Chapter 8

General discussion

The central aim of this thesis was to provide more insight into disease management of patients with type 2 diabetes. Different studies were performed to gain insight into disease management, and into one of the main elements of disease management: patient empowerment. In this final chapter, the main findings will be summarised, followed by a discussion of methodological considerations of the different studies included in this thesis. Furthermore, attention will be paid to some recent developments on disease management and patient empowerment. Finally, the implications of our results for clinical practice and further research will be discussed and final conclusions will be addressed.

Main findings

Disease management
Because of the high prevalence of diabetes and the risk of developing severe complications, it is of importance to gain further insight into the management of diabetes. Disease management systems have been shown to be effective in improving clinical characteristics, but conclusive evidence is lacking. Therefore, we evaluated the results of a disease management model, which was implemented in a region in the Netherlands, during a follow-up period of 7 years: The Diabetes Management System (DMS) West-Friesland. We found that the DMS was successful in improving and stabilising clinical characteristics. HbA1c showed a large decline from 7.7 to 7.0% after patients were entered into the system, followed by a stabilisation during follow-up. Cholesterol levels also improved, but the control of blood pressure was inadequate and remains a challenge. The estimated 10-year risk of developing a coronary heart disease event decreased from 19.6 to 12.3%, which we considered an important finding *(chapter 2)*.

The improvements in clinical characteristics after entry into the DMS could most likely be explained by an increased prescription of medication as a result of the structured care of the DMS. In particular, the prescription of insulin increased during 7 years of follow-up, but also the prescription of oral antihyperglycaemic drugs, antihypertensive medication, and lipid modifying medication increased. Intensive medication seems inevitable for the patients in order to achieve optimal control of risk factors *(chapter 3)*.

Patient empowerment
Patient empowerment is one of the main elements of disease management and therefore this was extensively studied in this thesis.

We found in our systematic review and meta-analysis that self-monitoring of blood glucose in patients who are not using insulin results in a statistically significant decrease of 0.39% in HbA1c, in comparison with no self-monitoring. This result was also clinically relevant: it is expected to reduce the risk of developing microvascular complications by 14%. There was limited data on other outcomes in the studies included in the review *(chapter 4)*.

Our cognitive behavioural treatment *(chapter 5)*, which was added to the care of the DMS, significantly improved the amount of physical activity, compared with the care of the DMS only. The estimated 10-year risk of developing a coronary heart disease slightly improved, but not statistically significant, and no effects were found on clinical characteristics. Quality of life and level of depression improved in the patients that were included in the intervention group. All differences were found between 0 and 6 months and disappeared between 6 and 12 months, indicating that the intervention was not effective on the long term *(chapter 6)*.

Finally, we compared baseline characteristics of screen-detected and clinically diagnosed patients to investigate when we should intervene and with whom. The results suggested a window of opportunity to offer a behavioural intervention after screening for type 2 diabetes. We found a stronger intention to change behaviour in screen-detected patients, than in clinically diagnosed patients, while patients in the latter group were more anxious. Because we found no impact of time since diagnosis, we concluded that the detection by screening had contributed to the differences between the two groups, rather than the more recent diagnosis in the screen-detected patients *(chapter 7)*.

Methodological considerations

In this section, some methodological considerations of the studies included in this thesis will be argued. We have already described some strengths and limitations of the studies in the previous chapters, but here we will address these and other considerations in more detail. We will start with a discussion of the different study designs used in this thesis. Secondly, we will explain why we made specific decisions when we were developing and implementing our cognitive behavioural treatment.

Study designs
In this thesis, three different study designs were used. Observational studies, including a longitudinal study *(chapters 2 and 3)* and a cross-sectional study *(chapter 7)*, a systematic review, including a meta-analysis *(chapter 4)*, and a

randomised controlled trial *(chapters 5 and 6).* Every design has some specific methodological considerations, which will be discussed in this section.

Observational studies

Observational studies are studies in which the natural course of a disease is studied. The main advantage is that observational studies provide an indication of what is achieved in daily practice (1). The disadvantage of observational studies is that it is not possible to investigate causal relationships (2). Therefore, from our studies we could only develop some hypotheses to explain our observations (chapters 2, 3 and 7). Further research in experimental studies is needed to conclude the value of our hypotheses. The advantage of observational studies is the possibility of a long follow-up period. The study performed in the Diabetes Management System (chapters 2 and 3) had a longitudinal follow-up of 7 years. For both ethical and practical reasons it is often difficult to follow patients for such a long period in an experimental design.

Also in our cross-sectional study *(chapter 7)* it is not possible to assess any causality. The aim of this study was to explore several hypotheses on health behaviours and cognitions in two different groups of patients: screen-detected and clinically diagnosed patients. The profit of the cross-sectional design is that it is an easy and timesaving method to investigate if a certain association exists. Also, ideas for new research questions often develop during the performance of cross-sectional studies. Our finding that screen-detected patients might provide a window of opportunity for behavioural interventions should be tested in a randomised controlled trial to investigate if this group of patients indeed benefits more from an intervention than other groups of patients.

