Living with
type 2 diabetes: piece of cake,
or bitter pill to swallow?

*Illness perceptions, and (their role in)
self-management and quality of life
during the first years of illness.*

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General introduction

BACKGROUND

Effective management of type 2 diabetes mellitus (T2DM) has become a matter of global, national and individual urgency. Over the past three decades, the increasing overweight and obesity rates, and the ageing of the population have resulted in an explosive growth in the number of individuals with T2DM. Worldwide, more than 425 million individuals have been diagnosed with diabetes and this number is expected to have increased even further to an estimated 629 million by the year 2045, of which around 90% is accounted for by T2DM [1]. In the Netherlands, approximately one million individuals are currently living with T2DM [2]. Although T2DM usually manifests itself as a rather mild and asymptomatic condition, patients are at risk of developing microvascular complications (retinopathy, nephropathy, neuropathy, and foot problems) and macrovascular complications (cardiovascular and cerebrovascular conditions) over the course of the illness, which can seriously impact their physical and mental health. In fact, T2DM is a significant cause of blindness, renal failure, lower limb amputation and cardiovascular disease [1] and, furthermore, the condition – and its complications in particular – is known to be related to higher rates of depression [3] and lower quality of life in patients [4–6]. Hence, with its growing prevalence rates, progressive nature and potential complications, T2DM places a burden on many individuals, as well as on health care systems.

Specific goals for T2DM management include keeping blood glucose, blood pressure and lipid levels as close to normal as possible in order to reduce the risks on (the progression of) serious long-term micro- and macrovascular complications [7–10]. In the Netherlands, guidelines for managing T2DM in primary care have been formulated by the Dutch College of General Practitioners [11,12], and include recommendations on lifestyle management, self-monitoring, pharmacotherapy, screening and management of risks for complications and associated conditions, and diabetes education. In addition to physical examinations and medical parameter checks, health care providers ideally aim to stimulate their patients to engage in self-management during the time in between their three-monthly check-ups. Encouraging and supporting self-management is of great importance since these day-to-day health behaviours, which occur mainly beyond the vision of health-care professionals, could significantly influence the course of their condition, making self-management an important strategy for improving health outcomes in individuals, and for being able to respond to the continuously growing care demands of the diabetes population.

Self-management in type 2 diabetes

Effective self-management in chronic illness generally entails that patients monitor their condition, and adapt their cognitive, behavioural and emotional responses to maintain a satisfactory quality of life [13]. Engaging in self-care behaviours (including medical management and healthy lifestyles), interacting with health care professionals, and coping with

the physical, psychological and social consequences of a condition are therefore important skills patients need to master in order to successfully manage their condition on a day-to-day basis [14]. In T2DM, the self-management regimen comprises a set of behaviours that patients are recommended to perform on a regular (often daily) basis to improve glycemic and cardiovascular control and, consequently, reduce the risk of complications [7–10] and maintain a satisfactory quality of life [4–6]. Recommendations regarding patients' lifestyle include 1) being physically active, 2) eating healthy food, and 3) not smoking. Also, T2DM patients are recommended to regularly check their feet for injuries, monitor their blood glucose levels and - when needed - take oral hypoglycaemic agents and/or inject insulin as part of their self-care routine [11,12,15]. Furthermore, in order to receive appropriate medical care for their diabetes and associated conditions, patients should be capable of expressing their needs and concerns to health care professionals, and engage in shared-decision making. Also, patients need to find their own ways in dealing with the consequences that T2DM and its comprehensive treatment may have on their physical and emotional functioning, and their social relationships [13,16,17]. Finally, considering the progressive nature of T2DM, self-management also implies that patients have to adapt their strategies several times over the course of illness, due to changes in their health status (e.g., as a result of complications) and/or treatment regimen.

