

Chapter 1

General introduction

The main objective of this thesis is to provide insight into disease management of patients with type 2 diabetes. Type 2 diabetes is a chronic disease that, despite an adequate treatment, leads to severe complications. Due to the chronic character of the disease, diabetes care not only involves treatment with medication, but also management of the disease. Disease management is the central theme of this thesis. In addition, patient empowerment, which is one of the main elements of disease management, will be discussed in detail by means of several intervention studies. Patient empowerment is concerned with how patients can learn to control their disease and, simultaneously, live a normal, enjoyable life.

This first chapter will introduce the problems in type 2 diabetes and the importance of the two main themes. The chapter will be completed with the objectives and outline of the thesis.

Type 2 diabetes

Diabetes mellitus is a metabolic disease, characterised by elevated blood glucose levels (hyperglycaemia), with two major types. Type 1 diabetes is caused by a destruction of beta-cells in the pancreas, resulting in absolute insulin deficiency. This leads to hyperglycaemia. Treatment involves daily administration of insulin, generally by means of subcutaneous injections. Diagnosis is usually before the age of 30 (1). Type 2 diabetes is due to a deficient beta-cell function (impairment of the beta-cells in the pancreas to release sufficient insulin) and insulin resistance (2). Patients with type 2 diabetes can control their disease with lifestyle changes such as a healthy diet, physical activity and smoking cessation, but when a certain stage is reached, oral medication is inevitable and finally, almost all patients have to use insulin to prevent high blood glucose levels (1). Hyperglycaemia leads to severe micro- and macrovascular complications, like retinopathy, neuropathy, nephropathy, foot problems and cardiovascular disease. In order to prevent and delay these severe complications, optimal diabetes care is required.

This thesis deals with type 2 diabetes only, which accounts for about 90% of people with diabetes worldwide (1) and is now a major health problem with an increasing prevalence and incidence. Worldwide, more than 200 million people have diabetes and this number is expected to double by the year 2030 (3). There is even an ongoing debate that diabetes is an epidemic (4,5). The main reasons for the rapid increase in the number of people that have diabetes are population growth, ageing, and incredible rises in the prevalence of obesity, due to unhealthy diets and a sedentary lifestyle (3,5).

Disease management

The main goal of diabetes care is to prevent or delay the onset of diabetes related complications, including cardiovascular disease, which is one of the main causes of death for patients with diabetes (6-8). In the Netherlands, the general practitioner (GP) is responsible for the care of patients with diabetes, guided by standard guidelines for type 2 diabetes from the Dutch College of General Practitioners (9). Three-monthly visits to the GP are recommended to control diabetes. In addition, an extensive yearly assessment is advised. Diabetes care involves a complexity of tasks for the GP like advice on diet and physical activity, medication treatment, and identification of psychological problems, which are more prevalent in diabetic patients than in the general population (10,11). Not only a strict glycaemic control but also control of cholesterol levels and blood pressure are important. However, implementation of guidelines into daily practice seems difficult (12). Reasons that have been addressed for the inadequate care are a lack of coordination of care between different disciplines, no availability of recall systems, which results in a poor patient compliance, and no central database with patients' clinical outcomes that is required to provide chronic, rather than acute, care (12,13).

During the last few decades, disease management for patients with type 2 diabetes has gained considerable interest due to the high prevalence of type 2 diabetes, the chronic character of the disease, and the risk for developing severe complications, which cause a considerable burden on both patients and health care. 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' (14). Disease management is addressed as having a high potential to improve outcomes for patients with diabetes. Its introduction has caused a shift in the organisation of care from general practices towards chronic care systems, with a multifaceted approach (14,15). Elements of disease management are: a multidisciplinary team including dieticians and diabetes nurses, a central organisation of care, increasing patient empowerment in order to improve patients' skills and confidence to manage their chronic disease, standard guidelines, and a central database that serves as a reminder system to recall patients for yearly check-ups and to give feedback to caregivers (16,17). The main task of disease management is to guarantee a central role for the patient.