Systematic review and meta-analysis

A systematic review establishes if the effects of healthcare are consistent by means of a systematic method. This systematic method involves a well-defined research question with an explicit search strategy to select possible relevant studies. Also, the assessment of the methodological quality of the selected studies is an obligatory part of the development of a systematic review. As a result, a systematic review provides valid information with a limited bias. Healthcare providers, consumers, researchers and policy makers can draw conclusions and decisions upon the information from systematic reviews, rather than assess the substantial amount of information presented in single studies (3). The reason why we had conducted our systematic review is in line with this; our purpose was to resolve conflicting evidence on the effects of self-monitoring of blood glucose (SMBG) for patients with type 2 diabetes who are not using insulin.

Because randomised controlled trials provided the best available evidence, we have focussed on the results shown in these trials to summarise the benefits of SMBG in this specific group of patients.

A meta-analysis is often part of a systematic review and summarises the results of the included studies. The advantages of a meta-analysis are that it increases power, which is the chance of detecting a real effect as significant, and that it improves precision of a treatment effect because it is based on more information than in a single study (3).

Despite the systematic methods to develop the review, some biases, typical for literature research, might have occurred in our review (2). Firstly, publication bias might have occurred, which refers to the possibility that not all studies on the specific topic are published and were therefore missed by the search strategy. This might result in an overestimation of the effect in a systematic review, because unpublished studies are generally the small studies with negative effects of the intervention. A solution for this type of bias is to search for unpublished studies. This is time consuming, and therefore we decided not to search for unpublished studies. However, this type of search has become more efficient during the last few years due to several sources on the world wide web, like the 'International Standard Randomised Controlled Trial Number Register' and electronic journals that have special interest in publishing study designs of planned trials, so before results are available. BioMedCentral is an example of such a journal, where we have published the design of our cognitive behavioural intervention *(chapter 5)*. Secondly, the methodological quality of the trials included in a review might differ significantly. Therefore, we have performed a methodological quality assessment by using a validated score list (4). One of the most striking limitations of all included studies in our review was the lack of a description of the method of randomisation. This might have resulted in selection bias, which refers to systematic differences between comparison groups in prognosis of responsiveness to treatment, for example when patients, who are more likely to have benefit from the intervention, are allocated to the intervention group. Thirdly, heterogeneity of the patients, interventions and outcome measures of the trials is a usual problem in literature research. The decision whether or not to perform a meta-analysis is very arbitrary. In our review we considered that there was clinical heterogeneity, which refers to differences between characteristics of study populations and methods of the interventions. However, there was no statistical heterogeneity, which means that evidence in the different studies was consistent and that it was possible to perform a meta-analysis, however, by taking into consideration the clinical heterogeneity. We decided to compromise by means of both a qualitative

analysis (5) and a quantitative analysis (6). We did consider the fact that this could be quite confusing for readers, which we have hopefully explained later in a letter to the editor (7-9). Our conclusion from this letter was that we used a different approach in the two publications, but that the results were the same and therefore we did not consider our way of presenting data as a problem. In addition, we concluded that the results of the meta-analysis should be interpreted with explicit caution, due to the clinical heterogeneity of the trials and the limited methodological quality.

Randomised controlled trials
It is generally acknowledged that randomised controlled trials provide the most reliable estimate of effects of an intervention on different patients' outcomes (3). The central question is: does the intervention work? We have investigated the effects of a cognitive behavioural intervention on lifestyle and patients' outcomes. We found that the intervention increased physical activity. This finding was statistically significant and therefore it is likely that there is a causal relationship between the intervention and physical activity. However, there still remains a possibility that the relation was caused by chance *(chapters 5 and 6)*.

An important consideration that has to be taken into account is that significant effects do not guarantee clinical relevance. As a result, randomised controlled trials can be proven effective but if the effects are not clinical relevant, then it is unlikely that the intervention will be implemented. The effect of our intervention was rather small and the 95% confidence interval quite large, which indicates that the clinical relevance of our intervention remains questionable. Even in case of clinical relevance, still more research is necessary: the intervention needs some adaptations or has to be tested in another study population. This means that it can take several years before an intervention will be used in a real-life setting.

Considerations on the design and implementation of the cognitive behavioural treatment
The cognitive behavioural treatment presented in this thesis was designed by us and therefore we would like to provide background information in this chapter. The research methods of the study have been described in our design article *(chapter 5)* and several methodological considerations have been already addressed in *chapter 6*. The advantage of a design article is that it provides the opportunity to describe the intervention in detail. In reality, things often turn out differently and several promises were made in the design article, that could

not all be satisfied. In the following chapter, we will pay more attention to the development of the design of this study and we would like to address some of the experiences we had during the implementation of the intervention into the Diabetes Management System (DMS) in West-Friesland.

