'.

This meta-analysis supports the importance of including self-regulation principles in weight reduction interventions in diabetes patients, in particular for HbA1c outcomes. To fully understand the relation between self-regulation, HbA1c, and weight more research is however needed.

Introduction

Since most patients with type 2 diabetes are overweight (BMI>25), weight reduction is an essential step in the treatment of diabetes type 2. Weight loss improves the insulin absorption and decreases high blood glucose levels which in turn reduce the risk of serious diabetes complications, such as cardiovascular damage, retinopathy, neuropathy or nephropathy ¹⁻³.

Various interventions have tried to achieve both weight loss and a decrease in HbA1c in overweight diabetes patients ⁴⁻¹³. However, the outcomes of these interventions are somewhat disappointing. Reported weight loss effects are often small and decrease in the long term ^{4,13} and some studies do not even report weight loss ¹⁰⁻¹¹. Intervention effects on HbA1c-levels appear somewhat higher and less susceptible to relapse ⁷⁻⁸, but some studies report a lack of effects on HbA1c-levels as well ⁶.

During the past years a number of (systematic) reviews and meta-analyses have tried to assess the effect of non-surgical and non-pharmacological weight reduction interventions in type 2 diabetic patients ¹⁴⁻¹⁷ on weight and HbA1c. In general, behaviour therapy and psycho-education generated no effects on weight ¹⁴⁻¹⁷, but positive effects on HbA1c ¹⁵ and stress outcomes ¹⁶ were found.

Differences in the approach and methodology of these meta-analyses make it however difficult to draw firm conclusions on the effects of interventions on weight loss and HbA1c in type 2 diabetics. Substantial differences were found in the number of studies that were included in the various meta-analyses as well as in the inclusion criteria that were used for selection of the studies. Some meta-analyses specifically selected randomized controlled trials ¹⁵⁻¹⁷ whereas other meta-analyses also included one group pretest-posttest designs ¹⁴. Some meta-analyses primarily focused on intervention effects on HbA1c and provided only limited data on effects on weight ¹⁵⁻¹⁶. Furthermore, although some meta-analyses described intervention characteristics such as 'frequency of contact', 'type of interventions' ¹⁵⁻¹⁶ or 'behavioral strategies' ¹⁷ none of them were grounded in sound psychological theory, nor were moderator analyses conducted to examine if differences in effect sizes could be explained on the basis of these characteristics. Therefore, the specific mechanisms which might explain why some interventions do and some interventions don't succeed in weight loss and decreasing HbA1c remain unexplored.

Self-regulation theory provides a framework from which specific intervention principles that can be used as moderators of effect can be derived. Self-regulation can be defined as a sequence of actions and/or steering processes intended to attain a personal goal ¹⁸. Self-regulation theory states that all human behaviors are goal driven, and that cognitive and affective processes regulate goal selection, active goal pursuit and goal attainment or disengagement ¹⁹. In a review

on self-regulation, physical health and illness Maes and Karoly ²⁰ described 15 principles that proved to be effective for the self-management of health problems. The 15 principles correspond to the three phases of self-regulation: 1) goal selection and goal setting, which includes personal relevance of goals, goal setting, specific action planning, and realistic outcome expectations, 2) active goal pursuit, which includes self-monitoring, feedback on goal progress, control over distracting events or processes, efficacy enhancement, and self-reinforcement, and finally 3) goal maintenance and attainment, which includes anticipatory coping, relapse prevention, reformulation of goals, and if necessary goal disengagement. Goal support of relatives and friends is believed to increase goal achievement and therefore encouraged.

In the present meta-analysis, we explored the value of self-regulatory principles present in weight reduction interventions in type 2 diabetic patients for explaining differences in study effect sizes.

The main research questions of this meta-analysis are:

- a) What is the overall effectiveness of weight reduction interventions on weight loss and HbA1c in type 2 diabetic patients?
- b) Do (specific) self-regulation principles moderate the effect of weight reduction interventions on weight loss and/or HbA1c, and if so, in which direction?
- c) Do other intervention characteristics, including length of intervention or number of sessions moderate the effect of weight reduction interventions on weight loss and/or HbA1c, and if so, in which direction?

Methods

WEB OF SCIENCE, PUBMED, and WEBSPIRS were searched for relevant articles on weight reduction interventions in patients with type 2 diabetes. Keywords that were used in different combinations for this search were: diabetes (type 2/II), (behavio(u)ral) interventions, weight, self-regulation, self-management, weight reduction, weight change, meta-analysis, review. In addition, reference lists from selected studies were screened for other relevant studies. The literature search was limited to randomized controlled trials published in English between 1990 and 2005. Furthermore the following inclusion criteria were defined: studies reported a non-surgical/non-pharmacological intervention in an outpatient setting, or included at least one non-surgical/non-pharmacological condition; interventions were carried out in adults with type 2 diabetes; the number of participants in the intervention and control group was more than 10; data specified the weight (loss) and HbA1c of participants (before and) after treatment which permitted the calculation of effect sizes. All studies were subjected to the Cochrane Depression,

Anxiety and Neurosis Criteria for the quality assessment of psychological randomized controlled trials. No exclusion criteria were applied concerning the use of medication in patients. This selection procedure yielded 34 studies (5469 patients in total) that met all the criteria and were included in the final meta-analysis.

Study features were independently rated by two health psychologists. The average agreement between the two coders across the moderator variables was 84% (Average Cohen's kappa= .7). The self-regulatory principles were coded according to the definitions of the self-regulation principles for interventions ²⁰ [see appendix 1]. The extent of tailoring was equalized to the presence of goal setting, goal ownership and planning. Self-regulation principles were coded as not present (0), present to some extent (1), and present to a great extent (2). The total amount of self-regulation was calculated by adding the scores (0-2) of the various self-regulation principles. Then, a median split divided the total self-regulation scores into a 'high score' (above the median) and a 'low score' (below the median).

Since many interventions were provided by various types of health care workers, the *professions* of the various *providers* were coded as either present or absent (yes/no).

Studies were coded for data that permit the computation of effect sizes. Pretest and posttest weight, BMI and HbA1c scores and change scores in weight, BMI and HbA1c were screened and coded. The *measurement point in time* for all posttest-data and change-scores was also coded. Measurement points up to six months were defined as short term measurements. Measurement points above six months were defined as long term measurements.

If a study compared two similar interventions to a control group (e.g. two different types of a diet), the intervention containing the highest number of self-regulation principles was selected as the experimental group.

Statistical Analyses

Standardized mean difference effect size estimates (*d*) were calculated using Borenstein, Rothstein and Cohen's Comprehensive Meta-Analysis Program (CMA, version 2.2) ²¹. Pretest-posttest scores for weight and Hba1c (raw means and standard deviations) were used to compute the study effect sizes. The mean differences were standardized by the posttest standard deviation (see formula 1 in appendix 2). If studies reported standard errors in stead of standard deviations, standard deviations were computed by multiplying the standard error with the square root of the number of subjects in the specific group. If studies reported change data only, we used the change scores (mean changes and standard deviations, or mean changes and paired *p*-values) to compute the study effect sizes, assuming a pretest-posttest correlation

of 0.50 (see formula 2 in the appendix 2). Since only one study reported a pretest-posttest correlation, we could not compute an average pretest-posttest correlation.

The population effect sizes (i.e., the weighted average effect size d) were also computed with CMA, for the short term and long term separately, and for the combined term. The combined term consisted of the study effect size for the longest term available. Q -statistics were computed to test the null hypothesis of homogeneity of a specific set of study effect sizes. For a heterogeneous set the random effect estimates with the 95% confidence intervals were reported, while for a homogeneous set the fixed effect estimates with the 95% confidence intervals were reported. To improve the power of the analyses, moderator analyses were conducted only for the study effect sizes of the combined term. Again, the Q -statistic was computed to test the homogeneity of the specific subset of study effect sizes. Depending on the homogeneity of the subset either the random population effect sizes with the 85% confidence intervals or the fixed population effect sizes with the 85% confidence intervals was reported. Calculating the 85% confidence intervals served as a significance test for the moderator effect under a random error model ²². A significantly different effect size in moderator subsets was indicated by non-overlapping 85% confidence intervals.

Results

Thirty-four studies were included in the meta-analysis ^{4-13, 23-45} (see Table 1). The average length of the intervention in this study sample was 43.8 weeks (SD = 42.9) with a minimum of six weeks ²³ and a maximum of 208 weeks ²⁴. The posttest measurements varied from twelve weeks ^{9,25} to four years ²⁴, with an average of 58.5 weeks (SD = 41.7). Almost all studies primarily used 'face-to-face' contacts to provide patients with information regarding weight loss and changes in HbA1c-levels. Therefore, this variable will not be included in the moderator analyses.

Table 1. Study and Intervention characteristics

Author	Subjects	Self-regulation principles*	FOCUS	IND/GR	CHAN	SESS	LENG	MSPO
Agurs-Collins <i>et.al.</i> , 1997	64 overweight African-Americans ages 55-79 with diabetes type 2	GS, PL, FE, REL, SM, AC	Diet + Exercise	Individual + Group	Face to face	19 sess	26 weeks	3, 6 m
Ash <i>et.al.</i> , 2003	51 overweight men with diabetes type 2 <70 years	SM	Diet	Individual	Face to face+ Phone	7 sess	12 weeks	12 w, 18 m
Campbell <i>et.al.</i> , 1990	70 subjects with diabetes type 2, BMI $\geq$ 25	GS, OW, PL, RE, AC, TA	Diet	Group	Face to face	13.5 h in 11 week	11 weeks	1, 3, 6 m
Campbell <i>et.al.</i> , 1996	59 diabetes type 2 patients in behavioral program	GS, OW, PL, FE, EF, EM, CO, SM, GR, TA	Diet + Exercise	Individual	Face to face + Phone	>6 sess	52 weeks	3, 6, 12 m
D'Eramo-Melkus <i>et.al.</i> , 1992	82 diabetes type 2 patients, 21-65 yrs, 20-75% of desirable weight	GS, OW, FE, CO, SM, SR	Diet	Individual + Group	Face to face	13 sess	11 weeks	3, 6 m
DiLoreto <i>et.al.</i> , 2003	182 diabetic type 2 patients in behavioral program	GS, OW, FE, EF, RE, CO, SM, GR, AC	Exercise	Individual	Face to face + phone	8 sess	104 weeks	2 y
Franz <i>et.al.</i> , 1995	179 men+ women 38-76 years, diabetes type 2	GS, OW, PL, FE, SM, TA	Diet	Individual	Face to face	3 sess	6 weeks	6 w, 6 m
Glasgow <i>et.al.</i> , 1992	102 persons > 60 years with diabetes type 2	GS, OW, PL, FE, EF, EM, REL, CO, SM, AC, TA	Diet + Exercise	Group-based	Face to face	10 sess + exerc sess	12 weeks	3, 6 m
Goldhaber-Fiebert <i>et.al.</i> , 2003	75 adults with diabetes type 2	GS, OW, PL, FE, EF, SM, TA	Diet + Exercise	Individual + Group	Face to face	11 sess + 36 exe	12 weeks	12 w

Table 1 Continued

Author	Subjects	Self-regulation principles*	FOCUS	IND/GR	CHAN	SESS	LENG	MSPO
Goudswaard <i>et.al.</i> , 2004	54 patients (39-75 years) taking maximal dosages of oral hypoglycaemic agents	GS, OW, FE, CO, SM, AC	Diet + Exercise	Individual	Face to face	6 sess	26 weeks	3, 6, 18 m
Keyserling <i>et.al.</i> , 2002	200 African-American women $\geq$ 40 yrs with diabetes type 2	GS, OW, EF, SM	Diet + Exercise	Individual + Group	Face to face + phone	7 sess	26 weeks	6, 12 m
Kirk <i>et.al.</i> , 2003	70 inactive diabetes type 2 patients	GS, FE, EF, REL, CO, SM, AC, TA	Exercise	Individual	Face to face + phone	1 sess	13 weeks	6 m
Kirk <i>et.al.</i> , 2004	70 inactive people with type 2 diabetes	GS, PL, FE, REL, CO, AC	Exercise	Individual	Face to face + phone	1 sess	39 weeks	6, 12 m
Kirkman <i>et.al.</i> , 1994	275 veterans with type 2 diabetes	GS, PL, FE, REL	Diet + Exercise	Individual	Phone	Only phone calls	52 weeks	12 m
Ligtenberg <i>et.al.</i> , 1997	58 patients with type 2 diabetes	GS, FE, EF, SM	Exercise	Individual + Group	Face to face + phone	18 sess	26 weeks	6, 12, 26 w
Mayer-Davis <i>et.al.</i> , 2004	152 diabetic persons living in rural communities	GS, OW, SM	Diet + Exercise	Individual	Face to face	26 sess	52 weeks	3, 6, 12 m
Nadeau <i>et.al.</i> , 2001	48 subjects with diabetes type 2	GS, PL, SM	Diet	Individual	Face to face	unkno wn	35 weeks	4, 8 m
Pascale <i>et.al.</i> , 1995	44 obese women with NIDDM	GS, FE, EF, EM, CO, SM, AC	Diet + Exercise	Group	Face to face	20 sess	16 weeks	16 w, 1y
Redmon <i>et.al.</i> , 2003	59 overweight or obese individuals with type 2 diabetes	GS, PL	Diet + Exercise	Individual	Face to face	3-6 sess	52 weeks	1y
Rickheim <i>et.al.</i> , 2002	170 subjects with type 2 diabetes	GS, OW, FE, EF, RE, EM, REL, CO, SM	Diet	Individual + Group	Face to face	4 sess	26 weeks	6 m

Table 1 Continued

Author	Subjects	Self-regulation principles*	FOCUS	IND/GR	CHAN	SESS	LENG	MSPO
van Rooijen <i>et.al.</i> , 2004	157 type 2 diabetes female subjects	GS, FE, EF, SM	Exercise	Individual + Group	Face to face	6 sess	12 weeks	12 w
Samaras <i>et.al.</i> , 1997	26 non-exercising NIDDM patients	GS, OW, FE, EF, SM	Exercise	Group	Face to face	6-12 sess	26 -52 weeks	6 m, 1 y
Sone <i>et.al.</i> , 2002	2205 patients with previously diagnosed type 2 diabetes	GS, FE, SM	Diet + Exercise	Individual	Phone	Only phone calls	156 weeks	3 y
Trento <i>et.al.</i> , 1998	120 patients < 80y with NIDDM	GS, FE, EF	Diet + Exercise	Group	Face to face	4 sess	52 weeks	1 y
Trento <i>et.al.</i> , 2001	112 type 2 patients	GS, FE, EF, EM, CO, SM, AC	Diet + Exercise	Group	Face to face	8 sess	104 weeks	2y
Trento <i>et.al.</i> , 2002	56 patients with type 2 diabetes + 56 controls	GS, PL, FE, EF, EM, CO, SM, AC	Diet + exercise	Group + Individual	Face to face	15 sess	208 weeks	4 y
Tudor-Locke <i>et.al.</i> , 2003	47 overweight/obese sedentary individuals from diabetes centre	GS, OW, PL, FE, SM, TA	Exercise	Group + Individual	Face to face + phone + mail	4 sess	16 weeks	16, 24 w
Uusitupa <i>et.al.</i> , 1993	86 patients with type 2 diabetes, aged 40-64	GS, OW, PL, SM	Diet + Exercise	Group + Individual	Face to face	6 sess	52 weeks	3, 9, 15, 27 m
Vanninen <i>et.al.</i> , 1992 male	45 male newly-diagnosed type 2 diabetes patients	GS, PL, EF, SM	Diet + Exercise	Group + Individual	Face to face	6 sess	52 weeks	1 y
Vanninen <i>et.al.</i> , 1992 female	33 female newly-diagnosed type 2 diabetes patients	GS, PL, EF, SM	Diet + Exercise	Group + Individual	Face to face	6 sess	52 weeks	1 y
Varroud-Vial <i>et.al.</i> , 2004	340 patients with type 2 diabetes	GS, PL, FE, SM	Diet + Exercise	Individual	Face to face	?	52 weeks	1 y

