Summary

Type 2 diabetes is a major chronic disease, characterised by elevated blood glucose levels. The incidence and prevalence of type 2 diabetes is increasing rapidly, due to population growth, ageing, and the large rise in the prevalence of obesity, which is caused by unhealthy diets and a lack of physical activity. Type 2 diabetes is associated with an increased risk to develop severe micro- and macrovascular complications, like cardiovascular disease. Adequate treatment is important to prevent or delay the onset of severe complications. However, due to the chronic character of the disease, diabetes care is complex and does not only involve treatment with medication, but also dealing with psychological problems, and a change of dietary intake and physical activity.

During the last few decades, disease management is believed to have a high potential to improve patients' outcomes above the classical healthcare system. Disease management is defined as 'a systematic, population-based approach to identify persons at risk, intervene with specific programs of care, and measure clinical and other outcomes'. The main element of disease management is patient empowerment, which is defined as 'helping people to discover and use their own ability to gain mastery over their disease'. It is known that disease management works in experimental settings but it is unclear if it works on the long term and in real-life settings. In addition, evidence on interventions focused on the increase of patient empowerment is inconclusive.

The aim of the present thesis was to gain more insight into disease management and patient empowerment for patients with type 2 diabetes.

Disease management

In *chapter 2*, the results of the 'Diabetes Management System' (DMS), West-Friesland, a disease management model, were presented. The DMS was implemented in 1997 in West-Friesland, a region in the Netherlands. General practitioners were asked to refer their diabetic patients to the system for additional care. The DMS is based on the chronic care model and consisted of three elements: coordination of care between different caregivers, feedback to both patients and general practitioners, and stimulation of patient empowerment. Every year, patients are invited to visit the system for a physical examination, followed by education by both a diabetes nurse and a dietician. In the present thesis, an observational 7-year follow-up study was performed to assess changes in clinical characteristics of patients after their entry into the system. We found that the DMS was successful in improving and stabilizing clinical characteristics. HbA1c showed an initial sharp decrease from 7.7 to 7.0% in the first year after entry into the system, and stabilized during follow-up.

Total cholesterol and triglycerides decreased, whereas HDL cholesterol increased. Blood pressure control, however, remained a challenge, since systolic blood pressure increased and diastolic blood pressure decreased. The risk of a coronary heart disease event decreased from 19.6% to 12.3%. This study implies that a disease management system may be a major step in the improvement of care for patients with type 2 diabetes.

The data from the DMS were also used in *chapter 3*. In this chapter, the changes in the prescription of medication for patients in the DMS were described in order to assess how many drugs were required to maintain risk factor control, which was described in chapter 2. Prescription of medication showed an incredible increase: the proportion of patients who were prescribed insulin increased from 11.7% at entry to 40.9% at seven years follow up; oral antihyperglycemic drugs increased from 65.9% to 80.7%; antihypertensive medication increased from 49.5% to 68.2%; and lipid modifying medication increased from 23.9% to 51.6%. These findings indicate that intensive prescription of medication is inevitable to maintain management goals of diabetes care. This study stresses the importance of strict medication treatment for patients with type 2 diabetes.

Patient empowerment

In *chapter 4,* a systematic review and meta-analysis were performed on the effectiveness of self-monitoring of blood glucose in patients with 2 diabetes who are not using insulin, in comparison with usual care. Self-monitoring is believed to increase patient empowerment by means that it provides insight into the effects of dietary intake, physical activity and medication on glucose levels. This might help the patient to gain control over the disease, but it is unclear if patients who are not using insulin benefit from self-monitoring. Randomised controlled trials were selected from the literature to investigate the effects of self-monitoring on glycemic control, quality of life, well-being, patient satisfaction, and hypoglycaemic episodes. We found that self-monitoring of blood glucose resulted in a statistically significant decrease of 0.39% in HbA1c, which was also considered clinically relevant. We concluded that SMBG is probably beneficial for the specific groups of patients. However, because methodological quality of the studies was poor and because data on other outcomes than glycaemic control was limited, further research on this topic is necessary.

In *chapter 5* the study design of a cognitive behavioural treatment aimed at changing lifestyle was described. This intervention was added to the care of

the DMS and the aim was to improve self-management of patients that were at high risk to develop severe diabetes related complications. The intervention was performed within the framework of a randomised controlled trial. The control group received usual care from the DMS. The intervention consisted of 3-6 sessions with either a diabetes nurse or a dietician. Techniques of Problem Solving Treatment were used to help the patients to set achievable goals in order to change lifestyle. The theoretical framework of the intervention was based on the ASE-model: according to this model it is believed that by changing people's attitudes, social influences and self-efficacy, the intention to perform a specific behaviour increases. This is likely to result in improvements in lifestyle, clinical characteristics, and finally in a decrease of cardiovascular disease risk.

Results of the cognitive behavioural intervention were described in *chapter 6*. Patients in the intervention group significantly improved physical activity, on the short term (0-6 months), even when they had already received managed care of the DMS. No effects were found on the long term and clinical characteristics did not change. We concluded that this study showed that patients were able to change their lifestyle, but it remains a challenge to find behavioural interventions that are beneficial on the long term and that are able to significantly improve clinical characteristics.

In *chapter 7*, a cross-sectional study was described to compare cognitions and behaviour for screen-detected and clinically diagnosed patients. This study was performed with data from the ADDITION *Plus* Study in Cambridge, United Kingdom. This was also a behavioural intervention to increase self-management of patients with type 2 diabetes. For the purpose of our study we used only baseline measurements to investigate whether there is a suitable group of patients to start behavioural interventions with. We showed that there are differences between the screen-detected and clinically diagnosed patients. The screen-detected patients were more motivated to change and therefore they might benefit more from a behavioural intervention. Because of the cross-sectional design of our study, it was not possible to clarify whether different groups respond differently to an intervention. However, this study highlighted the need for studies that pay attention to different subgroups of patients. Our conclusion was that diagnosis by screening might offer a window of opportunity for behavioural interventions.

Discussion

The main findings of the thesis were summarised and methodological considerations of the presented studies in this thesis were discussed in *chapter 8*. Special attention was paid to the development of the design of the cognitive behavioural treatment and to the implementation of this study into the DMS. Furthermore, recent developments on the topics of disease management and patient empowerment were described and compared with our findings. We found much literature on disease management and patient empowerment, probably due to the high prevalence and incidence of type 2 diabetes. The main lesson from the literature on disease management was that it seems that the effective component of systems like the DMS is probably the multifaceted approach. However, because of the lack of a clear definition of disease management it is difficult to implement such systems in a real-life setting. Concerning patient empowerment, the evidence on self-monitoring of blood glucose in patients that are not using insulin is still inconclusive, as we also found in our systematic review. Behavioural interventions were performed on a large scale worldwide. The overall conclusion was that it is clear that a theoretical framework should be used in the development and evaluation of interventions. However, it is unclear how interventions work, which patients would most likely benefit from them and which techniques should be used. Finally, implications for clinical practice and further research were addressed.

In conclusion, the message of this thesis is that the implementation of disease management systems can improve diabetes care. However, behavioural change of patients remains a challenge and should be further investigated to find which interventions work and for whom. Disease management systems should have a multifaceted approach with elements like coordination, and feedback to patients and caregivers. In addition, patient empowerment should be encouraged, to stimulate the patient to become decision-maker of the care. In this way, a central role of the patient is guaranteed and the patient and caregiver can work together towards excellent diabetes care.