Challenges of self-management

While the importance of self-management is widely acknowledged in the medical field, many T2DM patients seem to struggle with the multifaceted behavioural regimen. Patients indicate to experience difficulties or barriers in one or more aspects of their treatment regimen [18,19], with sustained engagement in dietary and exercise changes being identified among the most challenging parts of self-care [20–23]. Often, patients are required to make considerable changes in already lifelong existing lifestyle patterns, and integrate new behaviours within their other day-to-day activities, such as work- and family-related demands and activities. Furthermore, the progressive nature of T2DM may require patients to change their management strategies several times over the course of their condition. And as if this is not already challenging enough, patients' motivation for self-management may be heavily compromised by the self-regulatory dilemma caused by the long-term, and therefore often unobservable gains of self-care and lifestyle changes, while their drawbacks may become very apparent in the present [24].

Diabetes distress

When patients are unable to sufficiently manage their condition, diabetes-related distress is likely to arise. Diabetes-specific emotional distress is defined as a range of emotional responses (e.g., feelings of guilt, frustration, being overwhelmed, anger or fear) that are related to diabetes and its treatment, and is part of a person's experience of diabetes management

in the social context of family and health care providers [25–27]. The ongoing daily management may interfere with other valued goals and activities, burden patients emotionally and make them feel like they can never catch a break from their illness; something that is even further exacerbated by the chronic nature of T2DM. Furthermore, fear of developing complications, frustrations of having developed complications despite having committed to a (strict) self-care regimen, or feelings of guilt for not having stayed on track with diabetes management may evoke strong negative diabetes-related emotions in patients [28]. Supporting patients in tackling these emotions is not only important because of its impact on patients' quality of life, but also because distress has been found to interfere with self-management behaviours and glycaemic control [29–33] (e.g., through denial of the disease, and avoidant coping behaviours), thereby increasing the risk of complications.

Self-management support

Self-management being such an essential though challenging aspect of diabetes care has resulted in a tremendous amount of studies focusing on identifying successful methods for self-management support. So far, meta-analyses examining the effectiveness of diabetes self-management support programmes have shown positive, but predominantly modest and short-term effects on health-related behaviours and outcomes [34–37]. To a fair extent, this might be due to many interventions still following the classical didactical approach, and primarily aiming to increase knowledge in patients. However, with patients being increasingly perceived as active key players in their care process rather than passive recipients of care, self-management support should make the transition from traditional education methods to focusing more on personal and psychosocial determinants. Three factors that have been identified to be among the most important influencers of self-management and – directly and via self-management – quality of life in diabetes are 1) illness and treatment beliefs, 2) self-efficacy, and 3) social support.

Illness and treatment beliefs

Individuals' cognitions regarding their condition and its treatment have been found to account to a significant extent for the variation in the self-management behaviours found among T2DM patients [38–42]. Illness and treatment beliefs are shaped through information (e.g., from health care providers, the internet, or friends/family) and experiences (e.g., symptoms or complications, evaluations of own treatment and self-care behaviours) [43], and may therefore differ across individuals with the same condition. These personal beliefs are central components in the Common-Sense Model of Self-regulation [44,45], which consists of three stages that influence one another: illness representations, coping, and appraisal. In the first step, individuals form their own personal models, consisting of cognitive and emotional representations of a condition and its treatment, in response to a health threat. The perceptions that make up the personal cognitive models on illness and treatment are categorised into the

following dimensions: 1) identity (name of the illness, and the symptoms that are associated with the condition), 2) cause (e.g., risk behaviours, genetic predisposition or 'bad luck'), 3) timeline (acute or chronic; cyclical), 4) personal control (perceived ability to control the condition), 5) treatment control (perceived effectiveness of the treatment regimen), 6) consequences (perceived consequences of the condition), 7) emotional representations (e.g., anger, fear) and 8) illness coherence (understanding of the condition). These perceptions, in particular those concerning the seriousness and controllability of the condition, then determine which behavioural or emotional coping mechanisms are used by patients to deal with their condition, which ultimately influences their health outcomes [38,46,47]. In the third and final stage, the successfulness of the coping strategies are evaluated (appraisal), and this information is then fed back into the earlier stages of the model.