Table 1 Continued

Author	Subjects	Self-regulation principles*	FOCUS	IND/GR	CHAN	SESS	LENG	MSPO
Wing <i>et.al.</i> , 1991 1	49 obese diabetic patients with obese spouses	GS, EM, REL, SM, AC	Diet + Exercise	Group	Face to face	20 sess	20 weeks	20 w, 1 y
Wing <i>et.al.</i> , 1991 2	36 obese diabetic type 2 patients	GS, OW, PL, EF, EM, CO, SM, AC	Diet + Exercise	Group	Face to face	25 sess	20 weeks	20, 72 w
Wing <i>et.al.</i> , 1994	93 overweight persons with type 2 diabetes, 30-70 years	GS, PL, FE, EM, REL, SM	Diet + Exercise	Group	Face to face	52 sess	52 weeks	1, 2 y

* Self-regulation principles present at least to some extent

Goal-setting (GS), Ownership goal (OW), Planning (PL), Feedback (FE), Goal Efficacy (EF), Realistic outcome expectancies (RE), Emotional Control (EC), Relapse prevention (REL), Discussing Competing goals (CO), Self-monitoring (SM), Self-reinforcement (SR), Goal Reformulation (GR), Anticipatory Coping (AC), Tailoring (TA), Individual or Group-based Intervention (IND/GR), Channel (CHAN), Session (SESS), Length of intervention (LENG), Measurement points in study (MSPO), weeks (w), months (m), years (y)

Population effect sizes for weight and HbA1c

In Table 2 the population effect sizes for weight and HbA1c in the short and the long term are presented. Significant effects were found for all measurement periods on both weight and HbA1c.

The average population effect size estimate for weight (25 studies) in the short term was 0.18. This is only a small effect according to Cohen's Effect Size Classification ⁴⁶. In the longer term (> 6 months) the effect size decreases even further to 0.06. In general, the population effect size estimates for HbA1c were found to be higher and also more heterogeneous than for weight. For HbA1c the average population effect size estimate in the short term was 0.35, which can be considered a medium effect. Surprisingly, this effect did not decrease over time. The medium effect size remained 0.34, even in the longer term (> 6 months).

Table 2. Population Effect Size Estimates
for Weight Reduction Interventions in Type 2 Diabetics

Outcome	Measurement Period	<i>k</i>	<i>d</i>	95% CI		<i>Q</i>
Weight	Short	25	0.18***	0.08,	0.27	35.98*
	Long	21	0.06*	0.00,	0.13	24.63
	Combined	36	0.08**	0.03,	0.14	44.21
HbA1c	Short	23	0.35***	0.20,	0.50	47.95***
	Long	18	0.34***	0.14,	0.54	88.90***
	Combined	32	0.35***	0.21,	0.49	129.73***

k = number of studies; *d* = Weighted average standardized mean difference; 95% CI = 95% Confidence Interval; *Q* = test of homogeneity, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Moderator effects

Moderators were examined for the longest available term (see statistical analyses).

The total amount of self-regulation principles included in the interventions moderated the effect for both weight and HbA1c, which indicated that the effect of weight reduction interventions can be increased by including more self-regulation principles (table 3). 'Goal reformulation' was a significant moderator for weight, and 'emotional control' was a significant moderator for HbA1c. These effects were in the expected direction. Although the overlapping confidence intervals of the other self-regulation principles indicated that from a strictly methodological perspective these could not be seen as real moderators, trends of moderation were found with regard to 'Discussing competing goals', 'Positive reinforcement' and 'Anticipatory coping' on weight and HbA1c outcomes. For HbA1c these moderating effects were even stronger than for weight outcomes. 'Relapse Prevention' showed a moderating trend for HbA1c only. An unexpected negative trend was found with regard to the effect of 'Planning' on weight. Interventions which did not include 'Planning' had significantly higher effect sizes than interventions which did include 'Planning'.

With regard to other study features, only 'involvement of a partner or relative' in an intervention moderated the effect size for weight (table 4). Interventions which included a patient's partner or relative had significantly higher effect sizes than interventions which did not take into account a patient's partner or relative. None of the other intervention features, such as the focus of treatment, individual treatment versus group treatment, the length of the intervention or the number of sessions moderated the effect on either weight or HbA1c outcomes.

Table 3. Moderator-Analyses with SR- Principles to explain Differential Effects on Weight and HbA1c

Outcome	Self-Regulation (SR) Principle	k	N	D	85% CI		Q	Moderator /Trend
Weight	Self-regulation high/low							Moderator
	Low (<7 sr points)	17	3488	.04	-.01,	.08	17.669	
	High (≥ 7 sr points)	18	1520	.17***	.10,	.24	16.513	
HbA1c	Self-regulation high/low							Moderator
	Low (<7 sr points)	15	3315	.127***	.08,	.18	65.274***	
	High (≥ 7 sr points)	17	1459	.470***	.39,	.55	35.198**	
Weight	Goal setting							-
	Not at all	3	231	0.15	-.047,	.346	0.68	
	To some extent	21	2250	0.19***	.120,	.258	21.72	
	Very much	12	3025	0.01	-.039,	.066	12.97	
HbA1c	Goal setting							-
	Not at all	1	58	.29	-.09,	.67	.00	
	To some extent	19	1691	.34**	.18,	.49	77.13***	
	Very much	12	3025	.40***	.24,	.55	48.51***	
Weight	Goal Ownership							-
	Not at all	23	3773	0.06	.011,	.105	28.16	
	To some extent	6	546	0.08	-.050,	.200	2.25	
	Very much	7	725	0.21	.097,	.313	10.56	
HbA1c	Goal Ownership							-
	Not at all	20	3564	.34***	.21,	.48	85.90***	
	To some extent	5	485	.17	.04,	.31	9.12	
	Very much	7	725	.49***	.29,	.68	16.73***	
Weight	Planning							Trend
	Not at all	23	3698	0.22***	.133,	.300	37.97*	
	To some extent	13	134	0.04	-.042,	.118	5.43	
	Very much	-	-	-	-	-	-	
HbA1c	Planning							-
	Not at all	21	3645	.38***	.23,	.52	112.74***	
	To some extent	11	1129	.36***	.28,	.45	11.02	
	Very much	-	-	-	-	-	-	
Weight	Feedback							-
	Not at all	14	946	0.20**	.102,	.29.	9.21	
	To some extent	14	3223	0.02	-.034,	.067	14.86	
	Very much	8	875	0.20**	.098,	.294	10.85	
HbA1c	Feedback							-
	Not at all	11	712	.29	.03,	.55	52.08***	
	To some extent	14	3223	.34***	.22,	.46	37.20***	
	Very much	7	839	.51***	.30,	.69	20.54**	
Weight	Goal Efficacy							Moderator
	Not at all	20	3587	0.04	-.008,	.069	23.09	
	To some extent	13	1001	0.13*	.040,	.224	13.04	
	Very much	3	456	0.29**	.150,	.422	1.29	

Table 3 Continued

Outcome	Self-Regulation (SR) Principle	k	N	D	85% CI		Q	Moderator /trend
HbA1c	Goal Efficacy							-
	Not at all	16	3317	.32**	.17,	.47.	72.75***	
	To some extent	13	1001	.36***	.21,	.52	32.82***	
	Very much	3	456	.51*	.16,	.84	6.82**	
Weight	Realistic Outcome Expectancies							-
	Not at all	33		0.07*	.026,	.112	38.84	
	To some extent	3		0.19*	.064,	.325	3.64	
	Very much	-		-	-	-	-	
HbA1c	Realistic Outcome Expectancies							-
	Not at all	30	4342	.32***	.22,	.43	104.20***	
	To some extent	2	432	.68***	.24,	1.12	9.77**	
	Very much	-	-	-	-	-	-	
Weight	Emotional Control							-
	Not at all	24	3991	0.08**	.036,	.127	30.13	
	To some extent	12	1053	0.08	-.010,	.169	14.08	
	Very much	-	-	-	-	-	-	
HbA1c	Emotional Control							Moderator
	Not at all	21	3757	.25**	.14,	.37	68.79***	
	To some extent	11	1017	.55***	.41,	.70	21.59*	
	Very much	-	-	-	-	-	-	
Weight	Relapse Prevention							-
	Not at all	28	4501	0.08**	.033,	.120	36.12	
	To some extent	8	543	0.12	-.006,	.243	7.88	
	Very much	-	-	-	-	-	-	
HbA1c	Relapse Prevention							Trend
	Not at all	25	4277	.29***	.18,	.41	92.49***	
	To some extent	7	497	.59***	.38,	.80	14.96*	
	Very much	-	-	-	-	-	-	
Weight	Discussing Competing Goals							Trend
	Not at all	23	3879	0.06	.009,	.102	31.69	
	To some extent	13	1165	0.17**	.081,	.251	9.85	
	Very much	-	-	-	-	-	-	
HbA1c	Discussing Competing Goals							Trend
	Not at all	19	3609	.28**	.14,	.41	81.89***	
	To some extent	13	1165	.48***	.36,	.61	21.32*	
	Very much	-	-	-	-	-	-	
Weight	Self Monitoring							-
	Not at all	6	484	0.10	-.041,	.232	1.13	
	To some extent	8	2	0.13	.026,	.227	7.47	
	Very much	22	3728	0.16**	.078,	.242	35.04*	

Table 3 Continued

Outcome	Self-Regulation (SR) Principle	<i>k</i>	<i>N</i>	<i>D</i>	85% <i>CI</i>		<i>Q</i>	Moderator /trend
HbA1c	Self Monitoring							-
	Not at all	4	267	.74	.33,	.69.	31.41***	
	To some extent	7	815	.32***	.22,	.42	11.58	
	Very much	21	3692	.34***	.21,	.46	79.20***	
Weight	Reinforcement							Trend
	Not at all	33	4941	0.08**	.034,	.117	38.86	
	To some extent	3	103	0.35	.060,	.638	3.54	
	Very much	-	-	-	-	-	-	
HbA1c	Reinforcement			.				Trend
	Not at all	30	4707	.34***	.23,	.44	124.42***	
	To some extent	2	67	.71**	.33,	1.09	1.94	
	Very much	-	-	-	-	-	-	
Weight	Goal Reformulation							Moderator
	Not at all	34	4634	0.06*	.017,	.102	37.61	
	To some extent	2	410	0.33***	.181,	.472	0.18	
	Very much	-	-	-	-	-	-	
HbA1c	Goal Reformulation							-
	Not at all	30	4364	.35***	.24,	.46	126.134***	
	To some extent	2	410	.41***	.26,	.56	0.425	
	Very much	-	-	-	-	-	-	
Weight	Anticipatory Coping							Trend
	Not at all	21	3722	0.03	-.010,	.085	25.64	
	To some extent	11	786	0.21**	.100,	.313	9.52	
	Very much	4	536	0.21*	.089,	.33	2.08	
HbA1c	Anticipatory Coping							Trend
	Not at all	20	3705	.28**	.14,	.41	97.842***	
	To some extent	9	594	.47***	.34,	.59	10.870	
	Very much	3	475	.47***	.33,	.60	3.593	
Weight	Tailoring							-
	Not at all	30	4536	0.09**	.042,	.128	40.90	
	To some extent	6	508	0.05	-.081,	.178	3.16	
	Very much	-	-	-	-	-	-	
HbA1c	Tailoring							-
	Not at all	27	4327	.34***	.23,	.45	104.325***	
	To some extent	5	447	.42*	.12,	.72	18.558***	
	Very much	-	-	-	-	-	-	

k = number of studies; *d* = Weighted average standardized mean difference; 85% *CI* = 85% Confidence Interval; *Q* = test of homogeneity, * *p* < 0.05, ** *p* < 0.01, *** *p* < 0.001

Table 4. Moderator Analyses with INTV-Features to explain differential effects on weight and HbA1c

Outcome	Intervention (INTV) Features	k	N	d	85% CI		Q	Moderator/ Trend
Weight	Partner/family involved							Moderator
	Not involved	24	3885	.04	-.01,	.09	23.53	
	Involved	11	1159	.21***	.12,	.29	9.48	
HbA1c	Partner/family involved							-
	Not at all	22	3771	.30***	.17,	.43	103.47***	
	To some extent	10	1003	.46***	.33,	.58	13.37	
Weight	Focus of treatment							-
	Diet	7	557	-.01	-.13,	.12	1.45	
	Exercise	7	742	.20**	.10,	.31	3.71	
	Combination	21	3727	.06	.02,	.11	29.72	
HbA1c	Focus of treatment							-
	Diet	5	459	.37	.07,	.67	18.89***	
	Exercise	7	742	.31***	.20,	.41	2.30	
	Combination	20	3571	.39***	.24,	.54	102.08***	
Weight	Individual vs. Group							-
	Individual	12	3373	.04*	.04,	..22	19.786*	
	Group	10	659	.16*	.04,	.27	10.881	
	Combination	13	1009	.13*	.04,	.22	5.388	
HbA1c	Individual vs. Group							-
	Individual	10	3180	.41**	.22,	.60	65.72***	
	Group	9	589	.39***	.26,	.51	11.33	
	Combination	13	1003	.29*	.11,	.47	45.38***	
Weight	Length of Intervention							-
	≤ 26 weeks	17	1244	.12*	.04,	.20	16.520	
	27-52 weeks	14	1298	.14**	.06,	.22	10.097	
	> 52 weeks	4	2493	.02	-.05,	.26	8.573*	
HbA1c	Length of Intervention							-
	≤ 26 weeks	15	1137	.37**	.21,	.52	42.65***	
	27-52 weeks	13	2279	.32**	.13,	.50	48.24***	
	> 52 weeks	4	1356	.42*	.16,	.68	25.76***	
Weight	Number of Contact Sessions							-
	≤ 6 sessions	15	3156	.03	-.03,	.08	14.652	
	7-15 sessions	10	977	.22**	.13,	.31	7.504	
	> 15 sessions	8	505	.21*	.08,	.33	6.190	
HbA1c	Number of Contact Sessions							-
	≤ 6 sessions	14	3000	.35**	.17,	.53	77.15***	
	7-15 sessions	8	879	.42**	.23,	.62	21.23**	
	> 15 sessions	8	505	.27**	.10,	.36	12.54	

Table 4 continued

Outcome	Intervention (ITV) Features	k	N	D			Q	Moderator/trend
Weight	Intervals between sessions in weeks							
	≤ 2 weeks	15	1138	.16**	.07	.24	12.98	
	> 2 and ≤ 10 weeks	9	561	.21*	.08	.33	8.58	
	> 10 weeks	7	792	.19**	.09	.30	2.83	
HbA1c	Intervals between sessions in weeks							
	≤ 2 weeks	13	1060	.31***	.19	.43	19.35	
	> 2 and ≤ 10 weeks	9	561	.18	-.08	.43	33.15***	
	> 10 weeks	7	792	.66*	.38	.95	36.32***	

k = number of studies; d = Weighted average standardized mean difference; 85% CI = 85% Confidence Interval; Q = test of homogeneity, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Conclusion and Discussion

The purpose of this meta-analysis was threefold. First, the overall effectiveness of weight loss interventions on both weight and HbA1c was explored. Second, it was investigated whether specific self-regulation principles acted as moderators on weight and HbA1c outcomes. And third, the moderating influence of other specific intervention characteristics on the effect sizes of weight and HbA1c was examined.