Theoretical framework

The use of a theoretical framework has become a general assumption in behavioural intervention studies for several reasons. Firstly, they help to design the intervention, including the development of research questions and the selection of suitable outcomes measures. Theories stimulate researchers to consider which elements should be included in their intervention and why (10). Secondly, theories provide a good base for the evaluation of the intervention whereby not only the effectiveness of the intervention is taken into account but also the question: 'how does it work?'. This is an important issue, because in this way it can be investigated which elements are effective in the intervention or, of equal importance, why an intervention was ineffective (10-12). Thirdly, theoretical designs enable other researchers to repeat the intervention or to refine the intervention for use in their own setting (10). Unfortunately, a theoretical framework is still lacking in many intervention studies (10,12).

Our theoretical framework was based on a causal modelling approach (13), and was extensively described in the introduction of this thesis. Briefly, the theory of our intervention had four levels and we choose specific outcome measures to evaluate changes on each level, shown in *Table 1*. During the evaluation of our intervention, we analysed all outcomes measures of each level *(chapter 6)*. Level 1 is concerned with behavioural determinants according to the ASE-model (attitude, social influences and self-efficacy; the determinants of behaviour) (14,15). It is believed that past behaviour influences the determinants of current behaviour, that determine the intention of a person to change his/her behaviour, which is located at level 2. Next, behaviour change will improve physiological and clinical outcomes, at level 3. The final goal of the intervention can be found at level 4: to improve cardiovascular risk profile and quality of life.

At level 1, we chose to incorporate the ASE-model (14,15). Many other behavioural models, all concerned with the question how people make behavioural choices, have been used in earlier intervention studies (16). The usefulness of the different models is not entirely clear yet, although there are indications that the transition of people from one stage to another, according to the stages of change of the Transtheoretical Model of behaviour change (17), is too arbitrary to explain behaviour change (11,16). The Theory of Planned Behaviour (TPB) (18) has been used in many intervention studies, but there is

also inconclusive evidence supporting the utility of this theory in the development of interventions (19). The ASE-model seemed the most appropriate to use in our intervention because this is a commonly used model in interventions on lifestyle changes (20-23) and because it integrates several models (15), although there is no clear evidence on this theory as well. The ASE-model mainly incorporates the Theory of Reasoned Action (24) and Bandura's Social Cognitive Learning Theory (25). It is of course also very comparable with the TPB, because the TPB is based on the Theory of Reasoned Action. The main difference between the TPB and the ASE-model lies in the social influences determinant. The ASE-model assumes that there are three types of social influences: social support by others, social norms and perceived behaviour of others, whereas the TPB only addresses social norms (15). We considered this distinction of great value for the theoretical framework of our intervention, because of our target population of patients with type 2 diabetes. The lifestyle changes that a patient needs to make have to be implemented in daily life. Support from family and friends might help achieving lifestyle changes. In addition, it is very likely that lifestyle changes are more easy to achieve if the partner changes as well, which is embedded in the 'perceived behaviour of others' type. We believed that the techniques of 'Problem Solving Treatment (PST)', the method of our intervention, could increase the behavioural determinants of the ASE-model and in particular the self-efficacy determinant. Self-efficacy refers to the persons' belief whether he/she is able to perform the specific behaviour. The goal setting element of PST, followed by the evaluation and refining of the goal, might increase self-efficacy of the patient by means of positive experience with success and by encouragement of the diabetes nurses and dieticians. The patient might gain mastery of the required behaviour, which refers to the patient empowerment approach of the intervention (14).

Table 1. Theoretical framework of the cognitive behavioural treatment

Level	Causal model	Outcome measurements
1: Behavioural determinants	Past behaviour ↓ Attitude Social influences Self-efficacy } Intention to change	Physical activity (questionnaire) at baseline Dietary behaviour (questionnaire) at baseline Smoking status at baseline ASE-questionnaire
2: Behaviour	Behaviour	Physical activity (Δ 0-6 and Δ 6-12 months) Dietary behaviour (Δ 0-6 and Δ 6-12 months) Smoking status (Δ 0-6 and Δ 6-12 months)
3: Physiological and biochemical variables	Physiological and clinical outcomes	Body mass index (Δ 0-6 and Δ 6-12 months) Blood pressure (Δ 0-6 and Δ 6-12 months) HbA1c (Δ 0-6 and Δ 6-12 months) Cholesterol (total and HDL) (Δ 0-12 months) Triglycerides (Δ 0-12 months)
4: Health outcomes	Cardiovascular profile risk and quality of life	10-year risk for coronary heart disease (Δ UKPDS risk engine 0-12 months) Quality of life (Δ 0-6 and Δ 6-12 months) Depression (Δ 0-6 and Δ 6-12 months)