Self-efficacy

Another psychological concept that has been shown to influence self-management and that has received considerable attention in self-management (support) studies is self-efficacy. Self-efficacy refers to the beliefs of individuals in a) their own capabilities to perform certain behaviours and b) the likelihood of these behaviours resulting in the desired outcomes, and evolves as individuals acquire new information, skills, and experiences [48]. Bandura's Social Cognitive Theory (SCT) [48,49] posits that behaviour change will only be undertaken when individuals a) believe that their action will produce outcomes that are beneficial to them (outcome expectations) and b) they believe they are capable to successfully perform these behaviours (self-efficacy). Higher levels of self-efficacy regarding diabetes management have been found to be associated with improved self-management and health-related outcomes [42,50,51]. A strategy to increase self-efficacy is by supporting individuals to set realistic and achievable goals for the behaviours they deem important and beneficial [52,53]. In addition, allowing individuals to evaluate and adapt their behaviour and make plans to overcome barriers (e.g., by asking help from others) in order to meet their goals are important self-regulatory processes [54].

Social support

The third factor that is associated with variations in self-management is social support. As the majority of diabetes management takes place in a social context, the impact of diabetes is not only limited to the life of patients, but also concerns others in their close social environment as well, in particular partners. For instance, partners may worry about the effects that T2DM could have on the patient's health; in particular when they struggle with following the treatment recommendations [55]. Conversely, partners have also been found to have impact on chronic illness management in patients. Partners may provide practical support (e.g., cooking healthy meals, reminding of medication or monitoring), but are also an important source of emotional support [56]. Adequate support from partners can improve the ability of

patients in coping with diabetes and prevent or decrease diabetes-related distress, however, the reverse is also true: critical or overprotective partners may hamper self-management, and lack of emotional support from loved ones could result in stress in patients [57–61]. Strategies to mobilize support should therefore take into account the (potential gap between) expected available support and the actual received support, and help patients and partners communicate and recognise which types of support are appreciated and considered helpful to overcome barriers in self-management and cope with stress.

Hence, self-management in diabetes is best understood as a process of self-regulation, in which both personal perceptions and the social environment play indispensable roles in how the goals and recommendations of diabetes self-management are being pursued. While many programmes have focussed on increasing patients' self-efficacy [36,37,62,63], only few so far have targeted illness and treatment perceptions of patients and their partners as a starting point for self-management improvement in diabetes [64, 65]. Also, up until now, little attention has been paid to the influence that the phase of illness may have on self-management and diabetes distress and, as a consequence, the differences in support needs that may arise over the course of living with T2DM. With this in mind, we developed the Diacourse study: a study testing the effectiveness of diabetes support tailored to improve self-management and quality of life in different phases in the illness process.

Supporting patients over the course of illness – The Diacourse study

Dealing with T2DM is an ongoing process that, due to its chronic and progressive nature, may require multiple adaptations over time. Apart from the initial changes inherent to being diagnosed with T2DM, patients may have to face several changes in treatment over time, or may be confronted with (the consequences of) serious diabetes-complications; sometimes even with an acute cardiovascular event (ACE) as a result of their diabetes. To support patients in adequately dealing with the different challenges they may encounter over the years of living with T2DM, we developed three different self-management support programmes.

Programme 1 provided group-based support to recently diagnosed patients, and aimed to help them and their partners to successfully incorporate (the care for) diabetes within their daily lives by focussing on their illness and treatment perceptions. **Programme 2** focussed on helping patients cope with (fear of) loss of health by providing group-based peer support to patients who have been diagnosed for T2DM for longer than three years. **Programme 3** provided individual support to increase self-efficacy among those who had to cope with (the consequences of) an acute coronary event (ACE) in addition to their diabetes. The effectiveness of all three programmes was tested in randomised controlled trials. In this thesis, we focus on describing the rationale, development and effects of programme 1: the Living with diabetes programme.