As the overall intervention effect on weight was small, both in the short and the longer term, this meta-analysis confirms the findings of previous meta-analyses¹⁴⁻¹⁷. Clark⁴⁷ described the failure of obesity treatments to achieve significant and long-lasting weight loss and suggested that weight loss as a major intervention goal in diabetes type 2 patients might be a bridge too far. Clark stated that for motivational reasons, intervention targets in diabetes type 2 patients should ideally be formulated in terms of behavioral actions related to weight management rather than in terms of pounds or kilos. For HbA1c, a medium effect size was found, both in the short and the longer term, a finding that corresponds with the effect sizes found for HbA1c in some other meta-analyses¹⁵⁻¹⁶.

With regard to the second research question, self-regulation principles seem to act as a moderator of outcome effects. A moderating effect of the total amount of self-regulation principles integrated in an intervention was found for both weight and HbA1c. This moderating effect was stronger for HbA1c than for weight outcomes. With respect to specific self-regulation principles it was found that 'goal reformulation' moderated weight loss effects and 'emotion regulation' moderated the effect on HbA1c outcomes. The moderating effect of 'goal reformulation' is in line with the results of studies showing that trying to achieve unrealistic

weight loss goals is related to goal disengagement⁵⁰ and low compliance to surgical aftercare in bariatric surgery patients⁵¹. In general, goal adjustment has been found to be an important mechanism in the self-regulation of health outcomes⁵²⁻⁵³. The finding that 'emotional control' moderates intervention effects on HbA1c corresponds with findings indicating that emotions play a key role in the self-management of diabetes⁵⁴⁻⁵⁵. Whittemore and colleagues⁵⁶ demonstrated that fear of diabetes complications and concerns over health are important emotions in many type 2 diabetes patients. Van der Ven and colleagues⁵⁷ suggested the use of cognitive-behavioral strategies to reduce negative emotions and thus enhance diabetes self-care behaviors and glycemic outcomes, including HbA1c.

Moderating trends were found for 'discussing competing goals', 'positive reinforcement' and 'anticipatory coping' on both weight and HbA1c outcomes. A moderating trend of 'relapse prevention' was found for HbA1c. All moderating trends of self-regulation principles were stronger for HbA1c than for weight outcomes. A negative moderating trend of 'planning' was found for weight outcomes. From a theoretical point of view, 'planning' is only expected to be beneficial in the initial phase (short term) of behaviour change, and no longer in the long term. The moderator analyses in the present study could not be conducted for the short term and the longer term separately, but only for the longest available term, which may have been responsible for this unexpected result.

With regard to the third research question concerning a moderating effect of other intervention characteristics, only the inclusion of a patient's partner or relative in the intervention proved to have a moderator effect on weight. With the exception of the meta-analysis by Gary and colleagues¹⁵, none of the previous meta-analyses was able to detect moderating influences of intervention characteristics on weight or HbA1c outcomes. Gary and colleagues¹⁵ did find that interventions focusing on exercise generated larger effects on HbA1c (glycohemoglobin) than interventions focusing on diet. This finding could, however, not be confirmed by the present meta-analysis.

Some limitations of the present meta-analysis should be taken into account when interpreting the results. First, no unpublished studies were included in the meta-analysis. Despite our efforts to obtain unpublished studies from experts in the field, none of the experts was able to provide us with extra unpublished data. Second, although there were some exceptions to the rule, most studies did not clearly describe the theoretical background and content of the intervention that was used, which sometimes hampered the categorization of intervention characteristics and moderator variables.

Nonetheless, the results of the moderator analyses clearly indicate that self-regulation principles are potentially powerful ingredients of interventions targeted at weight loss and a decrease in HbA1c in diabetes patients. The fact that self-regulation principles moderate the effect on weight and HbA1c in diabetes patients, suggests the development of a diabetes self-regulation intervention that integrates as many self-regulation principles as possible. Evaluation of a comprehensive self-regulation intervention in a randomized controlled trial, can increase our knowledge on the effectiveness of self-regulation principles in diabetes care.

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3

Goal Planning and Diabetes Self-Efficacy Determine Weight Regulating Behavior in Patients with Type 2 Diabetes

A version of this chapter was submitted for publication (Huisman, Maes, De Gucht, Chatrou, Haak)

Abstract

This study examined the relationships between motivational cognitions (goal ownership, goal support, goal pressure, goal planning), diabetes self-efficacy and weight regulating behavior in a sample of 96 overweight patients with type 2 diabetes.

A series of regression analyses was performed to examine the relationships between these cognitions, diabetes self-efficacy and weight regulating behavior. An empirically derived path model was then constructed on the basis of these regression analyses.

Results showed that goal planning predicted both diabetes self-efficacy and weight regulating behavior. The relationship between goal planning and weight regulating behavior appeared to be mediated by diabetes self-efficacy. No direct effects of goal ownership, goal support or goal pressure on either diabetes self-efficacy or weight regulating behavior were found.

Although these findings must be confirmed by future research, the results suggest that goal planning and self-efficacy enhancement could be important intervention components of diabetes programs aiming at weight regulating behavior.

Introduction

Since 90% of the patients with type 2 diabetes is overweight ¹ (BMI > 25), weight reduction is an essential step in the treatment of type 2 diabetes ². Weight loss improves the insulin absorption and can lower high blood glucose levels which are responsible for many complications in diabetes patients. A 5 to 10% weight loss can lead to a strong improvement in blood glucose levels and thereby reduce the risk of serious complications, such as cardiovascular diseases, retinopathy, or nephropathy ³⁻⁴. As a consequence, diet and exercise became an important target of treatment of patients with type 2 diabetes. Understanding why diabetes patients do or don't perform self-management behaviors has been given a crucial role in diabetes care. Therefore psychological theories on human motivation and behavior change have been increasingly applied to the field of diabetes care throughout the years ⁵.

Self-regulation in diabetes care

Self-regulation theory provides a theory-based framework from which practical guidelines for interventions and specific working mechanisms for behavior change can be derived ⁶. Self-regulation theory argues that most human behaviour is goal-directed ⁷⁻⁸ and that goals can be defined as thoughts about desired states or outcomes ⁸. The achievement of a goal is facilitated by self-regulatory processes or mechanisms such as goal setting, goal monitoring, planning, problem solving and emotion regulation ⁶. These goal processes or mechanisms can be divided into three phases ⁹⁻¹⁰. In the motivational phase, cognitive determinants of intention (goal ownership and goal planning) are believed to play a key role. Persons who strive for goals which are personally relevant and important (autonomous goals) are more likely to attain their goal ¹¹⁻¹³. A study by Williams, Grow, Freedman, Ryan and Deci ¹⁴ showed that individuals who pursued autonomously set weight loss goals, attended a weight loss program more regularly and lost more weight during the weight loss program, and at follow-up.

Self-regulation theory also considers the support one perceives in the (planned) achievement of a goal. Many previous studies have demonstrated the importance of perceived social support in the achievement of behavioral changes ¹⁵⁻¹⁶. Within the context of diabetes self-management social support has been associated with diet and physical exercise ¹⁷⁻¹⁸. Negative consequences of social support on self-management, however, have also been found, when support is perceived as pressure or overprotection ¹⁹.

The importance of goal planning for the engagement in specific behaviours was acknowledged for several health behaviours ²⁰⁻²² including diabetes self-care behaviours, such as diet ²³⁻²⁴ and

physical exercise ²⁵. In general, it can be concluded that the facilitation of these goal cognitions contribute to goal achievement.

Self-regulation cognitions and self-efficacy

Although self-regulation theory postulates direct effects of self-regulatory cognitions on various health behaviors, it is also strongly suggested that self-efficacy plays an important role in the relationship between self-regulation cognitions and the achievement of a health goal. In his social cognitive model Bandura ²⁶ states that both self-efficacy and self-regulatory mechanisms facilitate the achievement of a (health) goal. The interplay of self-regulatory cognitions and self-efficacy as predictors of diabetes goal achievement was tested by Sénécal, Nouwen and White ²⁷. It was hypothesized that the effect of autonomous regulation (goal ownership) on diabetes self-care behaviors and life satisfaction would be mediated by self-efficacy beliefs. Results from this study pointed to the complementary nature of autonomous regulation and self-efficacy both of which appeared to make independent contributions to the prediction of dietary self-care and life satisfaction. However, self-efficacy was a significantly better predictor of self-reported dietary self-care than was autonomous regulation. Sénécal, Nouwen and White ²⁷ proposed a motivational model of diabetes dietary self-care “which postulates direct links between autonomous regulation and self-efficacy on the one hand and dietary adherence on the other”. In line with Sénécal, Nouwen and White ²⁷, the present study explores the direct and indirect relationships between self-regulation cognitions, self-efficacy and diabetes related health behaviour. More specifically this study will investigate the relationships between autonomous regulation (goal ownership), goal support, goal pressure, goal planning, diabetes self-efficacy (SE) and weight regulating behavior in a sample of overweight patients with type 2 diabetes.

Research Questions

The specific research questions that were formulated for this paper were:

- 1) Is there a relationship between self-regulation cognitions (goal ownership, goal planning, perceived goal support, perceived goal pressure) and weight regulating behavior (fat consumption and exercise behavior)?
- 2) If there is a relationship between self-regulation cognitions and weight regulating behavior, is this relationship mediated by diabetes self-efficacy?

Methods

Subjects

The sample consisted of 129 patients with type 2 diabetes from the diabetes clinic of a large general hospital in the Netherlands. Patients were included in the study on the basis of the following criteria: having diabetes type II according to the WHO classification 1999 ²⁸: fasting blood glucose levels > 126 mg/dl (7mmol/l) or levels > 200 mg/dl (11.1 mmol/l) two hours after an oral glucose tolerance test, BMI 27-45, age between 21 and 70 years old, being Caucasian, being able to understand, read and write Dutch. Patients with any severe somatic co-morbidity (except for cardiovascular diseases) and patients who were currently under treatment for a mental disorder were excluded from the study. In total 101 patients returned the baseline questionnaire. Due to the incompleteness of the responses of five patients, a final number of 96 patients was included in the analyses

Measurements

Patients' self-regulation cognitions were measured by two subscales of the Self-Regulation Skills Battery (SRSB) ²⁹ and two subscales of the validated 71-item Goal and Processes Inventory (GAPI) ³⁰. The subscales that were included in this study corresponded with the motivational phase of goal achievement in which patients have only recently formulated their (health) goal. Both the SRSB 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 disagree – totally agree). The motivational subscales of the SRSB are 'goal ownership' (Cronbach's $\alpha = .65$, 5 items, e.g. 'This is really my own goal'), and 'goal planning' (Cronbach's $\alpha = .73$, 4 items, e.g. 'I have a detailed step-by-step plan to help me attain this goal'). The two GAPI-subsubscales that were added were 'goal support' (Cronbach's $\alpha = .80$, 7 items, e.g. 'My partner supports me in the pursuit of this goal') and 'goal pressure' (Cronbach's $\alpha = .70$, 7 items, e.g. 'My partner puts pressure on me to attain this goal').

Weight regulating behaviour was assessed by means of a short self-report questionnaire. This self-report questionnaire assessed fat consumption (2 items) and physical exercise (1 item) during the past 7 days. The items for fat consumption were 'How many days in the past week did you control your fat consumption?' and 'How many days in the past week did you eat products that were high in fat (examples given)?'. The item for physical exercise was 'How many days in the past week did you engage in physical exercise for at least 30 minutes per day?'. Answers to these questions could be indicated on an 8-point scale (0 days – 7 days). The compound

variable 'weight regulating behaviour' was calculated by calculating an average score for these 3 items.

Diabetes related self-efficacy (SE) was measured by a Dutch version of the validated Diabetes Management Self-Efficacy Scale ³⁰. The DMSES consists of 20 items (e.g. 'I am able to take more exercise when the doctor advises me to') that assess self-efficacy with respect to diabetes self-management. A 10-point Likert scale (absolutely not able – I'm totally able) was used. The reliability of the DMSES was good (Cronbach α = .86).

Statistical Analyses

Analyses were conducted using SPSS 13.0 (2005) ³². Descriptive analyses (frequencies, averages and standard deviations) were conducted to describe baseline characteristics of study participants. Pearson correlation coefficients were used to examine the relationships between the various subscales and variables. Correlations were inspected for multicollinearity, but no multicollinear correlations were found.

In a series of hierarchical regression analyses the relationships between motivational self-regulation mechanisms, diabetes self-efficacy and weight regulating behaviour were explored. In all regression analyses, the effect of the independent variables was controlled for age and gender.

Results

Baseline demographics

The average age of participants was 58.14 years (SD = 8.86). Fifty-two percent of participants was female. Thirty-nine percent of participants was employed. Most participants were married or living together with a partner (83%) and had received lower primary or secondary vocational education (59%).

Bivariate relationships between variables in the study

Pearson correlation coefficients were used to test the bivariate relationships between the variables in this study. In table 1 the correlation coefficients and their levels of significance are presented. Goal ownership was positively related to goal support indicating that people who perceive weight loss as their own goal also perceive more support in (the pursuit of) this goal. Goal planning was positively related to weight regulating behavior and negatively related to goal pressure. The positive relationship between goal planning and weight regulating behavior indicates that people who use more planning strategies in the pursuit of their weight goal report

better weight regulating behavior. The negative relationship between goal planning and goal pressure indicates that people who are pressured in the pursuit of their weight goal use less planning strategies. As was expected, goal support was negatively related to goal pressure. Goal pressure was negatively related to gender indicating that women experience more goal pressure than men. Diabetes self-efficacy was positively related to goal planning, goal support and weight regulating behavior indicating that people who feel efficacious about the self-management of their diabetes perceive more support in (the pursuit of) their weight loss goal, use more planning strategies in the pursuit of this goal and report better weight regulating behavior. Furthermore diabetes self-efficacy was positively related to age, indicating that older people feel more efficacious about their diabetes self-management than younger people. Gender was positively related to weight regulating behavior indicating that women report better weight regulating behaviors than men.