Intervention

It is still unclear what kind of behavioural intervention is effective in changing lifestyle in patients with type 2 diabetes and therefore it was difficult to choose appropriate techniques to use in the intervention (26). To our opinion, the best strategy was to use well-described treatments that had been proven effective in other populations. This was the reason why Problem Solving Treatment (PST) was chosen as the method of the intervention (27-29). It has been shown that PST is effective in studies with other populations, like depression and anxiety (30-32). PST is considered with identifying problems and learning how to set achievable goals in order to gain control over the problems (33), which fits perfectly into the patient empowerment approach of patients with diabetes: 'helping people to discover and use their own ability to gain mastery over their diabetes' (34). Furthermore, the problem solving approach, including goal setting, has been described before in diabetes research, although less clear than in the studies with depression (34-36). Therefore, we chose to implement this method into the intervention. We defined an intervention completed if at least 3 PST sessions were followed, with a maximum of 6 sessions. This decision was based on the idea that a very intensive intervention usually results in a large dropout of patients. An intervention with less than 3 sessions would probably be too mild to result in any changes.

Motivational Interviewing (MI) was the second method that aroused our interest (37-39). A motivational phase should be preceding PST to motivate the patient to change. MI has shown successes in several studies and seemed a very useful method for our intervention, due to the advantage of a brief and client-centred approach (38). Unfortunately, we have to admit that we were not able to implement MI due to the complexity of PST only, experienced by the diabetes nurses and dieticians. We considered that is was more reasonable to focus on PST only.

Caregivers

The training for the intervention was given to four diabetes nurses and eight dieticians of the DMS. However, due to personnel changes in the group of dieticians, only four were available during the whole study. This did not cause any problems with the availability of caregivers and therefore we do not think that this had influenced our results.

The intervention was quite difficult to apply to regular care in the beginning and asked for a lot of effort and energy from all caregivers. The approach towards the patient was very different from what the caregivers were used to. The caregivers were familiar with patient empowerment, but not with

problem solving and goal setting, the main elements of the intervention. The strength of our intervention was that we standardised the intervention by means of protocols, supervision meetings and tape recordings. It is possible however that some caregivers have developed their own strategy to perform the intervention. They might also have missed some steps of the intervention, either arbitrarily or consistently. In addition, the personality and communication skills of each individual caregiver might have attributed to different approaches of performing the intervention. This is a common problem in intervention studies; it always remains questionable if the intervention was performed according to the standardised method. Treatment fidelity, which is defined as 'the methodological strategies used to monitor and enhance the reliability and validity of behavioural interventions', could have been assessed in our intervention by using the tape recordings (40). Due to time limits, we were not able to perform a study on treatment fidelity.

Although we did not analyse the capability of the caregivers, we do think that diabetes nurses and dieticians are a very suitable group of caregivers to perform behavioural interventions. After all, these caregivers are the people that have the best knowledge of diabetes and its complications and care. However, there are a few requirements that have to be taken into account when implementing the intervention into clinical care. An extensive training on the intervention should be organised. This demands for enough financial means and available time. In addition, the clinical care setting should offer the caregivers the possibility to practise with pilot patients in order to gain experience with the method of the intervention.

Study population and sample size

Patients were recruited from the DMS. The first 30 included patients were pilot patients in order to investigate if logistic pathways were feasible and to provide the opportunity for the caregivers to gain experience in performing the intervention. During the pilot study, caregivers had difficulties to succeed in performing the intervention to patients that were having good levels of their clinical outcome measures. Behavioural change was not really necessary for those patients and therefore we developed inclusion criteria for the study. We selected patients that were at high risk of developing complications. Patients were eligible to participate in the study if they fulfilled at least one of the following criteria: smoking and/or an HbA1c $\geq$ 7.0% and/or a body mass index $\geq$ 27.0 kg/m^2.

The recruitment of patients was done by research assistants of the DMS during regular yearly assessments. During the first months of the study, all

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research assistants were authorized to invite patients for participation in the study. However, because not all research assistants were able to explain the study and to motivate patients to participate, the sample size was growing too slowly. Therefore, we changed the procedure and one research assistant became responsible for the recruitment of patients. She succeeded in increasing the sample size of the study, but we were not able to include as many patients as we aimed for, resulting in a lack of power. The inclusion period was 1 year and it was not possible to extend this, because we recruited patients in the yearly assessments from the DMS, we had invited all patients in the period of 1 year. After this year, the same patients visited the DMS for their next assessment. It might be possible that some of the non-significant differences between the intervention and control group would be statistically significant in a larger population.