Randomised controlled trials on the effectiveness of disease management for patients with type 2 diabetes showed that patients outcomes improved on the short term (18-22). Only a few long-term follow-up studies have been performed

on structured care but the limitation of these studies was the lack of a theoretical design (23,24). In addition, it is still unclear if disease management works in real-life settings (21). Therefore, additional research on this topic is important to gain insight in the management of this progressive and highly prevalent disease.

Patient empowerment

The main element of disease management is patient empowerment. Patient empowerment was introduced in the 1990s and is defined as 'helping people to discover and use their own ability to gain mastery over their diabetes' (25). This approach came from the idea that, although caregivers are the experts on diabetes care, patients are experts on their own life and should therefore be the primary decision-makers in control of their diabetes. As a result, diabetes care becomes a collaboration between the patient and the caregiver, and the traditional role of the caregiver as an expert, who gives advice and recommendations, disappears (26). It is now generally acknowledged that patient empowerment results in benefits for both patients and caregivers. Patients would achieve better clinical outcomes, an improved quality of life and satisfaction and are better able to communicate with caregivers. The benefits for the caregivers are an increased satisfaction in work, and achievement of treatment goals (26).

Patient empowerment is concerned with several strategies, used by caregivers, to facilitate self-management of diabetes. Strategies include: education to promote decision-making on medication treatment and to learn patients how to set achievable goals for lifestyle change; stimulation of self-monitoring of blood glucose in order to increase patients' knowledge on the effects of different behaviours on their glycaemic control; provision of information to emphasize that the patient has the responsibility and expertise of the disease (25,27).

This thesis deals with the effectiveness of two interventions that are based on the patient empowerment approach and that both incorporated several of the above-mentioned strategies: 1) self-monitoring of blood glucose, and 2) behavioural interventions. These interventions will be further explained in the next paragraphs.

1) Self-monitoring of blood glucose

Self-monitoring of blood glucose (SMBG) aims for the collection of information on glucose levels at several time-points during the day. By means of a small fingerprick, patients can assess their blood glucose levels at any particular time

(28). SMBG provides insight into fluctuations in blood glucose concentrations in daily life. In contrast, HbA1c, which is usually measured by caregivers to assess glycaemic control, provides an estimate of the glycaemic control during the last 2-3 months (28).

SMBG is an important technical advance because it might help to increase self-management of patients. By means of the provided information, patients learn about the effects of dietary intake, physical activity and medication on their glucose levels. They can make adaptations in their lifestyle which might improve glycaemic control and minimise complications (29,30).

SMBG has been shown to be effective for patients who use insulin. By means of SMBG, insulin doses can be easily adjusted to glucose levels (30). There is an ongoing debate that SMBG might also be beneficial for patients who are not using insulin, because evidence on effectiveness is inconclusive. Several studies did not succeed in finding significant effects of SMBG on glycaemic control, while other studies did find that SMBG improves HbA1c (30-32). Therefore, there is need for more research on this topic. In this thesis, a systematic review was performed to summarise results from all performed SMBG studies. A systematic review provides insight into the overall effectiveness of SMBG and provides easily available information for researchers and care providers.

2) Behavioural interventions

Behavioural interventions have gained great acceptance in diabetes care during the last few decades. It has been shown that behavioural interventions lower risk factors, with the result that the risk of developing cardiovascular disease decreases (33-35).

All interventions that have been performed during the last few years are based on the patient empowerment approach and their general aim is to motivate people to increase self-management by using skills like goal-setting and problem solving in order to change behaviour (36). The final goals of an intervention are to optimise metabolic control, to prevent severe complications, and to increase quality of life (34).

Previously described interventions have used a wide range of techniques and behaviour models, but the design of the studies was not well described. Therefore it is difficult to identify successful factors in behavioural interventions (37). More research on this topic is important to gain more insight into the effectiveness of behavioural interventions and the techniques that should be used.