Table 1. Pearson correlation coefficients of study variables (N = 96)

	1	2	3	4	5	6	7	8
1. Goal Ownership	-							
2. Goal Planning	.134	-						
3. Goal Support	.279*	.165	-					
4. Goal Pressure	-.205	-.226*	-.392**	-				
5. Weight Regulation	.167	.317**	.213	-.217*	-			
6. Diabetes SE	.200	.392**	.234*	-.142	.338**	-		
7. Age	-.025	.118	-.028	-.010	.266**	.245*	-	
8. Gender	-.081	.107	.107	-.344**	.208*	.113	-.014	-

** p < .01, * p < .05 (two-tailed)

To test whether self-regulation cognitions determined weight regulating behavior, a hierarchical regression analysis of weight regulating behavior on self-regulation cognitions was performed. This regression analysis, which controlled for age and gender, revealed that age and goal planning are significant determinants of weight regulating behavior indicating that older patients and patients who use more planning strategies report better weight regulating behaviors. The total model of weight regulating behavior on self-regulation cognitions (controlled for age and gender) was significant [$F(6, 75) = 3.64, p = .003, R^2 = .225$] (see table 2).

Table 2. Total Regression Model of Weight Regulating Behavior on Self-Regulation Cognitions

Model		β	t	Sig.
1				
	Gender	.212	2.004	.048
	Age	.269	2.537	.013
2				
	Gender	.173	1.575	.119
	Age	.247	2.410	.018
	Goal ownership	.118	1.086	.281
	Goal planning	.226	2.136	.036
	Goal Support	.118	1.036	.303
	Goal Pressure	-.033	-.277	.782

To explore whether the relationship between goal planning and weight regulating behavior was mediated by diabetes self-efficacy (research question 2) additional hierarchical regression analyses were performed according to Baron and Kenny's four step approach³³. To test whether goal planning alone (controlled for age and gender) determined weight regulating behavior (Path C) a hierarchical regression analysis of weight regulating behavior on goal planning (without the other self-regulation cognitions) was performed. This analysis also revealed a positive relationship ($\beta=.272$, $t = 2.810$, $p = .007$) between goal planning and weight regulating behavior. The total model of weight regulating behavior on goal planning (controlled for age and gender) was significant [$F(3,88) = 6.74$, $p = .000$, $R^2 = .186$].

To test whether goal planning determined diabetes self-efficacy, a second hierarchical regression analysis of diabetes self-efficacy on goal planning (controlled for age and gender) was performed (path A). This regression analysis revealed a significant relationship between age and diabetes self-efficacy ($\beta=.204$, $t = 2.063$, $p=.042$) and goal planning and diabetes self-efficacy ($\beta=.359$, $t = 3.611$, $p=.001$) indicating that older patients and patients who use more goal planning strategies have more confidence in their diabetes self-care. The total model of goal planning as determinant of diabetes self-efficacy (controlled for age and gender) was significant [$F(3,83) = 6.90$, $p = .000$, $R^2 = .200$].

In the third step it was tested whether diabetes self-efficacy determined weight regulating behavior. A hierarchical regression analysis of weight regulating behavior on diabetes self-efficacy revealed a significant relationship between age and weight regulating behavior ($\beta=.202$, $t = 2.008$, $p=.048$) and diabetes self-efficacy and weight regulating behavior ($\beta=.268$, $t = 2.647$, $p=.010$) (controlled for age and gender), indicating that patients with more confidence in diabetes self-care report better weight regulating behavior. The total model of weight regulating

behavior on diabetes self-efficacy, controlled for age and gender was significant [$F(3, 86) = 6.38, p = .001, R^2 = .182$].

To check whether self-efficacy was a mediator between goal planning and weight regulating behavior (Path C') or had the same independent determinants as weight regulating behavior, we performed a final multiple regression analysis with weight regulating behavior as outcome and goal planning and self-efficacy as predictor variables (controlled for age and gender). This analysis showed that the regression coefficient of goal planning for determining weight regulating behavior became non-significant ($\beta = .182, p = .100$) when included together with diabetes self-efficacy in the regression analysis. Self-efficacy is thus a mediator between goal planning and weight regulating behavior³³. Figure 1 and 2 represent the two empirically derived path models that were constructed on the basis of these series of regression analyses.

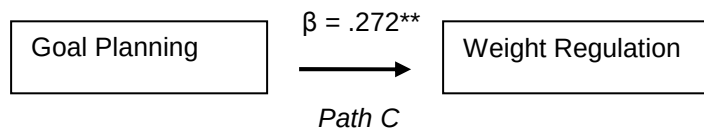


Fig. 1. Empirically Derived Path Model of Relationship between Goal Planning and Weight Regulation (controlled for age and gender), ** $p < .01$

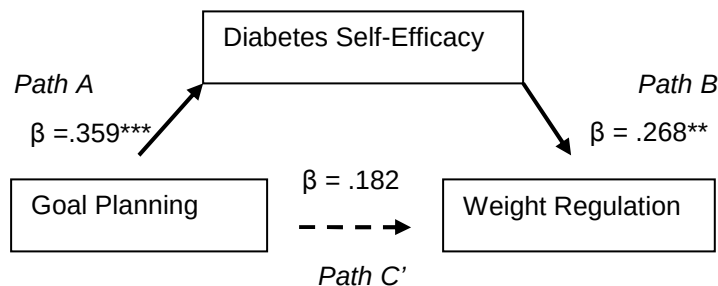


Fig. 2. Empirically Derived Path Model of Relationships between Goal Planning, Diabetes Self-Efficacy and Weight Regulation (controlled for age and gender), ** $p < .01$, *** $p < .001$

Conclusion and Discussion

This study explored the relationship between goal ownership, goal support, goal pressure, goal planning, diabetes self-efficacy and weight regulating behavior.

When interpreting the series of regression analyses that were conducted, it can be concluded that weight regulating behavior is determined by both goal planning and diabetes self-efficacy and that diabetes self-efficacy functions as a mediator in the relationship between goal planning and weight regulating behavior. No effects of goal ownership, goal support or goal pressure on diabetes self-efficacy or weight regulating behavior were found.

As was mentioned before, part of the results of this study is in line with the results of previous studies that indicated that goal planning and self-efficacy are important determinants of health behavior^{20-22, 34-35} and diabetes weight related behaviors specifically^{23-25, 36}. Furthermore, our results are in line with the findings of the study of Sénécal, Nouwen and White²⁷ as no direct effect of goal ownership on behavioral diabetes outcomes was found. The results of this study, however, differ from the study of Sénécal, Nouwen and White²⁷ in this respect that in the study of Sénécal, Nouwen and White²⁷ no mediating role of diabetes self-efficacy was found as self-efficacy appeared to be the predominant predictor of diabetes dietary behavior. In our study, goal planning predicts (diabetes) weight regulating behavior whereas autonomous regulation (goal ownership) does not. One of the reasons for this difference may be that autonomous regulation or ownership is more a personal characteristic, while planning is a skill that has already proven to bridge the gap between motivation and actions³⁷. However, diabetes self-efficacy or having confidence in one's ability to perform general diabetes self-care behaviors (using insulin, engaging in physical exercise) completely mediates the relation between planning and weight regulating behavior. These results indicate that diabetes self-efficacy is the most proximal predictor of actual behavior change, that is in turn influenced by planning strategies.

Although our study points at the importance of goal planning and diabetes self-efficacy for future diabetes weight regulating interventions, it is important to keep in mind the study limitations when interpreting the results.

A first limitation concerns the use of self-report measures for nutrition and exercise in this study. Using pedometers to register exercise could e.g. increase the reliability and validity of exercise measures in future studies. Future, longitudinal research could also relate goal planning and diabetes self-efficacy to other diabetes outcomes, such as HbA1c, cholesterol or weight. The use of biomedical instead of behavioral self-report outcomes would increase the objectivity of behavior change and decrease the chances of response bias that are known to influence self-report measures.

A second limitation concerns the congruence of the goal cognitions and the self-efficacy measures as the self-regulation cognitions (goal ownership, goal planning, perceived goal support, perceived goal pressure) are measured in relation to weight regulating behavior, while diabetes self-efficacy regards a larger scope of self-management behavior. In future studies it should be explored whether the (in)congruence of the goal and self-efficacy measures influences the relationship between these measures.

Another final limitation concerns the cross-sectional design of this study that prohibits any conclusions about causal relationships. For this reason, the directions and predictions that were found in this study need to be interpreted with care. Repeated measures are needed to make more reliable conclusions about the interrelations between self-regulation cognitions and self-efficacy and their relationship with diabetes self-care outcomes.

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4

Self-Regulation and Weight Reduction in Patients with Type 2 Diabetes: A Pilot Intervention Study

A version of this chapter was accepted for publication in *Patient Education and Counseling*
(Huisman, De Gucht, Maes, Schroevers, Chatrou, Haak)

Abstract

The objective of this study was 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).

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, standard deviation = 8.86).

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.

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.

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

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.

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?

Methods

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. Figure 1 represents a flow chart of the inclusion and allocation of patients to the three treatment groups. Figure 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.

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.

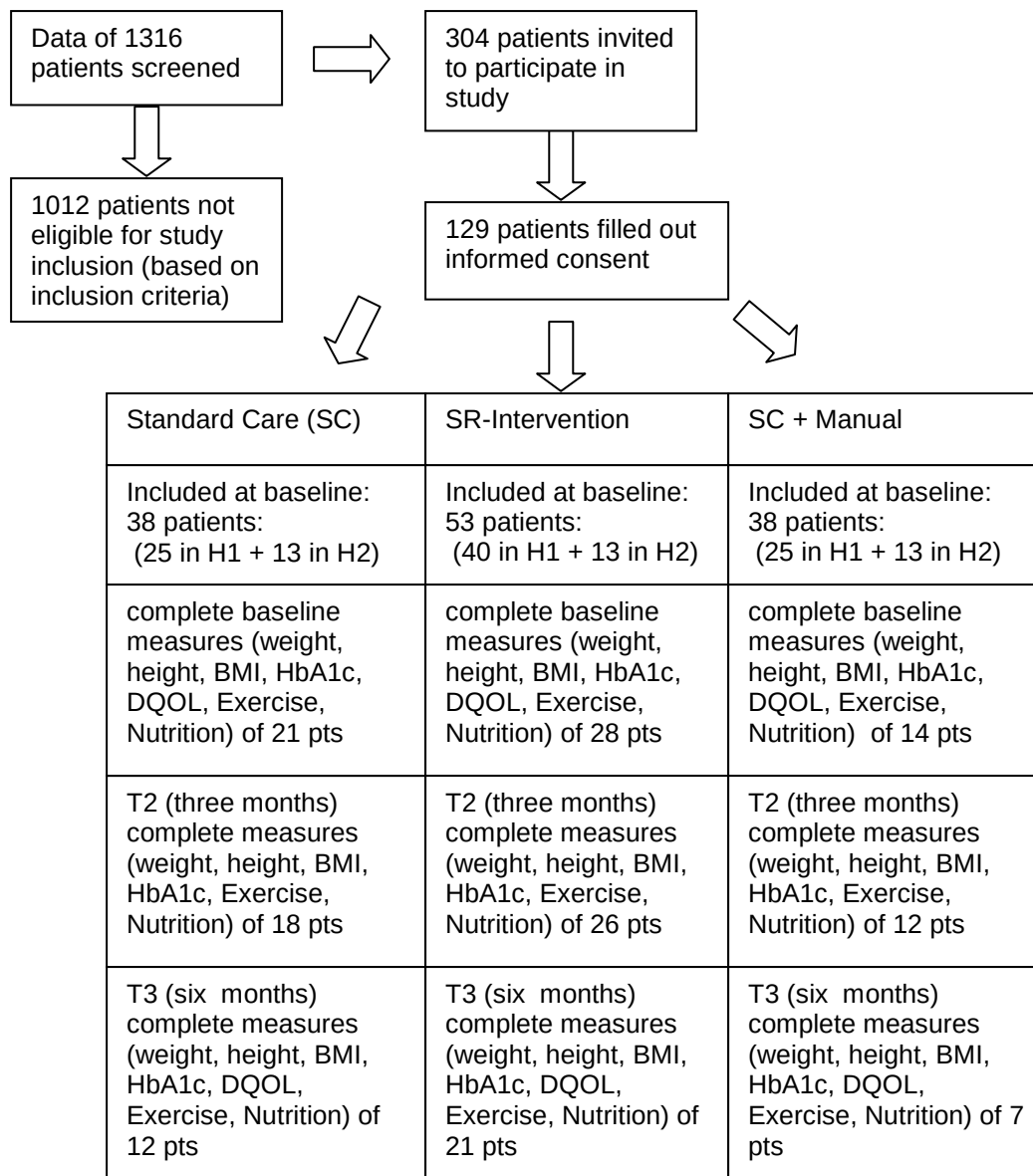


Figure 1. Flow Chart of Study Inclusion, Randomization and Attrition

H = hospital, BMI = Body Mass Index (kg/m²), HbA1c = glycosylated hemoglobin in %, DQOL = Diabetes Quality of Life, pts = patients

The self-regulatory weight reduction intervention consisted of:

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

a) Motivational Interview

To create weight reduction goals that were of personal importance, all patients in the intervention group were invited for an individual 1-hour 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.

b) 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-hour 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, stress). The sometimes abstract and complex self-regulation mechanisms and stages were translated into four concrete and practical steps: 1) Look at your current behaviour (goal setting, self-monitoring) 2) Choose a realistic goal (goal setting) and prepare for action (anticipatory coping, planning), 3) Act towards goal achievement (feedback, self-reinforcement, attention and emotion control, 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 following the four steps, and the patients were in turn stimulated to ask for social support and to share goal progress.

c) Diabetes self-regulation workbook

A diabetes self-regulation workbook, based on the self-regulation principles formulated by Maes and Karoly⁹ 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.

d) 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 multidisciplinary 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 twelve-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.

Primary Outcomes

The following data were collected at baseline, T2 and T3: weight (kg), height (meters) and glycosylated hemoglobin (HbA1c in %). Body mass index (BMI; kg/m²) was calculated from weight and height data by dividing weight (kg) by the square of height (meters). 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.

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 5-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 behaviour was assessed with a 7-item questionnaire regarding the frequency of six nutrition behaviours 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 products that were high in fat (examples given)?' 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 8-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 8-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 5-point Likert scale to what extent they agree with the statement (totally disagree – totally agree). The internal item consistency (Cronbach's α) 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 α = .61, 5 items, e.g. 'This is really my own goal'), 'goal efficacy' (Cronbach's α = .80, 4 items, e.g. 'I have the ability to reach this goal'), 'goal planning' (Cronbach's α = .81, 4 items, e.g. 'I have a detailed step-by-step plan to help me attain this goal'), 'help seeking' (Cronbach's α = .74, 4 items, e.g. 'I like others to support me in attaining this goal'), 'social comparison' (Cronbach's α = .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 α = .74, 6 items, e.g. 'I keep track of my overall progress toward this goal'), 'self-criticism' (Cronbach's α = .87, 5 items, e.g. 'I routinely criticize myself for unsatisfactory work on this goal'), 'self-reward' (Cronbach's α = .86, 5 items, e.g. 'I reward myself when I make progress toward this goal'), 'attention control' (Cronbach's α = .71, 4 items, e.g. 'I do not allow other things to distract me from this goal'), 'self-efficacy enhancement' (Cronbach's α = .71, 4 items, e.g. 'I like to learn from others, who know how to attain this goal') and finally 'emotion control' (Cronbach's α = .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.

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).

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. Pearson correlations were calculated for all self-regulation variables. Additional ANCOVA's and Chi Squares 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.

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. Appendix 3 represents the Pearson correlations of all self-regulatory variables.