The recruitment of patients from an existing care setting had both advantages and disadvantages. The advantage was that patients were familiar with the DMS and the caregivers, which could have increased their motivation to participate. The disadvantages are that some patients might have already participated in other studies of the DMS and were therefore not willing to volunteer in another study. In addition, the fact that we did not find any effects of the intervention on clinical outcomes might have been due to the high quality of care of the DMS. Patients that were participating in the intervention study were already under strict treatment in the DMS for a few years and were not able to gain further improvements. It seems that a strict medication treatment (*chapter 3)* is an easier method to improve clinical characteristics. Hence, it remains a challenge to change patients' behaviour, which was found to be effective in changing patients' outcomes in observational studies. Therefore, we still think that increasing patient empowerment is an important task of diabetes care, in addition to strict medication treatment.

Outcome measures
Several different outcome measures were chosen to investigate the effects of the intervention *(Table 1)*. Clinical measurements were performed and many questionnaires were used, which enabled us to provide an extensive assessment of the expected benefits of the intervention. We used validated questionnaires but, to our knowledge, no questionnaire was available on determinants of behaviour of the ASE-model. Experts in the field were consulted and we investigated their questionnaires to develop our questionnaire on determinants of behaviour. A 7-point Likert scale was chosen above a 5-point scale, which was

also seen in several questionnaires, because a 7-point scale is more sensitive for change.

We do consider the use of this unvalidated questionnaire as a limitation of the study. We do not have any information on the accuracy and sensitivity of the questionnaire. To assess the reliability, validity, and sensitivity to change, a validation study has to be performed, but this was beyond the scope of this thesis. However, Cronbach's □ were calculated to assess internal consistency of the items in the questionnaire and these were found to be satisfactory, which we considered valuable.

Another limitation of the outcome measures in our intervention was the use of a questionnaire to assess physical activity. In general, people tend to overestimate physical activity and therefore more objective measures would have provided more reliable measures. A more accurate measurement would have been provided by using an accelerometer to assess physical activity. However, the lack of financial sources was a major reason to decide to use questionnaires only.

Recent developments

A lot of scientific research has been performed on the topic of type 2 diabetes, likely as a result of its high prevalence and its severe complications. Hence, other research on disease management and patient empowerment has been carried out simultaneously with the performance of our studies. We would like to address some of those recent developments here.

Disease management

In *chapters 2 and 3*, we described the elements of our disease management system: coordination, feedback and patient empowerment. We found that our disease management system improved and stabilised clinical characteristics of the patients. The strengths of our study were the large study population, the long follow-up period and the fact that our disease management system was evaluated in a real-life setting instead of in an experimental setting.

Disease management has become a common studied topic in scientific research on diabetes. It is now generally believed that the traditional way of healthcare delivery is too fragmented and disorganised and does not fulfil the needs of the individual chronic patient (41). In *chapters 2 and 3* we provided some examples of randomised controlled trials and observational studies, based on the chronic care model (42-45). These studies were also successful in improving clinical characteristics.

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Based on our findings and the results of other studies we believe that disease management for patients with type 2 diabetes is successful in improving patients' characteristics. However, clear evidence on the effectiveness of disease management is still lacking. We found one systematic review on disease management for patients with diabetes by Norris et al. (41). They found that disease management interventions are effective in improving glycaemic control but that there are still many gaps in the literature on disease management. Their main concern was that the definition of effective interventions is unclear, which makes it difficult to start implementation of disease management in clinical practice. They were also concerned about the lack of long-term effects and effects on quality of life of the patients. Krumholz et al. (46) also acknowledged these problems. Their observation was that it is difficult to compare studies on disease management because of their heterogeneity and the lack of standardisation of the term 'disease management'. This complicates implementation of disease management. Therefore, they performed a qualitative review in order to provide a taxonomy for disease management. The goal of their taxonomy was to provide a framework that could be used to compare different disease management programs and to identify effective factors. By performing a qualitative evaluation of available literature they identified 8 domains that should be clearly described in new disease management systems in order to compare the several systems: 1) patient population, 2) intervention recipient, 3) intervention content, 4) delivery personnel, 5) method of communication, 6) intensity and complexity, 7) environment, 8) clinical outcomes.

Another difficulty of disease management systems is the lack of evidence on which elements of systems are the effective components (46,47). Several studies have identified effective elements like a multidisciplinary team of caregivers, a therapeutic plan, a central computer system, feedback to patients, and education. In addition, due to technological developments, the use of follow-up of patients by telephone calls and web-based support has become a subject of much research as well. However, the necessity of a multifaceted approach, as we applied to our disease management system, has reached general acceptance. As a consequence, the focus on the identification of the most effective elements has become less important. Krumholz et al. showed several components in their taxonomy that should be included in disease management systems, but in which way depends, to our opinion, on the setting and target population. It is clear that the central role of the patient in the care should be guaranteed in all systems. This was also addressed in a recent article by Bodenheimer (48). According to this article, the problem in traditional care is that clinicians do not verify whether the patients understands their

recommendations, which results in non-adherence to prescribed medication. In addition, clinicians do not encourage patients to make their own decisions, resulting in an uninformed and passive patient. Bodenheimer et al. described that encouragement of patients to become decision-maker of their care results in a participatory relationship between patient and caregiver. This relationship is probably a successful factor that is needed to achieve behaviour change in order to adapt a healthy diet and lifestyle. The chronic care model, which was also the basis of our disease management system, was also highlighted in this article and it was emphasized that chronic care requires 'a prepared, proactive practice team interacting with an informed, activated patient'. The task of the practice team is self-management support, by means of several activities like: providing information, promoting health behaviour change, training in problem solving skills, and regular follow-up visits.