The Living with diabetes programme

Being diagnosed with T2DM is a significant life event that often requires big changes. Immediately after being diagnosed, patients are posed with the task of adapting to live with diabetes on a daily basis; both emotionally and behaviourally. Patients have to come to terms with the diagnosis and how this might affect their daily routine and social and/or partner relations. Furthermore, they have to develop strategies to successfully implement self-care behaviours within their day-to-day lives and change, often lifelong, existing lifestyles. One year after diagnosis, however, the majority of the patients has been found to be unable to make sustainable changes in their lifestyle/behaviours [66]. As previously mentioned, getting patients properly engaged in self-management is already complicated as it is. Motivating recently diagnosed T2DM for self-management may, however, bring an additional challenge to the table. T2DM usually manifests itself as a rather mild condition with few – if any – symptoms, which may cause recently diagnosed patients to underestimate the (potential) seriousness of the condition and, consequently, the necessity of engaging in self-management [66]. Others may find it hard to accept that they have diabetes, or may even deny this and avoid engagement in diabetes management. Therefore, the challenge of self-management support in the early phase of illness primarily lies in getting patients to realise that engagement in healthy behaviours in the short term is important and effective in diminishing the risks of diabetes-related adverse events in the long-term. Furthermore, patients should be provided with the tools and skills to help them achieve their diabetes-related goals and targets, and be taught how they can use their social network to overcome barriers.

We therefore developed a support programme that starts from the perceptions of patients and their partners, guides them in setting realistic and specific goals for the (changes in) behaviours they deem important, and helps them overcome barriers by teaching them how to ask for (partner) support when needed: the Living with diabetes course. Leventhal's Common-Sense Model (CSM) [43–45] integrates both individual cognitions and social factors, and was therefore used as the main theoretical framework for our intervention. In addition, principles from Bandura's Social Cognitive Theory (SCT) [48,49] and social support theories [67,68] were integrated to further address self-efficacy/empowerment and partner support.

Similar CSM-based self-management support programmes have been previously developed and tested with a different aim, method of delivery or study population. Keogh et al., [64] focused their support programme specifically on poorly controlled T2DM patients and their partners and offered their intervention on an individual basis. The DESMOND trial [65] also offered group-based self-management support to recently diagnosed patients, but they specifically included participants within four weeks after diagnosis, while its Dutch version (the PRISMA programme) included T2DM patients in all phases of illness [69-71]. Similar to our intervention, the Beyond Good Intentions programme [72] targeted patients during the first few years of illness, although their focus was primarily on proactive goal setting and coping rather than illness perceptions. Hence, with our intervention we aim to contribute to

the existing literature by examining the effectiveness of CSM-based self-management group support, in which an important role is being assigned to the (support) from partners and close others, during the first years of T2DM.

Aim and outline of this thesis

- To gain insight into self-management behaviours and quality of life over the course of T2DM.
- To develop and evaluate the effectiveness of a group-based self-management support programme for recently diagnosed T2DM patients and their partners.

The first part of the thesis describes the (differences in) emotional and behavioural responses of patients over the course of T2DM. **Chapter 2**, reports the results of a study on the illness perceptions, self-care behaviours and their mutual relationship in recently diagnosed patients, and whether these differed in the presence of complications. In **chapter 3**, we examined the relation between diabetes duration and self-care, and the extent to which complications, medical treatment and diabetes distress added to this relationship. Likewise, the relation between diabetes duration and diabetes distress was examined in **chapter 4**.

The second part of the thesis provides insight into the development, evaluation and outcomes of the Living with diabetes self-management support programme. In **chapter 5**, the protocol of the study is described. **Chapter 6** provides insight into the theoretical background of the programme, and the feasibility and acceptability of the course during a pilot study. **Chapter 7** reports the programme's effects on (the determinants of) self-care and diabetes distress. In the general discussion section (**chapter 8**), we interpret and discuss the results of our studies and their clinical implications, and reflect upon the theoretical models and methods of the studies included in this thesis.

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2

Illness perceptions and self-care behaviours in the first years of living with type 2 diabetes: does the presence of complications matter?

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ABSTRACT

Objective

To assess illness perceptions, self-care behaviours and their relationship in recently diagnosed type 2 diabetes mellitus (T2DM) patients with and without diabetes-related complications.