Background of data collections

Four different data collections were used in this thesis to gain further insight into disease management and patient empowerment. The background of these data collections is addressed in this paragraph:

1. Data from the 'Diabetes Management System' (DMS), West-Friesland, the Netherlands were used to perform a longitudinal observational study. The DMS was implemented in 1997 in the region West-Friesland in order to provide adequate diabetes care for patients with type 2 diabetes, in addition to the care from the GPs. GPs were requested to refer all their patients with diabetes to the DMS. Care in the DMS is based on the theory of a chronic care model, which has been extensively described in the literature (16,17,38). The DMS incorporated 3 central elements, which are illustrated in Figure 1: 1) coordination of care by means of a central database and a recall system and coordination of care between different domains, like specialist and podotherapists, 2) feedback to both patients and caregivers by means of yearly assessments, 3) stimulation of patient empowerment by giving education, providing information and promoting self-monitoring of blood glucose.

Each patient is invited every year by the recall system for an assessment, which consists of two visits. During visit 1, a physical examination is performed, blood is collected for laboratory measurements and prescribed drugs are documented. About 2 or 3 weeks later, results are available and the patient will successively visit a diabetes nurse, to discuss clinical outcome measures, and a dietician, to discuss dietary intake, both for 30 minutes. The results are sent to the GP in order to provide feedback. If necessary, the patient is requested to consult a specialist or podotherapist for additional care.

Data from the DMS from 1998 - 2005 were used in this thesis to describe changes in patients' clinical characteristics and in the prescription of medication to the patients after their entry into the DMS. These studies would provide insight into the results of disease management on patients' characteristics.