In summary, disease management seems effective in improving clinical characteristics and it is likely that the multifaceted approach is the effective element of disease management. Further research on disease management is needed, mainly to gain consensus on what the exact definition of disease management is. A clear definition will facilitate implementation into real-life settings. In addition, patient empowerment should be further encouraged in order to give rise to an active participation of the patients in their own care. The next two sections pay more attention to the evidence on patient empowerment interventions.

Self-monitoring of blood glucose

In 2003, when we started to develop a systematic review on self-monitoring of blood glucose (SMBG) in patients with diabetes who are not using insulin, there was an ongoing debate on the effectiveness of SMBG in this group of patients. Almost simultaneously with the publication of our review, another review on the same topic was published by Sarol et al. (49). They included 3 additional studies, but reached the same conclusion: SMBG resulted in a reduction of HbA1c of 0.39%. Their opinion was that education on diet, exercise and medication is a requirement for optimal SMBG.

A meta-analysis by Jansen et al. in 2006 (50) concluded that among non-insulin requiring type 2 DM patients, SMBG is more effective than an intervention without self-monitoring.

Another recent review by McGeoch et al. (51), who included both observational studies (n=13) and randomised controlled trials (n=3) with at least 50 patients and with a follow-up of at least 6 months, showed that SMBG is probably beneficial as educational tool for patients who are not using insulin, but

that further research is needed on frequency of testing and patient education on how to respond to results.

A recent randomised controlled trial was published in 2007 by Farmer et al. (52). Patients were randomised into three groups: a control group, who received usual care including goal setting; a less intensive SMBG group who received usual care, goal setting and SMBG; and a more intensive SMBG group, receiving usual care, goal setting, SMBG and information on how to interpret glucose values and how to make adaptations to diet, physical activity and medication. They found no statistically significant differences in HbA1c between any of the groups after 12 months and concluded that there is no convincing evidence from this trial on the effect of SMBG for patients not using insulin.

Two recent observational studies showed opposite effects. Davis et al. (53) used cross-sectional and longitudinal data and compared SMBG-users with non-SMBG-users. They found no beneficial effects of SMBG on glycaemic control in non-insulin-treated patients. Martin et al. (54) performed an observational cohort study to investigate the relationship of SMBG with disease-related morbidity and mortality. The mean follow-up of patients was 6.5 years and SMBG was defined as performing self-measurement of blood glucose for at least 1 year. They found that SMBG was a marker for better clinical outcomes.

These studies indicate that there is still a controversy whether SMBG is an effective tool for patients who are not using insulin. This was again highlighted in a recent discussion (55,56). It is unclear if SMBG helps to increase patient empowerment by means that the information provided by SMBG might enable patients to understand the effects of diet, physical activity and medication on glucose levels. Hence, there is an urgent need for a large randomised controlled trial with a long follow-up, which can answer the question whether SMBG is effective for patients who are not using insulin. Such a trial would provide important information for patients and caregivers but also for policy makers and insurance companies.

Behavioural interventions

We have already compared our cognitive behavioural treatment with other recent self-management interventions in *chapter 6*. Several of these studies found improvements in weight and in cardiovascular disease risk, and also in quality of life. Gaede et al. (57) and Thoolen et al. (58) both found that a combination of strict medication treatment and a lifestyle intervention is the most effective. In fact, we also combined a lifestyle intervention on top of a strict medication treatment in the DMS, as described in *chapter 3*. Our intervention was of additional value to the care of the DMS, which was shown in

the increase in physical activity in the intervention group, compared with the control group, on the short term. Unfortunately, we were not able to show improvements in clinical characteristics and, as a consequence, we cannot state that our intervention should be used in clinical care. However, we still believe that behavioural interventions should be incorporated in diabetes care. The chronic character of the disease and the fact that most patients with diabetes are overweight do stress the importance of self-management including lifestyle change. It seems that other researchers agree with our idea, indicated by several design articles that we found in the literature of intervention studies that will be performed in the next few years (59,60).

A recent review by Peyrot et al. (61) tried to identify key interventions that can be implemented by diabetes care providers. They discussed the importance of the use of theory of behaviour in interventions, the rationale of elements that were most commonly used in interventions, and the importance of emotional support of patients with diabetes. They provided a list of steps that caregivers should go through to help patients increase their self-management. They also addressed that techniques that are most appropriate in behavioural interventions are, among other things, goal setting, problem-solving, environmental change, self-monitoring and social support. The conclusion of this study was that diabetes care could be improved by implementing these steps in standard diabetes care. We considered that their conclusion is postulated very positive, but we do hope that it encourages policymakers, caregivers and researchers to further develop interventions that fit into the patient-empowerment approach, enabling a central role for the patient.