Design

Cross-sectional survey among 192 recently diagnosed T2DM patients of whom 23% reported the presence of diabetes-related complications. Illness perceptions and self-care were assessed by the Revised Illness Perception Questionnaire (IPQ-R) and the revised Summary of Diabetes Self-Care Activities (SDSCA) measure.

Results

Generally, participating patients perceived T2DM as a chronic, but relatively controllable condition with minor consequences. In the presence of complications, however, T2DM was perceived as more unpredictable with more (serious) consequences and less controllable by self-care or medical treatment. Furthermore, engagement in exercise and foot care was reported more often by patients with complications. Self-care was related to certain illness perception dimensions, and interactions between perceptions and complications were found.

Conclusion

T2DM patients in the first years of their illness are often recommended to make lifestyle changes in the absence of noticeable diabetes-related symptoms or complaints. As many T2DM patients do not seem to perceive their condition to be serious and postpone lifestyle changes until diabetes-related complications appear, a major challenge for professionals is to convince asymptomatic patients of the importance of self-care.

INTRODUCTION

The importance of early treatment and lifestyle changes in type 2 diabetes mellitus (T2DM) patients is widely recognised in the medical field. In order to diminish the risk of serious long-term complications, guidelines recommend that T2DM patients engage in a diabetes self-care regimen (e.g. regular exercise, healthy diet, foot care, not smoking) directly after diagnosis [1,2]. Since these (changes in) behaviours most often need to be performed in the absence of noticeable diabetes-related symptoms or complaints, it is imaginable that sticking to this self-management regimen is challenging for many patients. Previous research has shown that the extent to which patients adhere to diabetes self-care recommendations is strongly related to their perceptions of their illness and its treatment [3]. Illness perceptions are the central concept of the Common-Sense Model of Self-Regulation of Health and Illness [4 – 6] (CSM). According to this model, people hold personal beliefs about their illness which, to a large extent, determine how people respond to their condition. Illness perceptions include perceived symptoms attributed to the condition (identity), beliefs about the timeline of the condition, its consequences, perceived ability to control the condition and the extent to which the treatment is effective in controlling the condition, comprehensibility or understanding of the condition, emotional responses and concerns regarding the condition, and beliefs on possible causes of the condition. The CSM presumes that these different beliefs correlate in a logical way and together act as a framework for coping strategies and behavioural responses of patients which, in turn, impact on their appraisal of health outcomes. Illness perceptions are constructed within the context of medical information, social communication (media, friends and family, other patients) and personal experience. As these perceptions are not static, but change over time as a result of new information and experiences [6,7], it is likely that T2DM is perceived differently by recently diagnosed patients than by patients with a longer illness duration; especially considering the rather progressive nature of the illness.

Overall, recently diagnosed patients have been found to be rather optimistic about their ability to control the condition and the effectiveness of treatment strategies. In addition, they experienced the emotional impact of diabetes to be relatively low and the consequences (for daily life) as not very serious [8–10]. Although these optimistic perceptions have generally been found to positively relate to self-care behaviour and glycaemic control [3,11–13], questions have been raised as to whether this also applies to the first years of living with T2DM. For example, Thoolen, De Ridder, Bensing, Gorter, and Rutten (2008) suggested in their review [14] that high levels of perceived controllability and low emotional impact might rather be non-conducive than conducive to self-care behaviours and these (overly) optimistic perceptions might actually be an indicator of patients not truly engaging in lifestyle changes and reflecting the seriousness of T2DM on their own condition.

Considering the great importance of diabetes self-care in recently diagnosed T2DM patients and the assumed key role of illness perceptions in guiding these activities, we assessed

the illness perceptions, self-care behaviours and their relationship in T2DM patients during the first years of illness. As we expected that concrete experiences with diabetes will alter patients' perceptions, we explored whether the illness perceptions of T2DM patients differ by the presence or absence of diabetes-related complications. Assuming that changes in illness perceptions contribute to changes in self-care in the presence of notable signs and symptoms, we also investigated the differences in self-care behaviours between patients with complications and patients without complications. Finally, we also studied whether illness perceptions associated differently with self-care in patients with complications, compared to patients without complications.