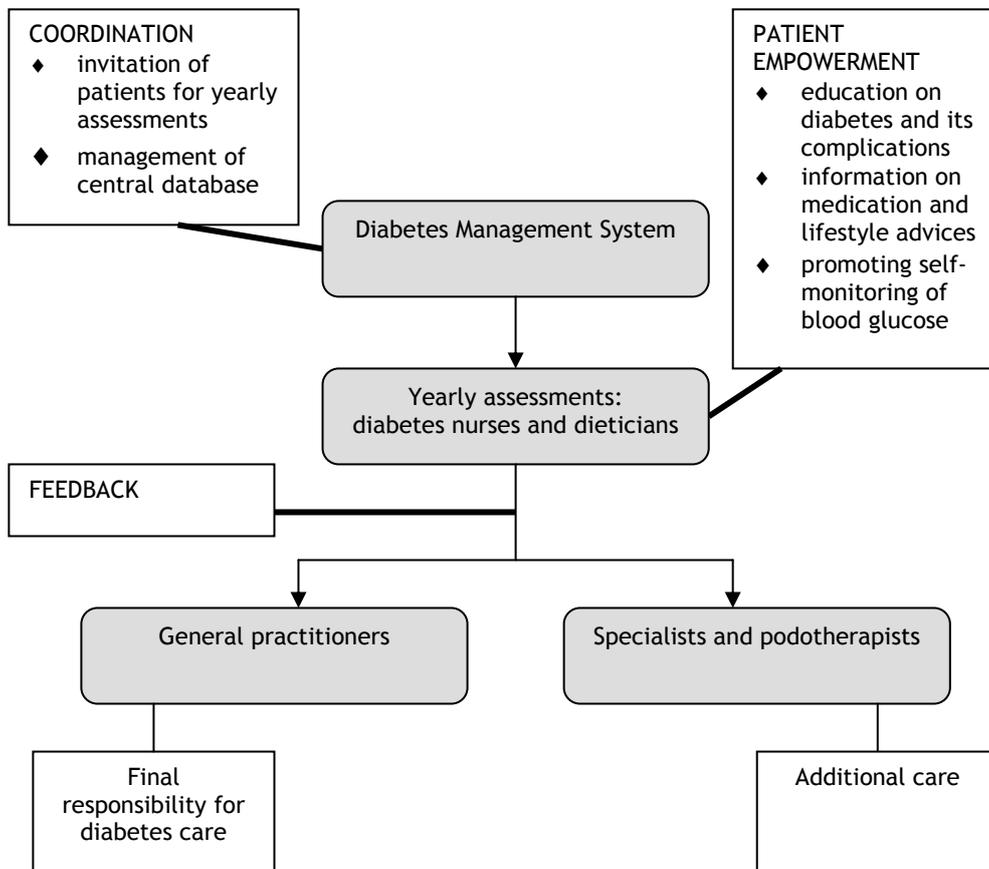


Figure 1. The Diabetes Management System, West-Friesland, the Netherlands

2. A systematic review and meta-analysis was performed on self-monitoring of blood glucose for patients who are not using insulin. This review was concerned with the second theme of the thesis 'patient empowerment'. This review might give an answer to the question if SMBG is beneficial for patients who are not using insulin. A thorough search of the literature was performed to summarise all available evidence regarding the effectiveness of self-monitoring of blood glucose for a specific group of patients with type 2 diabetes. The results of selected studies were combined in a meta-analysis.

3. A cognitive behavioural treatment focused on changing lifestyle was performed in a randomised controlled trial. It was added to the care of the previously mentioned DMS, in order to improve self-management of patients that were at high risk to develop severe complications. High risk was defined as fulfilling at least one of the inclusion criteria: HbA1c \geq 7.0%, or body mass index \geq 27.0 kg/m², or smoking.

GPs who were participating in the DMS were invited to participate in the study (n=14). Patients from these GPs were invited to take part in a behavioural intervention that consisted of a motivational phase guided by techniques of Motivational Interviewing (39-41), and a phase that was focused on the increase of self-management of the patients in order to facilitate behavioural change. Problem Solving Treatment was used in this phase (42-44). The intervention was given by dietitians in case of a dietary problem, and by a diabetes nurse, when physical activity or smoking was the main problem.

In Figure 2, the theoretical framework of the cognitive behavioural treatment is shown which is based on a causal model with four levels (45). We hypothesised that past behaviour can be discussed by Motivational Interviewing, resulting in changes in determinants of our behavioural theory: the Attitude, Social influences and self-Efficacy model (ASE-model) (46,47). According to this theory, the intention to change behaviour is determined by the attitude towards a specific behaviour, by self-efficacy concerning performing the behaviour and by social influences presented by relevant others. Problem Solving Treatment is concerned with goal setting and might therefore help to influence the intention to change behaviour. Consequently, behaviour change occurs, which improves outcome measures and finally, the risk to develop cardiovascular disease and quality of life.

This study investigates the effectiveness of a cognitive behavioural treatment, which might help to gain further insight into whether patient empowerment enables patients to change their lifestyle in order to gain control of their diabetes.