Motivational interviewing

Motivational interviewing (MI) (37) is a brief, client-centred counselling style directed at optimising motivation of a patient by exploring and resolving ambivalence. During the last few years, MI has been addressed as an important technique to use in behavioural interventions (61). We had planned to incorporate MI in our intervention as well, as we explained earlier in this chapter, but we were not able to implement it due to the complexity of PST only.

The rationale of MI is embedded in four guiding principles: 1) express empathy, which involves reflective listening of the caregiver. As a result, an atmosphere of respect and acceptance of the position of the patient is created; 2) develop discrepancies by creating a gap between the patient's current behaviour and his/her goals. This creates motivation for lifestyle change because the patient will start to recognise discrepancies between current behaviour and

goals, which will make change more likely to occur; 3) roll with resistance rather than challenging resistance because that usually results in the defence of the patient towards the current behaviour. Roll with resistance will invite the patient to consider new perspectives on lifestyle change; 4) support self-efficacy, which is a good predictor of treatment outcome. Self-efficacy can be supported by reinforcement of past success, presenting successful stories of other people (modelling), and expressing belief in the patients' ability to change.

The evidence of MI for patients with diabetes is scarce. To our knowledge, there are only two randomised controlled trials that used MI in their intervention with diabetic patients. Smidt-West et al. performed a study with female patients with diabetes and they showed that MI significantly improved weight loss (62). Clark et al. found that a brief intervention, based on MI, was successful in reducing fat intake and increasing physical activity levels (63). At least two reviews on the effectiveness of MI on behaviour change in other study populations have been written lately (38,39). Both reviews concluded that MI is effective in improving clinical outcomes of patients in a scientific setting, however, it is unclear whether MI can be implemented in daily practice and whether all healthcare providers can learn the techniques of MI, which we also experienced difficult in our intervention. However, recently, two studies found opposite results on this issue. Rubak et al. (64) evaluated the conception of general practitioners of MI methods and use in general practice after a course. They concluded that the general practitioners evaluated MI as more effective and not more time-consuming than traditional care (64). Brug et al. (65) also showed that training dieticians, working in diabetes care, results in changes in their counselling style with respect to showing empathy and making reflections. Also, the amount of time that the dieticians talked reduced, with the effect that the patient was given the opportunity to talk more. However, they found no evidence for effects of MI on clinical outcomes.

These trials and reviews suggests that MI is effective in changing people's behaviour and that the implementation in daily practice does not seem very difficult. However, more research on the effectiveness and implementation of MI in diabetes care is necessary.

Risk communication

Another recently addressed key area in behavioural science is risk communication (66). It has been shown that patients underestimate the risk to develop severe complications (67). In addition, they do not understand the explanation of caregivers on risks (68-70), because risks are usually presented in the percentage of people that will develop a specific complication (68,71,72). As a result,

patients are not encouraged and motivated to change their lifestyle. This idea was already presented in 1997 in Leventhal's self-regulation model (73-75). This theory assumes that the cognitions of a patient on diabetes and its treatment determine the attitude concerning self-management. Cognitions include the identity, timeline, cause, consequences and controllability of the disease. This theory can easily be combined with the theory used in our intervention: the ASE-model. By providing understandable information on the disease and its risk, patients are likely to change their cognitions. As a result, patients will increase their motivation to change by changing their attitude, which is embedded in the ASE-model. Finally, patients will change their lifestyle, which will reduce the risk of developing severe complications.

A few studies have been performed on risk communication (76,77) but, to our knowledge, not with patients with diabetes and therefore, further research on this topic is needed. It seems that patients are more likely to be able to understand a visual presentation of risks, rather than a presentation in percentages (76-79). Also, positive framing, which means that the benefits of behaviour change are highlighted instead of a frame that focuses on the effect of not changing in terms of loss of healthy years of one's life, seems to help to increase patients' motivation (78,80,81).

In conclusion, different behavioural interventions with diabetic patients as the target group are performed on a large scale worldwide. However it is still unclear how they work, what the most successful techniques are and which groups of patients would benefit from them. We have learned in the last few years that a theoretical framework should be guiding the intervention during both the development and evaluation of it and that at least 3 phases should be included in interventions. Firstly, the risk of having diabetes should be explained in a way that the patient can understand. Secondly, a motivational phase with techniques like MI has to be used. Thirdly, the patient should learn how to increase self-management. Important techniques that can be used in this stage are goal setting, problem-solving and self-monitoring.