Table 1. Baseline Characteristics

	Standard Care		SR-Intervention		Standard Care + Manual	
	N	M (SD)	N	M (SD)	N	M (SD)
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, SD = Standard Deviation

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).

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 (SD)	N	M (SD)	N	M (SD)
<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	3.63 (2.64)	42	4.38 (2.40)	23	5.30 (2.27)*
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)

Table 2 Continued

Variable	Standard Care		SR-Intervention		Standard Care + Manual	
	N	M (SD)	N	M (SD)	N	M (SD)
<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)

* $p < .05$, N = number of subjects in analysis, M = Mean, SD = Standard Deviation, BMI = Body Mass Index (kg/m²), HbA1c = glycosylated hemoglobin in %, DQOL = Diabetes Quality of Life

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 squared = .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 squared = .082].

Process Evaluation

At the end of the last group meeting, patients in the intervention group filled out an anonymous evaluation form. Table 3 summarizes the results of this evaluation. Patients rated the group meetings as very useful (Mean = 8.52, SD = 1.03), and indicated that the group meetings changed their nutrition and exercise patterns (Mean = 7.10, SD = 1.85). Most appreciated topics within the group meetings were 'being aware of your lifestyle' (Mean = 8.13, SD = 1.02), 'diabetes and exercise' (Mean = 7.94, SD = 1.41), and 'emotions' (Mean = 7.59, SD = 1.48). The least appreciated topics was 'self-reinforcement' (Mean = 6.48, SD = 2.06). The motivational interview, held two weeks before the first group meeting, was seen as beneficial (Mean = 7.77,

SD = 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, SD = 1.97). Group size, 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%).

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

	Mean	SD
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

SD = Standard Deviation

Discussion and Conclusion

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 maintain⁵⁻⁷. These findings,

however, are in contrast to the promising findings of another self-regulation based intervention²⁶ 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 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 results²⁷⁻²⁹.

Second, previous self-regulation intervention studies³⁰⁻³¹ that effectively changed health behaviors and medical outcomes in patients with type 2 diabetes, focused specifically on patients who had been diagnosed 3 to 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 regulators³⁴. 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 (six 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.

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, 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.

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.

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5

Lack of autonomous regulation predicts attrition from a weight intervention study in overweight patients with type 2 diabetes

A version of this chapter was submitted for publication (Huisman, Maes, De Gucht, Chatrou, Haak)

Abstract

The objective of this study was to examine predictors of drop-out from a weight reduction study in patients with type 2 diabetes. A clinical trial was conducted with 101 overweight (BMI > 27) patients with type 2 diabetes.

Patients were randomly assigned to a self-regulation intervention, an active control group, and a passive control group. Somatic, socio-demographic, psychological, and life-style variables were examined as predictors of drop-out from baseline to 6 months follow-up. Multiple logistic regression analysis indicated that autonomous regulation or 'goal ownership' was the best predictor of drop-out. It is suggested that the assessment of autonomous regulation prior to a weight reduction intervention could identify patients who are sufficiently motivated to participate. Patients who score low on 'goal ownership' may be offered pretreatment interventions to increase their motivation.

Introduction

Drop-out is a major cause of failure in weight reduction of obese patients ¹. A review on attrition ² showed that about one third drops out of weight loss programs and that psychological variables are important predictors of attrition. Recent studies ^{1, 3-5} confirmed the importance of psychological predictors such as emotional distress, lack of self-efficacy, high treatment expectations, and lack of motivation. These concepts are however diverse. To further improve attrition research Davis and Addis ² therefore recommended to focus on theoretically grounded psychological and treatment variables.

Self-regulation (S-R) or goal theory provides a framework for differentiation between relevant motivational cognitions. S-R theory states that human actions are goal-oriented, and that goal pursuit and attainment are more likely if goals are personally relevant (autonomous or own goals), if individuals feel competent to attain them (goal-efficacy), receive the necessary social support (goal support) and have an adequate plan for goal attainment (goal planning) ⁶. Several studies have shown that autonomous regulation (goal ownership) is associated with lifestyle changes, medical adherence and disease outcome in various patient groups, including diabetes ⁷⁻⁹. Self-efficacy was associated with diet and exercise in diabetic patients ¹⁰ and with BMI in a diabetes prevention program ¹¹. Goal support has been associated with better diabetes regulation ¹², increased physical activity ¹³ and weight loss ¹⁴. Goal planning proved to be related to diabetes self-care and weight-related behaviours, such as diet ¹⁵⁻¹⁶ and physical exercise ¹⁷.

These S-R variables have thus been proven to be predictors of treatment success, but they have seldom been used as potential predictors of attrition. The aim of this study is therefore to examine whether S-R variables predict attrition from a weight reduction intervention in patients with type 2 diabetes, next to socio-economic (age, gender, educational level, having a partner and hours of employment), somatic (BMI, Waist, HbA1c), distress and lifestyle (eating habits, physical activity) variables.

Methods

At baseline (T1), a total of 129 adult overweight (BMI 27 - 45) patients with type 2 diabetes were included in the study. Only 101 patients, however, returned their baseline questionnaire. All patients were randomly assigned to a) a self-regulatory weight reduction intervention in addition to standard care, or b) an active control condition consisting of a self-help diabetes lifestyle manual in addition to standard care and c) a passive control condition consisting of standard care for diabetes type 2. Data were taken at T1 and 6 months later (T2). Details of the study design have been described elsewhere ¹⁸.

Psychosocial measures were S-R cognitions (goal ownership, goal efficacy, goal support and goal planning) ¹⁹, diabetes distress ²⁰ and diabetes self-efficacy ²¹, all with good reliability and validity estimates. Bio-medical measures included weight, BMI, waist circumference and glycemic control (HbA1c). Lifestyle measures were self-reported nutrition and exercise behavior assessed with 8 items regarding the frequency of various nutrition and exercise behaviors within the past week.

Results

For power reasons, the active and passive condition formed one control group in the analyses. Of the 101 patients participating at T1, 34 patients (35%) dropped-out at T2. ANCOVA's (HbA1c, demographic variables, Diabetes Self-Efficacy, Diabetes Distress) and MANCOVA's (BMI and Waist, Goal related variables, Lifestyle variables) (Table 1) indicated that study non-completers were employed for more hours [$t(98) = -1.98, p = .050$] and scored lower on 'goal ownership' [$t(94) = 11.53, p < .000$], 'goal support' [$t(88) = 5.99, p = .000$] and 'diabetes self-efficacy' [$t(90) = 2.55, p = .013$]. Interestingly, study non-completers scored higher on 'goal planning' [$t(89) = -2.99, p = .004$] than study completers.

These significant variables were entered, together with the dichotomous variable 'allocated to intervention or control group' in a multiple logistic regression analysis to predict drop-out at T2. The first step of the regression analysis controlled for possible 'gender' and/or 'age' differences. 'Goal ownership' appeared to be the only significant predictor of attrition [OR = .138, 95% CI (.038-.510), $p = .003$]. Table 2 presents the univariate pearson correlation coefficients of the study variables. Table 3 presents the results of the multiple logistic regression analysis.

Table 1. Baseline Characteristics (Means and Standard Deviations) of study completers and noncompleters

	Overall		Intervention Group		Control Group	
	Completers	Noncompleters	Completers	Noncompleters	Completers	Noncompleters
<u>Somatic variables</u>						
BMI (kg/m ²)	34,62 (5,27) N=57	36,24 (5,51) N=31	35,01 (6,17) N=26	37,09 (5,46) N=7	34,29 (4,47) N=31	36,00 (5,62) N=24
Waist (cm)	117,42 (11,52) N=56	118,98 (12,15) N=32	120,17 (13,63) N=26	116,43 (10,86) N=7	115,03 (8,88) N=30	119,70 (12,61) N=25
HbA1c (%)	7,26 (1,07) N=56	7,57 (0,86) N=30	7,39 (1,25) N=26	7,07 (0,77) N=6	7,15 (0,89) N=30	7,70 (0,85) N=24
<u>Socioeconomic variables</u>						
Age (y)	59,21 (7,40) N=61	56,67 (10,23) N=36	60,71 (6,55) N=31	57,67 (8,78) N=9	57,67 (7,99) N=30	56,33 (10,80) N=27
Gender (m/f)	28/33	20/19	16/15	6/4	12/18	14/15
Having a Partner (yes/no)	52/9	31/8	26/5	7/3	26/4	24/5
Educ.Lev. (high/low-med)	14/46	8/31	9/21	2/8	5/25	6/23
Hours of Employment	8,07 (15,56)* N=61	14,87 (18,46) N=39	6,52 (14,04) N=31	12,90 (17,39) N=10	9,67 (17,08) N=30	15,55 (19,07) N=29
<u>Psychological variables</u>						
Goal Ownership	4,06 (0,64)*** N=59	2,18 (0,95) N=37	4,09 (0,59)*** N=30	2,61 (1,11) N=9	4,02 (0,70)*** N=29	2,04 (0,87) N=28
Goal Planning	3,20 (0,68)** N=57	3,70 (0,90) N=34	3,25 (0,60) N=31	3,68 (1,10) N=9	3,16 (0,76)* N=29	3,71 (0,83) N=25
Goal Efficacy	3,41 (0,56) N=60	3,50 (0,66) N=37	3,44 (0,58) N=31	3,50 (0,70) N=9	3,39 (0,55) N=29	3,50 (0,66) N=28
Goal Support	3,17 (0,40)*** N=54	2,24 (1,03) N=36	3,12 (0,42)** N=27	2,41 (0,85) N=9	3,22 (0,39)*** N=27	2,18 (1,09) N=27
Diabetes Self-Efficacy	7,56 (1,08)* N=57	6,65 (2,32) N=35	7,44 (1,09) N=28	7,56 (2,21) N=7	7,66 (1,06)* N=29	6,42 (2,33) N=28
Diabetes Distress (PAID)	38,07 (13,14) N=56	37,00 (12,54) N=33	36,79 (13,11) N=28	40,00 (13,31) N=9	39,36 (13,28) N=28	35,88 (12,34) N=24
<u>Lifestyle variables</u>						
Healthy eating	5,21 (1,23) N=57	4,87 (1,26) N=34	5,15 (1,21) N=28	5,06 (1,28) N=8	5,27 (1,26) N=29	4,81 (1,27) N=26
Unhealthy eating	2,93 (1,24) N=58	3,32 (1,35) N=30	3,17 (1,24) N=29	3,00 (1,36) N=8	2,69 (1,21)* N=29	3,43 (1,37) N=22
Average Days with > 30 min. Physical Activity	4,69 (2,39) N=61	3,65 (2,63) N=37	4,71 (2,38) N=31	3,67 (2,18) N=9	4,67 (2,44) N=30	3,64 (2,79) N=28

* $p < .05$, ** $p < .01$, *** $p < .001$

Table 2. Pearson Correlation Coefficients of Study Variables ->

	1	2	3	4	5	6	7	8
1. BMI	-							
2. Waist	.809**	-						
3. HbA1c	.182	.289**	-					
4. Age	-.175	-.166	-.265*	-				
5. Gender	.303**	-.004	.095	-.018	-			
6. Relationship	.091	.114	-.107	-.084	.062	-		
7. Educational level	-.230*	-.054	-.125	.005	-.319**	.014	-	
8. Hours of Employment	.067	-.087	.167	-.384	-.315**	.052	.223*	-
9. Goal Ownership	-.128	-.070	-.163	.224	-.048	-.082	.140	-.143
10. Goal planning	.031	.021	.283*	-.103	-.012	-.034	-.256*	-.002
11. Goal efficacy	-.161	-.118	.032	-.066	.042	.019	.109	.051
12. Goal support	-.074	-.097	-.239*	.259*	.030	-.220*	.157	-.086
13. Diabetes SE	-.169	-.232*	.023	.248*	.101	-.027	-.006	-.204
14. PAID Distress	.163	.118	.003	-.079	.084	.035	-.124	.151
15. Healthy eating	-.039	-.160	-.118	.298**	.124	-.021	.039	-.254*
16. Unhealthy eating	.140	.208	-.028	.174	-.167	.261*	-.077	.087
17. Exercise	-.076	-.241*	.007	.177	.113	-.234*	-.107	-.250

* Correlation is significant at the 0.05 level (2-tailed).

** Correlation is significant at the 0.01 level (2-tailed).

Table 2. Continued

9	10	11	12	13	14	15	16	17
-								
-.393**	-							
-.093	.307**	-						
.656**	-.442**	-.163	-					
.289**	-.189	.165	.157	-				
-.020	-.105	-.285**	.017	-.303**	-			
.110	.083	-.030	.161	.091	-.142	-		
-.098	.173	-.041	-.123	-.058	-.099	.230*	-	
.196	.125	-.040	.229*	.297**	-.120	.244*	-.027	-

* Correlation is significant at the 0.05 level (2-tailed).

** Correlation is significant at the 0.01 level (2-tailed).

Table 3. Multiple Logistic Regression of Drop-Out

		B	Sig.
Step 1	Gender	.603	.487
	Age	.046	.408
Step 2	Employment	.031	.264
	Ownership	-2.005	.002
	Planning	-.430	.494
	Support	-1.080	.215
	Self-Efficacy	-.204	.564

Conclusions

The results indicate that study non-completers are best characterized on the basis of their S-R cognitions. Lack of autonomous regulation or 'goal ownership' appears to be the best predictor of drop-out over a 6-month time period. Patients who set or adopt weight loss as their own goal are thus less likely to drop out. Lack of goal ownership has already been associated with goal disengagement⁷⁻⁹, but, to the best of our knowledge, it has not yet been linked to drop-out from a (diabetes) weight loss intervention. It can therefore be suggested that assessment of autonomous regulation²² prior to a weight loss intervention could identify patients who are sufficiently motivated to take part in the intervention. Patients who score low on 'goal ownership' may be offered pre-treatment interventions, based on motivational interviewing and autonomy support to increase their personal motivation and commitment to treatment²³. Perceived autonomy supportiveness from diabetes care providers proved to increase patients' autonomous motivation and perceived competence, resulting in significant reductions in their HbA1c values over 12 months⁷. In addition, techniques to increase 'goal ownership' in overweight women with Non-Insulin Dependent Diabetes have been proven successful in increasing session attendance and improving glycemic control²⁴.

Due to the small sample size of this study, it is hard to generalize the findings. More research is needed to confirm the importance of self-regulation cognitions and skills as predictors of drop-out. Our findings point however at least at an important avenue, which merits to be explored further in future studies.

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6

General Discussion

Introduction

The central focus of this thesis was to examine the role of self-regulation principles in predicting and changing self-care behaviors of diabetes type 2 patients. Various psychosocial models have added to our general knowledge about diabetes cognitions, emotions and (health) behaviors, including models from a self-regulation perspective ^{1, 2}. Although these models clearly have improved our understanding of important psychosocial aspects of diabetes self-care, a systematic use of important mechanisms from all phases of self-regulation in diabetes self-care was not yet found. This thesis described the systematic use of the self-regulation principles ³ within a context of diabetes weight loss interventions.

The aim of this general discussion is to discuss the main findings of this thesis and to put them in a broader perspective. This chapter therefore starts with a summary of the main findings, followed by an attempt to integrate these findings from a theoretical, methodological and clinical perspective. Finally, recommendations for future research are made.