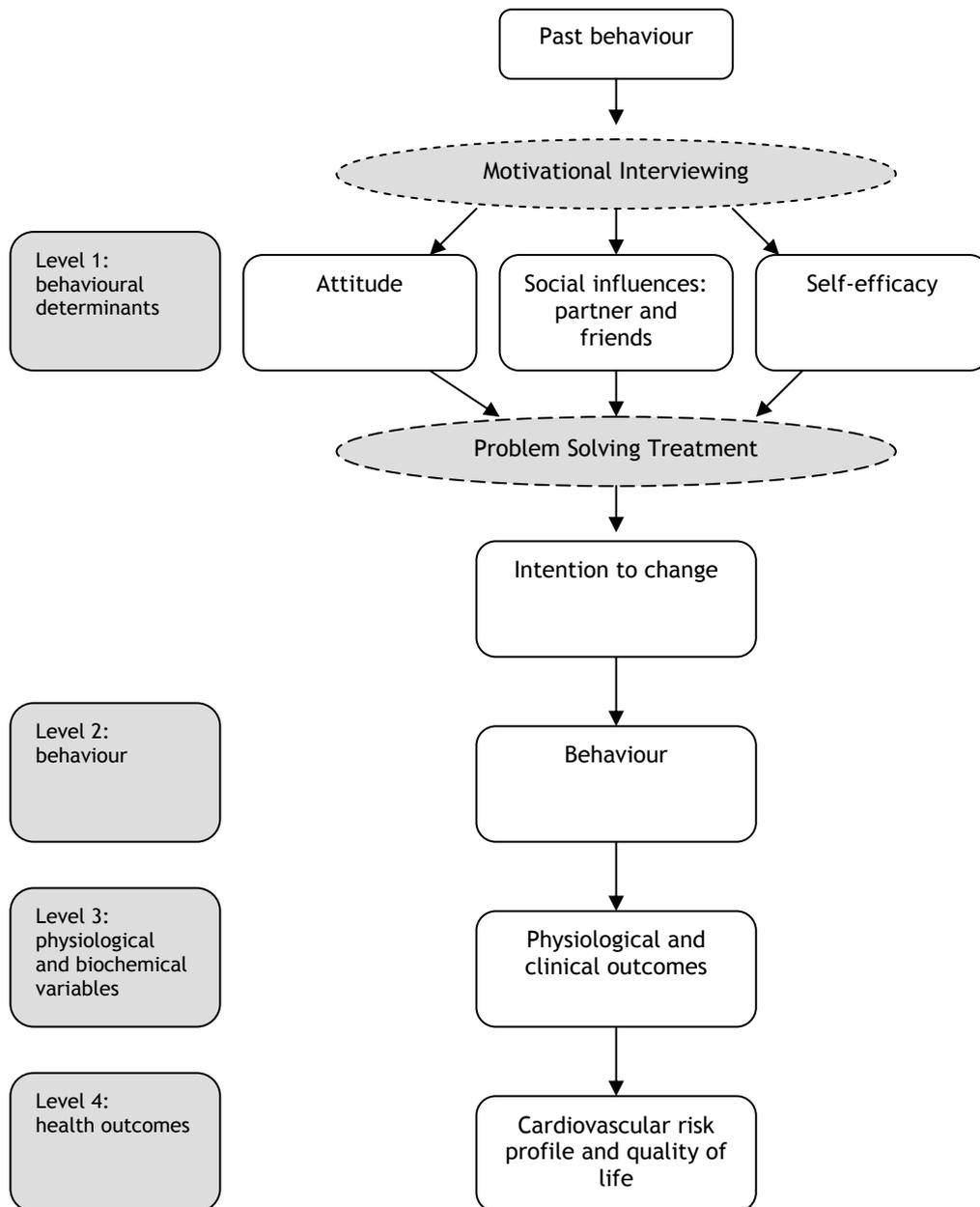


Figure 2. Theoretical framework of the cognitive behavioural treatment

4. The last study on patient empowerment was performed with baseline data from a randomised controlled trial: the *ADDITION Plus* Study, which was performed in Cambridge, United Kingdom (48). The trial is assessing the additional benefits of a behavioural intervention delivered by trained facilitators over and above intensive general practice care for people with type 2 diabetes detected by screening and clinically diagnosed. The main goal of *ADDITION Plus* was to increase and maintain four health behaviours: physical activity, dietary change, taking medication and smoking cessation. A behavioural model, The Theory of Planned Behaviour (49) was used in the theoretical framework. GPs in the East of England (n=26) were recruited to take part in the study. Screen-detected patients were selected by means of a stepwise screening programme, which consisted of a risk score, followed by a random and fasting capillary blood glucose and HbA1c test in general practice, and, finally, by a confirmatory standard 75g oral glucose tolerance test (OGTT) in a clinical research facility. Patients diagnosed with diabetes were invited to participate in *ADDITION Plus*, the behavioural intervention study. Patients clinically diagnosed with diabetes within the previous three years from 19 of the above practices and 8 newly recruited practices were also recruited for the study.

In this thesis we investigated whether there is a suitable group of patients to start behavioural interventions with and therefore only baseline data of the *ADDITION Plus* study were used with the aim to compare characteristics of the screen-detected and clinically diagnosed patients.