Implications for clinical practice

♦   This thesis suggests that disease management systems improve patients' clinical characteristics and that such systems should therefore be implemented in clinical care in order to improve diabetes care. Such systems should have a multifaceted character with coordination of care between different caregivers and a recall system for patients, feedback to all involved caregivers, and stimulation of patient empowerment. Standard guidelines for diabetes care should be followed by caregivers. The main aim of the systems ought to be to guarantee a central role for the patient.

♦   Patient empowerment should be further stimulated in clinical practice. Self-monitoring of blood glucose seems to improve glycaemic control, also in patients not using insulin. Policy makers should consider this when developing new policies on financial expenses in health care. In addition, interventions that teach patients how to manage their own disease and how to make lifestyle changes are of great importance in clinical practice. Finally, a collaborative partnership between a patient and the caregiver should be encouraged.

Implications for further research

♦   The results from our Diabetes Management System imply that such systems are able to improve clinical characteristics and achieve strict medication treatment. However, because we did not have the availability of a control group, we do not know if our system was more effective than usual care in the Netherlands or care from other systems. In addition, it is unclear if disease management systems are cost-effective. Such a system can be cost-effective in a direct way when costs of disease management systems are lower than of care from general practitioners and specialists. Also, a reduction in hospital admission days attributes to cost-effectiveness. In addition, an indirect reduction in costs would also be beneficial. Indirect costs are, for example, costs due to sickness leave or incapacitation for work. Furthermore, quality of life and patient satisfaction should be assessed to investigate whether the burden on patients, which is caused by having diabetes, can be reduced by disease management *(chapters 2 and 3)*.

♦   Our systematic review and meta-analysis suggested that there is need for a large randomised controlled trial, with a long follow-up and a good methodological quality to assess the effects of self-monitoring of blood glucose in patients with type 2 diabetes who are not using insulin. Such a trial should not only investigate the effects on glycaemic control, but also

incorporate other outcome measures like quality of life, well-being and patient satisfaction. This would gain further insight into the self-management of diabetes *(chapter 4)*.

◆ The cognitive behavioural treatment suggests that patients are able to change their lifestyle on the short term, even when they have already received managed care. As a next step, we would like to investigate the validity of the causal model of our intervention by means of assessing associations between the four levels of the model.

Our intervention implies that patient empowerment needs to be further encouraged, but it remains a challenge to find behavioural interventions that have beneficial effects on the long term and on clinical outcome measures. New, larger intervention studies, based on a theoretical framework, should be performed to find the most effective intervention that can be implemented in clinical care *(chapters 5 and 6)*.

◆ In our final study we compared the cognitions and behaviour of two different groups of patients: screen-detected and clinically diagnosed patients. The results of this study suggested that there are differences between these patients: the screen-detected patients were more motivated to change and are therefore more likely to benefit from a behavioural intervention. However, this was a cross-sectional study, which means that it is unclear whether these groups indeed respond differently to an intervention. A randomised controlled trial should help to assess if we can predict which patients are likely to benefit from interventions and which patients need other methods to change their lifestyle. This study highlights the need for studies that take into account different subgroups of patients. This requires large study populations to provide enough statistical power to detect differences between the groups *(chapter 7)*.

Final conclusions

From this thesis on disease management for patients with type 2 diabetes, with special attention for patient empowerment, can be concluded that:

◆ A disease management system *(Chapter 2)* is successful in improving and stabilising HbA1c and the estimated 10-year risk of developing a coronary heart disease event. A disease management system might therefore be a major step in the improvement of diabetes care for patients with type 2 diabetes *(chapter 2)*.

♦ Diabetes is a progressive disease, which needs intensive medication treatment. An increase in medication prescription every year seems inevitable in order to maintain management goals *(chapter 3)*.

♦ Self-monitoring of blood glucose might be an effective tool to improve glycaemic control in the self-management of patients with type 2 diabetes who are not using insulin *(chapter 4)*.

♦ Adding a cognitive behavioural intervention focused on changing lifestyle might provide additional benefit for patients with type 2 diabetes on the short term, when added to a disease management system. The intervention in this thesis increased physical activity, but other effects were not found *(chapters 5 and 6)*.

♦ Diagnosis by screening might offer a window of opportunity for behavioural interventions *(chapter 7)*.

Overall, from the present thesis can be concluded that diabetes care can be improved by the implementation of disease management systems. The multifaceted approach with elements like coordination, feedback and patient empowerment seems to be beneficial to improve patients' outcomes. However, we did not succeed in showing effects of our behavioural intervention on cardiovascular risk factors. It seems that strict medication treatment, as was achieved in our diabetes management system, is an easier way to improve clinical characteristics of patients. Therefore, it is important that caregivers should strictly follow standard guidelines on diabetes care.

Patient empowerment remains a challenge in diabetes care. A central role of the patient should be further established and the patient should be encouraged to become the decision-maker of the care. As a consequence, the patient and the caregiver can work together in a collaborative partnership towards excellent diabetes care.

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