Summary of the main findings

The previous empirical chapters of this thesis described: a) the results of a self-regulation based meta-analysis on diabetes weight interventions b) the relationship between self-regulation cognitions, diabetes self-efficacy and weight regulating behavior, c) the short term results of a pilot self-regulation weight reduction intervention for overweight diabetes type 2 patients, and d) the results of an attrition study on self-regulatory predictors of drop-out from a weight loss intervention study. The orienting principles for self-regulation interventions of Maes and Karoly (2005) formed the theoretical background for all of these chapters. The next section summarizes the main findings of each empirical chapter.

Chapter 2

The meta-analysis explored the general effect of weight loss interventions for diabetes type 2 patients on weight and HbA1c as well as the additional effect of self-regulation principles and study characteristics in moderator analyses. Results confirmed the findings of previous meta-analyses ⁴⁻⁷ with regard to general low effect sizes for weight. Low effect sizes for weight were found in our meta-analysis for the short term (< 6 months). In the longer term these low effect size for weight decreased further. For HbA1c effect sizes were somewhat higher in the short term and remained fairly stable in the longer term. Results of the moderator analyses indicated that the total amount of self-regulation included in interventions increased the effect sizes for both weight and HbA1c. Furthermore 'Goal Reformulation' and 'Emotion Regulation' moderated

the effect sizes for weight and HbA1c respectively. These findings indicate that interventions that include self-regulation principles are more effective for weight loss and decreasing HbA1c than general weight loss interventions and that 'Goal Reformulation' and 'Emotion Regulation' might be important mechanisms in effectively changing weight and HbA1c respectively.

Chapter 3

Chapter 3 described the relationships between baseline self-regulation cognitions (goal ownership, goal planning, goal support and goal pressure), diabetes self-efficacy and weight regulating behavior. Goal planning was found to have direct effects on both diabetes self-efficacy and weight regulating behavior. However, this direct effect of goal planning on weight regulation disappeared when included in a regression analysis together with diabetes self-efficacy, indicating that diabetes self-efficacy is a mediator in the relationship between goal planning and weight regulating behavior. No direct or indirect effects of goal ownership or autonomy support (goal support or goal pressure) were found on diabetes self-efficacy or weight regulating behavior. Although the cross-sectional character of the study does not allow for any conclusion regarding causality, the results from this chapter underline the possible importance of self-regulation cognitions, specifically goal planning for diabetes self-care behaviors such as fat consumption and physical exercise.

Chapter 4

Chapter 4 described the development and first results of a pilot self-regulation weight reduction study. The effects of this self-regulation intervention were evaluated against standard care with and without a diabetes self-help manual. Contrary to our expectations, no differences were found between the intervention and control groups for medical outcomes or psychosocial outcomes three and six months after baseline. In additional analyses, the role of self-regulation for explaining weight and HbA1c in the total patient group was explored. No differences in weight were found between patients with many or only few self-regulation skills. However differences in HbA1c were found between patients with many self-regulation skills and patients with only few self-regulation skills after three (T1) and six months (T2). Patients with many self-regulation skills were found to have lower HbA1c-levels after three and six months. The results of this chapter indicate that it might be important to enhance self-regulation skills in patients with low glycemic control.

Chapter 5

An attrition analysis examined the psychological predictors of drop-out from our weight reduction intervention. In both univariate and multivariate analyses psychological baseline variables (self-regulation, self-efficacy and distress variables) were examined to distinguish study 'drop-outs'

from 'stay-ins'. Drop-outs appeared to be best characterized on the basis of their baseline self-regulation cognitions. The best predictor of 6 month drop-out in a logistic regression analysis appeared 'goal ownership'. Patients who experienced weight loss as an autonomous instead of a coerced goal were less likely to drop-out of the weight loss intervention than patients who experienced weight loss as a coerced goal.

General Conclusion

Overall, the results in this thesis indicate that self-regulation cognitions and skills might be important intervention targets of future diabetes (weight) interventions. The studies in this thesis indicated that self-regulatory cognitions were related to diabetes behavior (weight regulating behavior), HbA1c and drop-out from a diabetes weight loss intervention.

Theoretical Integration of findings

Self-regulation in diabetes self-care; is it an effective approach?

The surplus value of self-regulation in explaining and influencing health behaviors has been proven in many different areas ³. Self-regulation theory provides a solid theoretical framework from which effective principles for interventions can be derived. Self-regulation theory also proved effective in explaining and predicting behaviors in a diabetes context. The importance of key elements in self-regulation theory, such as 'goal ownership' ⁸⁻⁹, 'goal setting' ¹⁰, 'feedback' ¹¹, 'self-monitoring' ¹² or combinations of these principles have been extensively researched in the context of diabetes interventions. The added value of self-regulation theory in diabetes research is confirmed by our meta-analysis (chapter 2) that indicated that self-regulation principles are moderators of the effect of weight loss interventions in diabetes type 2 patients. Weight loss interventions including more self-regulation principles generated higher effect sizes for weight and HbA1c than weight loss interventions with only few or without these self-regulation principles. These findings led to the conclusion that self-regulation interventions are more effective for weight loss and for decreasing HbA1c than general weight loss interventions. However, the results of the pilot self-regulation intervention study (chapter 4) indicated that no differences in weight or HbA1c were found between patients in the self-regulation intervention group and patients from the control groups. Within the total patient group self-regulation principles explained differences in HbA1c but not in weight. The results of the meta-analysis and the pilot self-regulation intervention suggest several theoretical considerations.

Firstly, as was found in the previous meta-analyses described in chapter two ⁴⁻⁷, weight loss in patients with type 2 diabetes in general is difficult to obtain even if the interventions are based on self-regulation principles. This is especially true for patients that have been diagnosed with

diabetes a long time ago and for patients that experience complications of their diabetes. For most patients in the present study the diagnosis of diabetes had occurred many years (> 10 years) before. In addition, about 20% of our patients suffered from serious diabetes complications such as kidney failure, cardiovascular damage, unbearable nerve pains (neuropathy) or foot amputations. For this reason, some patients were not able to engage in some of the exercise assignments and could therefore not fully profit from the intervention.

Previous self-regulation intervention studies that proved to be effective in changing health behavior and medical outcomes ^{1, 13} in patients with type 2 diabetes, specifically focused on patients who had only been diagnosed with type 2 diabetes 3 to 33 months previously. These newly diagnosed patients are most likely to differ psychologically, behaviorally and medically from our sample consisting of patients that had been diagnosed with diabetes type 2 many years previously. The diagnosis of diabetes type 2 of most patients in our study had occurred more than ten years before the start of our intervention. Many patients reported to have changed behavior and have lost weight initially after the diagnosis but to have relapsed months or years later. The cycle of behavioral actions, relapse and new attempts to change behavior had taken place several times between diagnosis and our intervention, years later. By then, many patients had entered a phase in which striving for behavior change and weight loss was no active goal anymore.

In conclusion, one might say that expecting to change behaviors and medical outcomes in overweight/obese patients that have been diagnosed with diabetes type 2 a long time ago might have been too optimistic. The results of the pilot intervention as well as our experiences with this group of patients taught us more about the complexity of their treatment both from a medical and a psychological perspective.

These findings are confirmed by Clark's ¹⁴ descriptive review of the literature on weight loss interventions in a general and a diabetes population. In this review Clark concludes that weight loss in patients with type 2 diabetes might be an unrealistic intervention goal. She suggests that intervention goals for this population should be formulated in terms of behaviors and actions instead of kilos or pounds. Clark concludes with the statement that the obese diabetes patient still *'poses a formidable therapeutic challenge'* (Clark, 2004, p.281). Putting together this conclusion with the notion that treatment adherence in patients with type 2 diabetes in general is considered to be problematically low ¹⁵, helps to realize that the treatment of the overweight/obese diabetes type 2 patient is extremely challenging.

A second theoretical consideration in this thesis concerns the absence of effect of the self-regulation intervention on psychosocial or medical outcomes. This absence of effect should be

put in the light of more fundamental theoretical discussions about the trait or process definitions of aspects of self-regulation^{3, 16-17}. The finding that our self-regulation intervention did not increase self-regulation skills in patients who lacked these skills points at the importance of trait aspects of self-regulation. On the basis of the specific intervention results and our experiences with this group of patients it is speculated that there might be a group of patients that is just more 'externally regulated'. These 'coerced regulators' might not easily be changed into 'autonomous regulators'. It is hypothesized that this group of 'coerced regulators' does not and will not easily profit from a self-regulation intervention, but would probably profit from more externally controlled therapies.

A third theoretical consideration concerns the relationships between self-regulation skills and behavioral outcomes. Although our intervention did not show any effects of self-regulation on medical outcomes such as weight, BMI and HbA1c, this thesis demonstrated relationships between self-regulation cognitions and diabetes self-care behaviors, such as fat consumption and physical exercise (chapter 3). Furthermore, self-regulation cognitions predicted attrition over all groups in our study. All of the above mentioned behavior changes demonstrate that self-regulation cognitions and skills can indeed predict diabetes related behavioral outcomes. The effect of a self-regulation intervention on medical outcomes such as weight and HbA1c might, however, only be visible in the longer term, when (increased) engagement in the diabetes health behaviors has led to a change in physical outcomes. The research period of six months in this thesis might have been too short to reflect changes in biomedical outcomes. This suggestion is in line with findings of previous studies that prove that self-regulation interventions are mostly effective in the longer term¹⁸⁻¹⁹.

The fourth consideration concerns the potential impact of other than self-regulatory factors on diabetes (self-care) behaviors (e.g. diet and exercise) and outcomes. The focus of this thesis was clearly on the role of self-regulation theory in explaining and influencing diabetes self-care behaviors in overweight type 2 patients. Although the previous chapters have attempted to prove the importance of self-regulation theory in diabetes research, other than self-regulation factors might account for additional variance in the prediction of diabetes self-care behaviors. The frequent presence of anxiety (e.g. hypo-anxiety) in diabetes patients, for instance, might also form a plausible explanation for the lack of behavioral actions of patients who claimed that weight loss was a highly personally relevant health goal. Patients with hypoglycemic anxieties are known to consciously raise their blood glucose levels by means of eating or non-adherence to medical regimens. Increases in both weight and HbA1c often are found in these patients²⁰. Our intervention did not specifically address the issue of diabetes-related anxieties in patients

and might therefore have overlooked important working mechanisms for behavior change in these patients.

Strengths and limitations

Strengths: what is the surplus value of this thesis?

The meta-analysis in chapter two is one of the first meta-analyses that examined effective intervention strategies from a self-regulation perspective. A self-regulation based meta-analysis within the context of diabetes (weight loss) interventions has not been published before. Other meta-analyses have attempted to distil important working mechanisms in diabetes interventions, but were not based on a solid theoretical framework, such as self-regulation theory. Furthermore, our meta-analysis did not only point at the possible importance of self-regulation principles, but also distinguished other intervention characteristics, such as the inclusion of partners/family in interventions, that moderate the effect of diabetes interventions on weight and HbA1c.

Secondly, to the best of our knowledge, the intervention described in this thesis is the first intervention based on the principles for self-regulation interventions as described by Maes and Karoly³. Other self-regulation based interventions have been conducted in the context of diabetes^{1-2, 21}. These interventions, however, did not systematically take into account the various self-regulation principles that are believed to facilitate goal achievement in all three phases of self-regulation. Albeit a pilot intervention, our self-regulation intervention was the first to implement these theoretical principles into a practical diabetes weight reduction intervention. Future studies could build on the results and experiences from this self-regulation intervention and take into account the limitations that might have partly explained the lack of effect of our intervention.

A third strength of this study concerns the choice to develop an intervention for this specific 'formidable challenging' population. Having tried to lose weight or change behaviors for many years, many patients (and doctors, nurses, dieticians and physiotherapists) had given up hope on improvement of their diabetes situation. Even though our intervention did not (yet) generate the results we expected or hoped for, the relevance of the self-regulation intervention for this specific population was reflected in highly positive evaluations of the intervention by patients. Patients, but also doctors, nurses, dieticians and physiotherapists expressed great appreciation for the intervention and many patients indicated to have changed their nutrition and/or exercise behavior because of the intervention.

Limitations

The first limitation concerns the limited number of data on which some of the studies in this thesis (chapter 3, 4, 5) were based. In a power analysis prior to the inclusion of patients it was calculated that the inclusion of 270 patients in a randomized controlled design would generate sufficient power to detect significant differences between the intervention and two control groups. The hospitals database of diabetes patients consisted of approximately 1400 diabetes patients of which 90% was diagnosed with type 2 diabetes. The medical files of all of these diabetes type 2 patients were screened to select patients who fulfilled all inclusion criteria. Inclusion criteria concerned ethnical (only Caucasians), psychosocial (not being under psychological or psychiatric treatment), demographic (being able to read, write and speak Dutch) as well as medical aspects (no other comorbidity than cardiovascular diseases). Since comorbidity rates in diabetes patients are notoriously high ²² the latter inclusion criterion excluded a great part of these 1260 eligible patients. After screening the medical files, a total number of 300 patients was addressed to participate in our intervention study. However, only 125 patients (42%) agreed to participate in the study at baseline. Of these 125 patients 96 patients (77%) returned the baseline questionnaire. Having in mind the results of the power-analysis, this relatively small sample of patients clearly is an important methodological limitation of the studies described in this thesis.

A second limitation, related to the first, concerned the high number of patients that dropped out of the intervention, especially in the active and passive control groups. Weight loss interventions in general are known for their high drop-out rates ²³ and our study was no exception to this rule. The attrition article in chapter five demonstrated a 6 month drop-out rate of 35%. Reasons for study drop-out were: hospitalization, change of treatment plan, family related reasons, work related reasons or not feeling comfortable in the specific research condition. It may be obvious that the small research sample at baseline did not profit from this high drop-out rate during the study. The limited study power at baseline even further decreased and limited the possibility of detecting differences between intervention and control groups.

Thirdly, although the meta-analysis is an important part and strength of this thesis, the outdatedness of the literature that was used in the meta-analysis is considered an important limitation of this chapter. The results of the meta-analysis as described in chapter 2 might not reflect the content and effect of more recent diabetes weight interventions and should therefore be updated. At the moment, an update of the literature on diabetes weight loss interventions is being made and will be added to the meta-analysis as soon as possible. The meta-analysis will be extended with a number of 12 studies with a total sample of 6785 subjects.

Fourthly, our intervention might have put too strong a focus on weight loss instead of HbA1c and diabetes self-care behaviors. The specific weight loss goal that was formulated by all patients at baseline might have better been formulated in terms of specific diabetes self-care behaviors than in terms of pounds or kilos. Previous studies mentioned the importance of goal setting in terms of behaviors and not in terms of biomedical outcomes ¹⁴. Especially when taking into account the complexity of treatment for this specific patient sample, striving for a specific weight loss goal might be a bridge too far. Setting short term behavioral goals to influence blood glucose might be more realistic and rewarding for this specific group of patients that is found to have adherence problems in general ²⁴. Furthermore, short term behavioral goals to change blood glucose levels might also indirectly facilitate weight loss.