Objectives and outline of the thesis

The objectives of this thesis lie within the two central themes of the thesis:

Disease management:

1. To describe the results of a disease management model: The Diabetes Management System, West-Friesland, the Netherlands.

In *chapter 2*, the Diabetes Management System is introduced and changes in clinical characteristics after entry into the system are described in an observational 7-year follow-up study. *Chapter 3* focuses on changes in prescription of medication.

Patient empowerment:

2. To systematically review the literature regarding self-monitoring of blood glucose in patients with type 2 diabetes who are not using insulin. The aim of this review was to investigate the effects of self-monitoring of blood glucose relative to usual care on glycemic control, quality of life and well-being,

patient satisfaction, and hypoglycemic episodes in patients with type 2 diabetes who are not using insulin. The results are described in *chapter 4*.

3. To determine the effectiveness of adding a cognitive behavioural treatment aimed at changing lifestyle to managed care for patients with type 2 diabetes. In *chapter 5*, the design of this randomised controlled trial is described. *Chapter 6* focuses on the effects of the behavioural intervention on cardiovascular risk profile, clinical characteristics, lifestyle (physical activity, dietary behaviour and smoking) and determinants of behaviour change. Effects on quality of life and depression are also assessed.
4. To investigate if there is a window of opportunity for behavioural interventions. It is known that behavioural interventions are effective in changing lifestyle of patients with diabetes. However, it is unclear when and with whom to intervene. Therefore, differences in cognitions and behaviour of patients with screen-detected diabetes and patients who are clinically diagnosed are investigated in *chapter 7* to assess the presence of a window of opportunity for behaviour change.

In the general discussion in *chapter 8*, an overview of the main findings of the thesis is provided and methodological issues are discussed. Finally, suggestions for future research and implications for clinical practice are addressed followed by a final conclusion.

References

1. World Health Organization. Definition and diagnosis of diabetes mellitus and intermediate hyperglycemia: report of a WHO/IDF consultation. 2006.
2. Kahn SE: The relative contribution of insulin resistance and beta-cell dysfunction to the pathophysiology of type 2 diabetes. *Diabetologia* 46:3-19, 2003
3. Wild S, Roglic G, Green A, Sicree R, King H: Global prevalence of diabetes: estimates for the year 2000 and projections for 2030. *Diabetes Care* 27:1047-1053, 2004
4. Wareham NJ, Forouhi NG: Is there really an epidemic of diabetes? *Diabetologia* 48:1454-1455, 2005
5. Wild SH, Forouhi NG: What is the scale of the future diabetes epidemic, and how certain are we about it? *Diabetologia* 50:903-905, 2007
6. Intensive diabetes management: implications of the DCCT and UKPDS. *Diabetes Educ.* 28:735-740, 2002
7. Shichiri M, Kishikawa H, Ohkubo Y, Wake N: Long-term results of the Kumamoto Study on optimal diabetes control in type 2 diabetic patients. *Diabetes Care* 23:B21-B29, 2000
8. Stratton IM, Adler AI, Neil HA, Matthews DR, Manley SE, Cull CA, Hadden D, Turner RC, Holman RR: Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. *BMJ* 321:405-412, 2000
9. Bouma M, Rutten GE, de Grauw WJ, Wiersma T, Goudswaard AN: [Summary of the practice guideline 'Diabetes mellitus type 2' (second revision) from the Dutch College of General Practitioners]. *Ned.Tijdschr.Geneeskd.* 150:2251-2256, 2006
10. Lustman PJ, Griffith LS, Freedland KE, Kissel SS, Clouse RE: Cognitive behavior therapy for depression in type 2 diabetes mellitus. A randomized, controlled trial. *Ann.Intern.Med.* 129:613-621, 1998
11. Lustman PJ, Clouse RE: Depression in diabetic patients: the relationship between mood and glycemic control. *J.Diabetes Complications* 19:113-122, 2005
12. de Sonnaville JJ, Bouma M, Colly LP, Deville W, Wijkel D, Heine RJ: Sustained good glycaemic control in NIDDM patients by implementation of structured care in general practice: 2-year follow-up study. *Diabetologia* 40:1334-1340, 1997
13. Renders CM, Valk GD, Griffin SJ, Wagner EH, Eijk VJ, Assendelft WJ: Interventions to improve the management of diabetes in primary care, outpatient, and community settings: a systematic review. *Diabetes Care* 24:1821-1833, 2001
14. Bodenheimer T: Disease management--promises and pitfalls. *N.Engl.J.Med.* 340:1202-1205, 1999
15. Wagner EH: The role of patient care teams in chronic disease management. *BMJ* 320:569-572, 2000
16. Bodenheimer T, Wagner EH, Grumbach K: Improving primary care for patients with chronic illness: the chronic care model, Part 2. *JAMA* 288:1909-1914, 2002
17. Bodenheimer T, Wagner EH, Grumbach K: Improving primary care for patients with chronic illness. *JAMA* 288:1775-1779, 2002
18. Olivarius NF, Beck-Nielsen H, Andreasen AH, Horder M, Pedersen PA: Randomised controlled trial of structured personal care of type 2 diabetes mellitus. *BMJ* 323:970-975, 2001
19. Piatt GA, Orchard TJ, Emerson S, Simmons D, Songer TJ, Brooks MM, Korytkowski M, Siminerio LM, Ahmad U, Zgibor JC: Translating the chronic care model into the community: results from a randomized controlled trial of a multifaceted diabetes care intervention. *Diabetes Care* 29:811-817, 2006

