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. 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 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 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 \(^1\) \(^3\), \(^13\) 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 in stead 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. 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 term.

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 patients. 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 Karoly \(^3\). Other self-regulation based interventions have been conducted in the context of diabetes \(^1\text{-}^2\text{,}^\text{21}\). 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. 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. 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. 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-injections. 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.

References