A final limitation of the studies in this thesis concerns the extensive use of self-report measures. Apart from the medical outcomes, such as weight, BMI, waist circumference and HbA1c, the studies in this thesis were predominantly based on self-report outcome measures. Critics of self-report measures point at the danger of response bias and decreased reliability and validity when assessing outcomes with self-report measures ²⁵. Although not all the methodological downsides of self-report measures can be avoided, the use of questionnaires with sound psychometric properties helps to minimize chances of decreased reliability and validity. Most of the questionnaires used in this study were reliable and validated instruments that had been evaluated and tested in previous research. However, the assessment of diet and exercise behaviors was based on a non-validated instrument that was specifically developed for the purpose of our intervention. The assessment of self-regulation cognitions and skills was based on the Self-Regulation Skills Battery that was developed during the data collection of this thesis. Therefore, it was not possible to include the final version of the Self-Regulation Skills Battery in this thesis. In appendix 4 the development of the final Self-Regulation Skills Battery as well as the small differences with the version that was included in this thesis is described.

Suggestions for Future Research

This thesis provided interesting data on the effects and relevance of a self-regulation based intervention for weight reduction in type 2 diabetes patients, as well as ideas for future research. With respect to self-regulation cognitions and skills in diabetes type 2 patients, further exploration of effective self-regulation cognitions and skills for changing weight and HbA1c is recommended. The results of the meta-analysis indicate that self-regulation in diabetes is worth the investigation. However, more research on self-regulation skills in diabetes type 2 patients is needed to demonstrate its effect in practice. The self-regulation intervention in this thesis was

conducted as a pilot intervention to explore and learn about (changing) self-regulation skills in overweight diabetes type 2 patients. Future studies could build on the results and experiences described in this thesis and deal with the limitations that might have influenced our results. The highly positive evaluation of the self-regulation intervention by patients, physicians, nurses and dieticians indicated that the application of self-regulation theory in diabetes care is appreciated and should be further investigated. Further examination of self-regulation skills and self-regulation interventions in diabetes patients would also add to the discussion about the dynamic versus trait definition of self-regulation. A further exploration of the dimension of 'externally-' versus more 'self-regulated' patients might teach us more about which patients and behaviors can and cannot be changed by a self-regulation intervention. Furthermore, an exploration of self-regulation skills and interventions in other diabetes groups would be interesting. One might explore the role of self-regulation skills in younger or more recently diagnosed diabetes patients and compare the dynamic or trait components of self-regulation aspects in various groups of patients or stages of life.

Secondly, the possibilities of screening patients' self-regulation cognitions and skills prior to an intervention should also be further investigated. The results in chapter 4 and 5 indicated that self-regulation cognitions might be indicators of intervention outcomes and study drop-out respectively. Screening patients 'ownership' and self-regulation skills relative to the intervention goal might detect a group of patients that is not likely to benefit from a self-regulation intervention. Maybe these patients would profit more from 'ownership' increasing or more externally regulated interventions than from self-regulation interventions. Screening patients' self-regulation skills prior to an intervention could therefore help to match patients to suitable interventions. The possibilities and effects of screening patients' self-regulation skills should therefore be further examined.

Thirdly, future self-regulation interventions in diabetes patients should put less focus on weight loss and more on HbA1c and diabetes related behaviors. Since weight loss in diabetes type 2 patients in general is seen as a difficult goal ¹⁴, patients might rate their self-regulation skills with regard to weight loss much lower than their self-regulation skills with regard to general healthy diabetes self-care behaviors such as diet and exercise. As was suggested in the previous paragraph, focusing on more short term behavioral goals to influence blood glucose levels might be more rewarding and realistic for this specific patient population. Future studies could examine the effect of formulating such behavioral diabetes goals.

Finally, future studies could further explore the role of diabetes-anxiety on relevant health behavior change. Specific diabetes anxiety measures were not included in this thesis, but might

well have influenced and explained the lack of behavior change for some patients. Health care providers in diabetes care are frequently confronted with non-compliance of patients because of severe anxiety about hyperglycaemia, hypoglycaemia or self-injections²⁶⁻²⁸. These patients might show a lack of self-regulation skills for important health goals that, in fact, are anxieties in disguise. Learning more about the interaction of anxiety and self-regulation skills in diabetes patients would be of great importance for diabetes care. Future diabetes (self-regulation) interventions should be more specific in detecting and tackling these diabetes anxieties before heading for behavior change.

Clinical Implications

Findings from the studies reported in this thesis can be applied to regular diabetes care as well as to the continued development of diabetes interventions. The next paragraph discusses the clinical implications of the main findings in this thesis; first from a self-regulation perspective, then from a more general psychological perspective.

Clinical implications from a self-regulation perspective

Recognizing which specific psychological mechanisms influence diabetes outcomes such as weight and HbA1c gives meaning and direction to the general and broadly defined term of 'self-regulation' that is currently used in clinical diabetes practice. The results of our meta-analysis (chapter 2) points at the possible importance of such specific self-regulation principles, such as 'goal reformulation' and 'emotional control' that might be important in diabetes (weight) interventions. Teaching diabetes health care providers how to increase their patients' specific self-regulation skills might be a contribution to the treatment of overweight diabetes type 2 patients.

The relationships that were found between goal planning, diabetes self-efficacy and weight regulating behavior (chapter 3) and between total self-regulation skills and HbA1c (chapter 4) indicate that assessing self-regulation skills might help dieticians and diabetes nurses or other health care providers to understand or even influence weight regulating behavior and HbA1c in diabetes patients. For some patients, increasing patients' self-regulation cognitions or skills might be more important than increasing general diabetes or nutrition knowledge.

The finding that autonomous regulation ('goal ownership') appears the strongest predictor of 6-month drop-out from a weight reduction intervention indicates that self-regulation baseline characteristics might be good candidates for predicting which patients will and will not participate throughout the entire intervention program. This provides health care workers and interventionists with a possible screening tool of patients' motivation to participate in

interventions. Screening of patients' 'ownership' with regard to intervention goals could help health care providers and interventionists to match patients to suitable interventions. Furthermore, screening of patients' goal ownership could determine which patients could profit from pre-intervention interventions to increase goal ownership, such as 'motivational interviewing' and 'autonomy support'.

Clinical implications from a general psychological perspective

The evaluation of the intervention showed that patients were highly satisfied with the intervention and reported to have changed their nutrition and exercise behavior because of it. The appreciation of our intervention was reflected in high marks in the evaluation as well as in positive comments about the intervention. Many patients expressed their appreciation for the emphasis that the intervention put on psychological aspects in diabetes self-care. For most patients, looking at medical diabetes problems from a psychological perspective was eye-opening. The time and effort that was spent on discussing the psychological well-being of the patients was highly appreciated by them and indicates that many patients would like more assistance in the psychology of diabetes self-care.

More generally, this thesis points at the possible importance of recognizing psychological mechanisms underlying diabetes self-care behaviors. Changing these psychological mechanisms might have even greater impact on medical diabetes outcomes than changing pharmacological parameters in the treatment of diabetes type 2 patients. Furthermore, this thesis illustrates the more general surplus value of including psychologists in the treatment of diabetes. A multidisciplinary approach in the treatment of diabetes reflects better the multidimensionality of having diabetes (or a chronic disease in general) that many patients are confronted with on a daily basis. Improvement in patients' diabetes self-care is most likely when this multidimensionality is recognized and acted upon. The inclusion of psychologists in the treatment of diabetes should therefore not be regarded a luxury but a necessity for optimizing diabetes (self-)care.

Conclusion

This thesis described the role of self-regulation cognitions and skills in the treatment of overweight patients with type 2 diabetes. The promising results of the meta-analysis, the results of our pilot self-regulation intervention as well as the theoretical and practical implications of it, point at the possible importance of psychological research within the field of diabetes care. The study limitations that are described in the general discussion, however, also point at the need for careful interpretation of our study results. Therefore, more extensive research is needed to

further understand the psychological and theory based mechanisms that underlie diabetes self-care behaviors. There is still much more to know about the role of specific self-regulation mechanisms in diabetes self-care. Implementing the results of this thesis in future self-regulation studies in diabetes patients might bring the application of self-regulation theory in the field of diabetes up to a next level.

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Appendices

Appendix 1: 'Principles for Self-Regulation Interventions'

- ✓ Explore risk perception, the perceived cost/benefit of intervention targets, perception of support from important others, and the individual's perceived competence to carry out recommended actions regarding health behavior change or self-management targets (**realistic outcome expectancies**).
- ✓ Explore and eventually change the individual's representation of the health problem or illness (identity, time-line, cause, consequences, and cure or control) as well as the way in which these representations are organized by the individual (**illness representations**).
- ✓ Encourage the individual to **set personal goals**. These goals should be specific, important to the individual, not too easy or too difficult to carry out, and attainable in a restricted time frame (**goal ownership**).
- ✓ Help the individual to observe or monitor his or her current problem behavior, its antecedents, and its emotional consequences (**self-monitoring**).
- ✓ Assist the individual in building an action plan by asking when, where, how, and how long the patient will act in relation to his or her goal (**planning**).
- ✓ Ask the individual to build a "goal ladder" in order to define steps towards goal attainment. Help the individual in developing a standard for assessing progress. **Provide feedback to evaluate goal progress**.
- ✓ Encourage the individual to ask for support from health professionals and relatives or friends (**facilitate social support**).
- ✓ Increase the individual's self-efficacy via modeling and verbal persuasion (**goal efficacy**).
- ✓ Encourage the individual to use self-incentives when progress is made (**self-reinforcement**).
- ✓ Teach the individual the skills to control distracting information or negative mood during goal pursuit (**attention control and emotion control**).
- ✓ Ask the individual to report and discuss conflicting or competing goals and to try to align these competing goals (**control over competing goals**).
- ✓ Reassure the individual that relapse is not failure, but an opportunity for learning (**anticipatory coping**).
- ✓ Teach the individual how to cope with relapse (**relapse prevention**).
- ✓ Inform individuals that they should feel free to **reformulate a goal** in a more *manageable* way if their goal is too difficult to attain.

Appendix 2: Formulas used in meta-analysis

Formula 1 and 2 were used to compute the standardized mean differences between the treatment group (T) and control group (C) of the change in weight or HbA1c from pretest to posttest. Formula 1 was applied if a study reported raw pretest and posttest means of the two groups, denoted with $M_{preT}, M_{postT}, M_{preC}, M_{postC}$, and raw pretest and posttest standard deviations, denoted with $S_{preT}, S_{postT}, S_{preC}, S_{postC}$. The sample sizes are denoted with n_T and n_C .

$$\text{Formula 1: } d_{change} = \frac{(M_{preT} - M_{postT}) - (M_{preC} - M_{postC})}{S_{post-pooled}}.$$

The standardization was done by the pooled post score standard deviation, where

$$S_{post-pooled} = \sqrt{\frac{(n_T - 1)S_{postT}^2 + (n_C - 1)S_{postC}^2}{n_T + n_C - 2}}.$$

Formula 2 was applied if a study reported only change scores from pretest to posttest for the treatment and control group, denoted with $M_{changeT}, M_{changeC}$, and the standard deviations of the change, denoted with $S_{changeT}, S_{changeC}$.

$$\text{Formula 2: } d_{change} = \frac{M_{changeT} - M_{changeC}}{S_{post-pooled}}$$

To compute the pooled post score standard deviation, we assumed a pre-posttest correlation of 0.50. In this case, the posttest standard deviations are equal to the change score standard deviations:

$$S_{postT} = \frac{S_{changeT}}{\sqrt{2(1 - r_{prepost})}} = \frac{S_{changeT}}{\sqrt{2 * 0.50}} = S_{changeT}$$

$$\text{The standard error (SE) of } d_{change} = \sqrt{\left(\frac{1}{n_T} + \frac{1}{n_C} + \frac{d_{change}^2}{2(n_T + n_C)} \right)}.$$

Appendix 3: 'Correlation Table with Self-Regulation Correlations'

Correlations between SR-Variables at three months after baseline (T2) (N = 68)

	1	2	3	4	5	6	7	8	9	10	11	12
goal autonomy (1)	1											
goal planning (2)	.146	1										
goal efficacy (3)	.392(**)	.555(**)	1									
help seeking (4)	.086	.249(*)	.264(*)	1								
social comparison (5)	-.345(**)	.098	.004	-.007	1							
self-monitoring (6)	.259(*)	.543(**)	.462(**)	.263(*)	.072	1						
self-criticism (7)	-.180	.094	-.001	.058	.164	.122	1					
self-reward (8)	-.156	.113	.070	.281(*)	.368(**)	.368(**)	.292(*)	1				
attention control (9)	.079	.496(**)	.338(**)	.238	.236	.477(**)	.217	.285(*)	1			
self-efficacy enhancement (10)	.139	.491(**)	.561(**)	.481(**)	.163	.455(**)	.065	.382(**)	.532(**)	1		
emotion control (11)	.523(**)	.291(*)	.374(**)	-.071	.026	.242(*)	-.143	-.197	.220	.254(*)	1	
coping with problems (12)	.112	.272(*)	.090	-.047	-.041	.180	-.067	.140	.164	-.042	.025	1

** Correlation is significant at the 0.01 level (2-tailed).

* Correlation is significant at the 0.05 level (2-tailed).

Appendix 4: 'The development of the Self-Regulation Skills Battery (SRSB)' (De Gucht, Maes)

In 2001 the Leiden Health Psychology Group developed the GAPI (Goals and Processes Inventory) that measured goal related cognitions, such as goal ownership and goal support. Goal cognitions were found important determinants of goal selection, goal pursuit and goal attainment ¹⁻³.

In function of interventions it was decided to develop an additional questionnaire that measured goal related skills. This resulted in the development of the Self-Regulation Skills Scale. The Self-Regulation Skills Scale was based on a literature review of Maes and Karoly ⁴ that described fourteen important principles in the development of self-regulation interventions (see appendix 1). Of these fourteen principles, the following fourteen self-regulatory skills were derived: social comparison, self-monitoring, planning, self-criticism, self-reward, goal efficacy, goal communicative actions, coping with problems, attention control, emotion control, persistence, disengagement, self-determination and outcome expectancies. Data on these fourteen self-regulation skills were collected in a general population (N = 161). Principal component analysis with VARIMAX rotation revealed nine subscales that measured: commitment and persistence (12 items, $\alpha = .97$), goal efficacy (4 items, $\alpha = .95$), social comparison (4 items, $\alpha = .90$), goal communicative actions (4 items, $\alpha = .86$), self-criticism (4 items, $\alpha = .95$), self-determination (4 items, $\alpha = .89$), self-reward (4 items, $\alpha = .95$), emotion control (4 items, $\alpha = .95$), coping with problems (4 items, $\alpha = .93$).

Subsequently, the Self-Regulation Skills Scale and the Goal Systems Assessment Battery (GSAB) ⁵ were integrated. This integration resulted in the Self-Regulation Skills Battery ⁶ consisting of 13 subscales: goal ownership (5 items), goal efficacy (4 items), need for feedback (4 items), help seeking (4 items), social comparison (4 items), planning (4 items), self-monitoring (6 items), self-criticism (5 items), self-reward (5 items), attention/stimulus control (4 items), coping with problems (5 items), self-efficacy enhancement (4 items), emotion control (4 items).