20. Rothman RL, Malone R, Bryant B, Shintani AK, Crigler B, DeWalt DA, Dittus RS, Weinberger M, Pignone MP: A randomized trial of a primary care-based disease management program to improve cardiovascular risk factors and glycated hemoglobin levels in patients with diabetes. *Am.J.Med.* 118:276-284, 2005
21. Vargas RB, Mangione CM, Asch S, Keeseey J, Rosen M, Schonlau M, Keeler EB: Can a chronic care model collaborative reduce heart disease risk in patients with diabetes? *J.Gen.Intern.Med.* 22:215-222, 2007
22. Wagner EH, Grothaus LC, Sandhu N, Galvin MS, McGregor M, Artz K, Coleman EA: Chronic care clinics for diabetes in primary care: a system-wide randomized trial. *Diabetes Care* 24:695-700, 2001
23. Hansen LJ, Olivarius NdF, Siersma V, Beck-Nielsen H, Pedersen PA: Encouraging structured personalised diabetes care in general practice. A 6-year follow-up study of process and patient outcomes in newly diagnosed patients. *Scand.J.Prim.Health Care* 21:89-95, 2003
24. Florkowski CM, Scott RS, Moir CL, Graham PJ: Clinical and biochemical outcomes of type 2 diabetes mellitus in Canterbury, New Zealand: a 6-year cohort study. *Diabetes Res.Clin.Pract.* 40:167-173, 1998
25. Funnell MM: Patient empowerment. *Crit Care Nurs.Q.* 27:201-204, 2004
26. Funnell MM, Anderson RM: Empowerment and self-management of diabetes. *Clin.Diabetes* 22:123-127, 2004
27. Funnell MM, Nwankwo R, Gillard ML, Anderson RM, Tang TS: Implementing an empowerment-based diabetes self-management education program. *Diabetes Educ.* 31:53, 55-56, 61, 2005
28. Saudek CD, Derr RL, Kalyani RR: Assessing glycemia in diabetes using self-monitoring blood glucose and hemoglobin A1c. *JAMA* 295:1688-1697, 2006
29. Ipp E, Aquino RL, Christenson P: Point: Self-monitoring of blood glucose in type 2 diabetic patients not receiving insulin: the sanguine approach. *Diabetes Care* 28:1528-1530, 2005
30. Blonde L, Karter AJ: Current evidence regarding the value of self-monitored blood glucose testing. *Am.J.Med.* 118:205-265, 2005
31. Coster S, Gulliford MC, Seed PT, Powrie JK, Swaminathan R: Self-monitoring in Type 2 diabetes mellitus: a meta-analysis. *Diabet.Med.* 17:755-761, 2000
32. McGeoch G, Derry S, Moore RA: Self-monitoring of blood glucose in type-2 diabetes: what is the evidence? *Diabetes Metab Res.Rev.* 23:423-440, 2007
33. Ismail K, Winkley K, Rabe-Hesketh S: Systematic review and meta-analysis of randomised controlled trials of psychological interventions to improve glycaemic control in patients with type 2 diabetes. *Lancet* 363:1589-1597, 2004
34. Norris SL, Engelgau MM, Narayan KM: Effectiveness of self-management training in type 2 diabetes: a systematic review of randomized controlled trials. *Diabetes Care* 24:561-587, 2001
35. Norris SL, Nichols PJ, Caspersen CJ, Glasgow RE, Engelgau MM, Jack L, Snyder SR, Carande-Kulis VG, Isham G, Garfield S, Briss P, McCulloch D: Increasing diabetes self-management education in community settings. A systematic review. *Am.J.Prev.Med.* 22:39-66, 2002
36. Knight KM, Dornan T, Bundy C: The diabetes educator: trying hard, but must concentrate more on behaviour. *Diabet.Med.* 23:485-501, 2006
37. Peyrot M, Rubin RR: Behavioral and psychosocial interventions in diabetes: a conceptual review. *Diabetes Care* 30:2433-2440, 2007
38. Wagner EH, Austin BT, Davis C, Hindmarsh M, Schaefer J, Bonomi A: Improving chronic illness care: translating evidence into action. *Health Aff.(Millwood.)* 20:64-78, 2001