More precisely, our research questions were as follows:

1. Which illness perceptions are held by diabetes patients during the first years of T2DM? Do these illness perceptions differ between patients with and without diabetes-related complications?

2. Which self-care behaviours are performed during the first years of T2DM? Do these self-care behaviours differ between patients with and without diabetes-related complications?

3. How are illness perceptions and self-care behaviours related during the first years of T2DM? Does this relationship differ in the presence of diabetes-related complications?

METHOD

To answer our research questions, we used the baseline data from the Diacourse study. For the inclusion of patients in this study, a two-stage sampling procedure was applied. First, general practices in the North, West, South-West and center of the Netherlands were recruited. Then, patients meeting the inclusion criteria were selected from the medical records kept in the participating general practices. All Dutch inhabitants are obligatory listed with a general practice. Criteria for patients to be included in the study were 1) being diagnosed with T2DM one to three years ago, as recorded by their GP, and 2) being aged between 18 - 85 years. Patients were excluded if they 1) were not able to speak, read and/or understand the Dutch language sufficiently, 2) had insufficient mental or intellectual capacities to participate in the study, 3) were under treatment for severe psychological or psychiatric conditions, and 4) were recently diagnosed with a severe or life-threatening comorbid condition (e.g. cancer, stroke), according to their GP. Selected patients received a written invitation for participation. After informed consent, participating patients filled in the baseline questionnaire. The Diacourse study was approved by the Medical Ethical Committee of the VU University Medical Center, Amsterdam.

Measures

Illness perceptions

The Revised Illness Perception Questionnaire (IPQ-R)[15] was used to assess illness perceptions. In the first section of this questionnaire, 'illness identity' was measured as the number and frequency in which symptoms are identified as part of the illness. We used the original 14 item symptom list of common symptoms (e.g. fatigue, headaches) [15] for this purpose. Patients indicated for each symptom whether they had experienced this symptom recently and whether they perceived this symptom to be related to their diabetes (yes/no). The sum of the yes-rated items on the second rating forms the illness identity subscale (range 0 – 14). The second section of the IPQ-R contained 38 items in seven subscales: 'timeline acute/chronic' (6 items, e.g. " My diabetes will last for a long time", Cronbach's α = .87); 'timeline cyclical' (4 items, e.g. "My diabetes is very unpredictable", α = .89); 'consequences' (6 items, e.g. "My diabetes is a serious condition", α = .74); 'personal control' (6 items, e.g. ''The course of my diabetes depends on me", α = .74); 'treatment control' (5 items, e.g. "My treatment can control my diabetes", α = .56); 'coherence' or understanding of T2DM (5 items, e.g. "My diabetes doesn't make any sense to me", α = .79) and 'emotional representation' (6 items, e.g. "When I think about my diabetes I get upset", α = .83). All items were scored on a five-point Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree). Mean subscale scores were computed by summing the items and dividing it by the number of items resulting in a subscale score (range 1 – 5). Higher scores on the subscales indicated a greater perceived impact of T2DM on the patient's life (consequences) or emotional state (emotional representation), a more chronic timeline perception (timeline acute/chronic), a stronger belief in an unpredictable course (timeline cyclical), a stronger belief in controllability of the illness either by self-care (personal control) or professional treatment (treatment control), and a better understanding of T2DM and its treatment (coherence).

In the third section, patients' causal beliefs (18 items) were measured, using the same Likert type scale as in section two. Based on suggestions of Moss-Morris et al. (2002) and an exploratory factor analysis, we constructed two scales: one scale representing beliefs about psychological factors as a cause of T2DM (6 items: "Stress or worry", "My mental attitude", "Family problems or worries", "Overwork", "My emotional state", and "My personality"; α = .84) and one scale representing own (risky) behaviour in the past as a causal factor (5 items: "Diet or eating habits", "Poor medical care in my past", "My own behaviour", "Smoking", and "Alcohol"; α = .72). For these two subscales, mean scores were computed, ranging from 1 to 5, with higher scores being indicative of a stronger belief in a certain cause. The single item "My diabetes was caused by chance or bad luck" was treated as a third causal factor (range 1 - 5).