Data on the Self-Regulation Skills Battery were collected in a sample of 156 patients with rheumatoid arthritis. Principal Component Analysis resulted in 13 subscales, measuring:

- Goal ownership (2 items; $\alpha .89$)
- External regulation (2 items; $\alpha .82$)
- Goal efficacy (4 items; $\alpha .82$)
- Planning (4 items; $\alpha .74$)
- Self-monitoring (3 items; $\alpha .78$)

- Attention control (2 items; α .76)
- Emotion control (4 items α .85)
- Social comparison (4 items α .91)
- Self-reward (5 items; α .89)
- Self-criticism (5 items; α .85)
- Help seeking (4 items; α .75)
- Feedback (5 items; α .86)
- Coping with problems (5 items; α .76)

Since the development of the Self-Regulation Skills Battery occurred parallel to the data collection for this thesis, the studies in this thesis did not include the latest version of the Self-Regulation Skills Battery that distinguished between 'Goal Ownership' and 'External Regulation'. Neither did the version of the Self-Regulation Skills Battery that was included in these studies include the subscale 'Feedback'. Furthermore, the Self-Regulation Skills Battery that was used in the studies that were described in this thesis was similar to the above mentioned data about the components of the Self-Regulation Skills Battery (2006).

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Een balans vinden:

Zelfregulatie bij patiënten met diabetes type 2 en overgewicht

Diabetes

Diabetes mellitus is de gebruikelijke naam voor verschillende aandoeningen die worden gekenmerkt door een teveel aan glucose (suiker) in het bloed (hyperglycemie). Deze hyperglycemie wordt veroorzaakt door het slecht functioneren van het hormoon insuline dat verantwoordelijk is voor het transport en de opslag van glucose in het lichaam. Een teveel aan glucose in het lichaam kan op de lange(re) termijn leiden tot ernstige complicaties, zoals aantasting van de zenuwen (neuropathie), nierfunctie stoornissen (nefropathie), verminderd zicht of blindheid (retinopathie), gewrichtsproblemen of hart-en vaatziekten.

Over het algemeen worden vier verschillende typen diabetes onderscheiden: diabetes type 1, diabetes type 2, diabetes gravidarum (zwangerschapsdiabetes) en diabetes ten gevolge van andere aandoeningen ¹. Diabetes type 1 en diabetes type 2 zijn de bekendste en meest voorkomende vormen van diabetes. Dit proefschrift betreft alleen patiënten met diabetes type 2. De alvleesklier van patiënten met type 2 diabetes produceert meestal (nog) wel insuline, maar de productie of de opname van de insuline in het lichaam is verstoord. Deze verstoring in de productie of opname van insuline gaat heel geleidelijk en komt daardoor meestal pas op middelbare leeftijd (toevallig) aan het licht ²⁻⁴. Om deze reden wordt diabetes type 2 ook wel 'ouderdomsdiabetes' genoemd. Deze term raakt echter meer en meer in onbruik vanwege het feit dat er tegenwoordig zelfs kinderen gediagnosticeerd worden met type 2 diabetes.

Diabetes type 2 wordt veroorzaakt door een combinatie van genetische en leefstijlfactoren ⁵. Mensen met een genetische predispositie voor diabetes type 2 die een gezonde leefstijl hanteren en een gezond gewicht hebben zullen meestal geen diabetes ontwikkelen. Echter, mensen met een genetische predispositie die een ongezonde leefstijl hanteren en (ernstig) overgewicht hebben zullen waarschijnlijk op enig moment in hun leven diabetes krijgen. Tachtig tot negentig procent van de mensen met diabetes type 2 heeft last van (ernstig) overgewicht. De wereldwijde toename van het aantal mensen met overgewicht wordt gezien als een belangrijke oorzaak voor de stijging in het aantal mensen met diabetes type 2 ⁶⁻⁸. Momenteel zijn er wereldwijd zo'n 180 miljoen mensen gediagnosticeerd met diabetes, waarvan 90-95% diabetes type 2 patiënten ⁹. Schattingen zijn gemaakt dat dit aantal van 180 miljoen diabetes patiënten in

2030 zal zijn verdubbeld. De toename van het aantal kinderen met overgewicht wordt gezien als voornaamste oorzaak van de dalende leeftijd waarop de gemiddelde diabetespatiënt wordt gediagnosticeerd met diabetes type 2 ¹⁰.

De behandeling van diabetes bestaat in eerste instantie uit het verlagen en stabiliseren van de concentraties glucose in het bloed. De gemiddelde concentratie glucose in het bloed in de voorgaande 6 tot 8 weken wordt uitgedrukt in een zogenaamde HbA1c-waarde. Het verlagen van de HbA1c-waarde van diabetes type 2 patiënten kan geschieden door toediening van orale anti-diabetica en/of leefstijlaanpassingen. Gewichtsreductie door aanpassing van voeding en lichaamsbeweging is voor veel patiënten met diabetes type 2 een belangrijk doel van de behandeling. Een afname van het lichaamsgewicht van 5-10% kan in zeer grote mate bijdragen aan het verlagen van het HbA1c. Wanneer orale anti-diabetica en leefstijlaanpassingen onvoldoende verlaging van glucose in het bloed opleveren kan ook worden overgegaan tot het dagelijks onderhuids toedienen van insuline via injecties.

Zelfregulatie theorie en diabetes

Het groeiende besef dat leefstijlaanpassingen in grote mate kunnen bijdragen aan het verlagen van de gemiddelde glucosewaarden (HbA1c) van diabetes type 2 patiënten, heeft ertoe geleid dat, over de jaren, de interesse in psychologische theorieën van gedragsverandering is gegroeid ¹¹. Psychologische theorieën over patiëntenvoorlichting en hoe patiënten te motiveren hun gedrag te veranderen zijn in toenemende mate geïntegreerd in de diabeteszorg ¹². Het vanuit psychologisch oogpunt begrijpen en kunnen ingrijpen in waarom patiënten wel of geen zelfzorg toepassen voor hun chronische ziekte (zelfmanagement) heeft meer en meer aandacht gekregen binnen de diabeteszorg. Eén van de moderne theoretische perspectieven van waaruit kan worden gekeken naar zelfmanagement (bij chronisch zieken) is het perspectief van de zelfregulatie theorie.

Zelfregulatie theorie verschaft een theoretisch kader waarvan praktische richtlijnen voor interventies en specifieke werkingsmechanismen voor gedragsverandering kunnen worden afgeleid ¹³. Zelfregulatie kan worden gedefinieerd als een 'serie aan acties of aansturingsprocessen, ook wel mechanismen van verandering en behoud genoemd, met de intentie een doel te bereiken' ¹³. Deze aansturingsprocessen of mechanismen kunnen worden ingedeeld in drie verschillende fasen: a) een fase van doelselectie, b) een fase waarin een doel actief wordt nagestreefd, c) een fase waarin een doel wordt bereikt, behouden of losgelaten. De diverse aansturingsprocessen of zelfregulatiemechanismen van verandering en behoud spelen dus een grote rol in het bereiken van een (gezondheids)doel. Vanuit het oogpunt van interventies en op basis van deze aansturingsprocessen of zelfregulatiemechanismen hebben

Maes en Karoly ¹³ een aantal principes van zelfregulatie geformuleerd. Deze zelfregulatieprincipes vormen de theoretische leidraad van dit proefschrift.

Onderzoeksvragen

De centrale focus van dit proefschrift is de rol van zelfregulatie bij diabetes type 2 patiënten met overgewicht. De volgende onderzoeksvragen worden in dit proefschrift behandeld:

- 1) Wat is de rol van zelfregulatieprincipes in gewichtsreductie interventies voor diabetes type 2 patiënten? (Hoofdstuk 2)
- 2) Zijn zelfregulatie cognities van diabetes type 2 patienten met overgewicht gerelateerd aan diabetes 'self-efficacy' en gewichtsregulatie? (Hoofdstuk 3)
- 3) Wat zijn de effecten van een pilot zelfregulatie gewichtsreductie interventie voor diabetes type 2 patiënten met overgewicht? (Hoofdstuk 4)
- 4) Kunnen zelfregulatiecognities studieuitval uit een gewichtsreductie studie voor diabetes type 2 patiënten met overgewicht voorspellen? (Hoofdstuk 5)

Overzicht van hoofdstukken in dit proefschrift

De onderzoeksvragen worden ingeleid en behandeld in zes afzonderlijke hoofdstukken in dit proefschrift.

Hoofdstuk 1 geeft een korte introductie op het onderwerp diabetes en zelfregulatie en presenteert de onderzoeksvragen van dit proefschrift.

Hoofdstuk 2 beschrijft een meta-analyse naar de effecten van 34 gewichtsreductie interventies voor patiënten met type 2 diabetes. Algemene effecten van deze interventies op gewicht en HbA1c worden beschreven. Daarnaast beschrijft de meta-analyse welke zelfregulatie principes de algemene effecten van deze 34 interventies modereren. Resultaten laten zien dat de algemene effecten van de gewichtsreductie interventies voor patiënten met diabetes type 2 beperkt zijn. Het gemiddelde gewichtsverlies van patiënten na dergelijke interventies is zeer beperkt op zowel de korte als de lange termijn. Het effect van de gewichtsreductie interventies op HbA1c is gemiddeld hoger en stabiel. De totale hoeveelheid zelfregulatie principes in de gewichtsreductie interventies blijken het effect van de interventies op zowel gewicht als HbA1c te verhogen. Het principe 'doel herformulering' blijkt het effect van de interventies op gewicht te verhogen. Ook 'de inclusie van een partner of bekende in de interventie' verhoogt het effect van de interventie op gewicht. Het principe 'emotie regulatie' verhoogt het interventie effect op HbA1c.

In hoofdstuk 3 worden de baseline data van de zelfregulatie interventie gepresenteerd. Cross-sectionele relaties tussen zelfregulatie cognities, de eigen effectiviteit ten aanzien van diabeteszelfzorg (diabetes 'self-efficacy') en gewichtsregulatie zijn onderzocht bij 96 patiënten met overgewicht en diabetes type 2. De zelfregulatie cognities die in dit hoofdstuk zijn onderzocht zijn de zelfregulatie cognities die van belang zijn in de motivationele fase van doelbereik. In deze motivationele fase zijn de volgende zelfregulatie cognities van belang: 1) cognities over de mate waarin iemand een doel als 'eigen' doel ervaart ('goal ownership'), 2) cognities met betrekking tot steun die iemand van anderen ervaart bij het nastreven van een doel ('goal support'), 3) cognities met betrekking tot de druk die iemand van anderen ervaart bij het nastreven van een doel ('goal pressure') en 4) cognities ten aanzien van plannen om een doel na te streven/te bereiken ('goal planning'). Alle zelfregulatie cognities zijn bevraagd voor het doel 'gewichtsverlies'. De resultaten laten zien dat cognities ten aanzien van het maken van plannen voor gewichtsverlies ('goal planning') een goede voorspeller blijken van zowel gewichtsregulatie als de eigen effectiviteit ten aanzien van diabeteszelfzorg (diabetes 'self-efficacy'). Eigen effectiviteit ten aanzien van diabeteszelfzorg (diabetes 'self-efficacy') blijkt echter een nog sterkere voorspeller van gewichtsregulatie dan cognities ten aanzien van het maken van plannen voor gewichtsverlies ('goal planning'). Geen directe effecten van cognities over de mate waarin iemand een doel als 'eigen' ervaart ('goal ownership'), de mate waarin iemand steun ervaart ('goal support'), of de mate waarin iemand druk van anderen ervaart ('goal pressure') zijn gevonden op eigen effectiviteit ten aanzien van diabetes zelfzorg (diabetes 'self-efficacy') of gewichtsregulatie. Uit de resultaten blijkt dat eigen effectiviteit ten aanzien van diabetes zelfzorg (diabetes 'self-efficacy') kan worden gezien als een mediator tussen cognities over het plannen van gewichtsverlies ('goal planning') en gewichtsregulatie.

In hoofdstuk 4 worden de resultaten van de pilot zelfregulatie interventie na 3 en 6 maanden uiteengezet. Het effect van de zelfregulatie interventie op gewicht, BMI, HbA1c, lichaamsbeweging, voeding en kwaliteit van leven is onderzocht in de interventie en controle groepen. Uit de resultaten blijkt geen verschil te bestaan in deze uitkomstmaten tussen de interventie en controlegroepen na 3 of 6 maanden. Mogelijkerwijs kan het gebrek aan effect van de interventie worden toegeschreven aan de grote uitval van patiënten uit de studie. Bezien over de gehele patiëntengroep blijken patiënten met betere zelfregulatie vaardigheden lagere HbA1c waarden te hebben dan patiënten met beperktere zelfregulatie vaardigheden.

Hoofdstuk 5 beschrijft de voorspellers van studieuitval uit een gewichtsreductie studie voor diabetes type 2 patiënten na zes maanden. Verschillen in somatische, socio-demografische, psychologische en leefstijl kenmerken tussen patiënten die uitvallen en patiënten die in de studie blijven, zijn onderzocht. Uit de resultaten van dit hoofdstuk blijkt dat patiënten die uitvallen uit een gewichtsreductie studie (na 6 maanden) het beste kunnen worden gekarakteriseerd op basis van hun zelfregulatie vaardigheden. Cognities over de mate waarin iemand 'gewichtsverlies' als eigen doel ervaart ('goal ownership') blijken de allersterkste voorspeller van studieuitval na 6 maanden.

Hoofdstuk 6, het laatste hoofdstuk in dit proefschrift, probeert om de belangrijkste onderzoeksresultaten uit dit proefschrift te bediscussiëren en te integreren vanuit een theoretisch, methodologisch en klinisch oogpunt. Ook worden de pluspunten, beperkingen en implicaties van dit proefschrift besproken. Aanwijzingen voor vervolgonderzoek worden gegeven.

De resultaten uit dit proefschrift impliceren dat zelfregulatie cognities en vaardigheden belangrijke handvatten zouden kunnen bieden bij het ontwikkelen van toekomstige (gewichtsreductie) interventies voor diabetes type 2 patiënten. Zo blijken zelfregulatie cognities gerelateerd te zijn aan gewichtsregulatie, HbA1c en studieuitval. Ook wijzen de veelbelovende resultaten van de meta-analyse op het mogelijke belang van zelfregulatie onderzoek binnen het veld van diabetes. Echter, de beperkingen van de studies wijzen ook op de noodzaak om de studieresultaten met enige voorzichtigheid te interpreteren. Meer en uitgebreider onderzoek naar de rol van zelfregulatie bij het veranderen van gedrag van diabetes type 2 patiënten is noodzakelijk. Wanneer de resultaten van dit proefschrift kunnen worden geïmplementeerd in toekomstige zelfregulatie studies kan de toepassing van zelfregulatie theorie in het veld van diabetes naar een volgend niveau worden gebracht.

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Curriculum Vitae

Sasja Huisman was born on November 3, 1977 in Amsterdam, the Netherlands. She completed secondary education (Gymnasium) at Stedelijk Gymnasium 'Johan van Oldenbarnevelt' in Amersfoort in 1996. In November 2000, she graduated in Clinical and Health Psychology at Leiden University. Between November 2000 and August 2001 she worked as a research assistant at the department of Clinical and Health Psychology at Leiden University.

In August 2001 she started working as PhD student at the department of Clinical and Health Psychology of Leiden University, initially in the area of 'Risk Perception and Food Safety'. In October 2004 she started the research project that has led to the present thesis. During the period of August 2001 and July 2006 she also held a teaching position at the department of Clinical and Health Psychology at Leiden University. She has recently become assistant professor at this same department.