39. Burke BL, Arkowitz H, Menchola M: The efficacy of motivational interviewing: a meta-analysis of controlled clinical trials. *J.Consult Clin.Psychol.* 71:843-861, 2003
40. Miller WR, Rollnick S: *Motivational Interviewing, preparing people for change*. The Guilford Press, New York, 2002
41. Rubak S, Sandbaek A, Lauritzen T, Christensen B: Motivational interviewing: a systematic review and meta-analysis. *Br.J.Gen Pract.* 55:305-312, 2005
42. D'Zurilla TJ, Goldfried MR: Problem solving and behavior modification. *J.Abnorm.Psychol.* 78:107-126, 1971
43. D'Zurilla, T. J. *Problem Solving Therapy: a social competence approach to clinical interventions*. 1986. New York, Springer.
44. D'Zurilla TJ, Nezu AM: Problem-Solving Therapies. In *Handbook of Cognitive Behavioral Therapies*. 2 ed. Dobson KS, Ed. Guilford Press, 2001, p. 211-245
45. Hardeman W, Sutton S, Griffin S, Johnston M, White A, Wareham NJ, Kinmonth AL: A causal modelling approach to the development of theory-based behaviour change programmes for trial evaluation. *Health Educ.Res.* 20:676-687, 2005
46. de Vries H, Dijkstra M, Kuhlman P: Self-efficacy: third factor besides attitude and subjective norm as a predictor of behavioral interventions. *Health Education Research* 3:273-282, 1988
47. de Vries H: Determinanten van gedrag. In *Gezondheidsvoorlichting en gedragsverandering*. Damoiseaux V, van der Molen HT, Kok GJ, Eds. Assen, Van Gorcum, 1993, p. 109-132
48. Lauritzen T, Griffin S, Borch-Johnsen K, Wareham NJ, Wolffenbuttel BH, Rutten G: The ADDITION study: proposed trial of the cost-effectiveness of an intensive multifactorial intervention on morbidity and mortality among people with Type 2 diabetes detected by screening. *Int.J.Obes.Relat Metab Disord.* 24 Suppl 3:S6-11, 2000
49. Ajzen I: The theory of planned behavior. *Organizational behavior and human decision processes* 50:179-211, 1991