Self-care

Self-care was measured by the Dutch version of the revised Summary of Diabetes Self-Care Activities (SDSCA) measure [16]. This questionnaire measured six aspects of the diabetes regimen: exercise (2 items; α = .76), glucose monitoring (2 items, α = .64), foot care (2 items; α = .70), general diet (2 items; α = .82), specific diet (2 items, α = .02) and smoking (1 item). Respondents reported the frequency (days per week) these various activities were performed in the previous seven days. The two items measuring the specific diet subscale were analysed separately because of their low internal consistency, as was also suggested by Toobert et al.[16]. Furthermore, the subscale assessing blood-glucose monitoring was left out in this study, since this aspect of self-care is not part of the diabetes care regimen in the majority of the (recently diagnosed) Dutch T2DM patients [17].

Complications

To assess diabetes-related microvascular complications, patients were asked to indicate whether they suffered from 1) eye problems: retina problems (retinopathy), 2) kidney problems: proteinuria or dialysis (nephropathy), 3) nerve damage (neuropathy), and 4) foot problems (need for adapted shoes, wounds, amputation). Complications were summed and dichotomised into 'complications absent'(0) and 'one or more complications present' (1).

Background variables

We included a number of socio-demographic and illness-related characteristics in this study to describe our sample and to adjust for in the multivariate analyses. Apart from age and gender, which were derived from the GP records, self-reported level of education and marital status were included. Level of education was categorised into low (no education, primary school or low vocational training), middle (high school or middle vocational training) and high (college or university), based on the reported highest type of education completed. Marital status was dichotomised into 'married or cohabiting' and 'other' (single, divorced, widowed). Diabetes duration was also derived from the GP records. Type of diabetes treatment was self-reported by patients and categorised into 1) lifestyle advice only, 2) oral hypoglycemic agents, and 3) insulin injections. For the multivariate analyses, treatment was dichotomised into non-pharmacological treatment (lifestyle advice only) and pharmacological treatment (oral hypoglycemic agents, insulin injections). The presence of comorbidity was assessed by asking patients to indicate whether they suffered from 1) heart and vessel disease (e.g. serious heart condition or infarction), 2) cancer, 3) respiratory problems (asthma, COPD), 4) joint conditions (neck and back problems, osteoporosis, arthritis) or 5) 'other' and dichotomised into no comorbidity (0) vs. comorbidity (1).

Data analysis

Population characteristics are reported for the total sample and for patients with and without diabetes-related complications separately. Inter-correlations between the IPQ-R subscales for patients with and without complications were calculated to explore whether illness perceptions correlate in a comparable way in both groups. Chi-square and independent samples t-tests were used to test the differences between patients with or without complications on illness perceptions and self-care behaviours. Linear regression analyses were conducted to analyse the independent effect of illness perceptions (model 2) and the presence of complications (model 3) on self-care behaviours, (exercise, foot care, general and specific diet), adjusted for age, gender, comorbidity, type of treatment and diabetes duration (model 1). For smoking, a logistic regression analysis was performed in the same manner. Moderation between complications and illness perceptions was determined by conducting regression analyses for each illness perception subscale separately, estimating the main effects of the illness perception dimensions and complications together with their interaction effect (model 2) on self-care, adjusted for the aforementioned demographic and illness-related characteristics (model 1). All variables in the regression and moderation analyses were centered, following the guidelines described by Kraemer & Blasey [18]. Statistical significance was set at $p < .05$.

RESULTS

Study population characteristics

In total, 195 patients participated in the study. Three patients had a diabetes duration of four years or more at the time of the measurement and were therefore excluded. The socio-demographic and illness-related characteristics of the remaining 192 patients are shown in Table 1. Of five participants, it was not known whether they had diabetes-related complications or not. These participants were therefore included in the total group results, but not in the subgroup analyses.

The mean age of the participating patients was 64.3 years (range 27.0 – 84.2) and the mean diabetes duration was 2.3 years (range 1.0 – 3.8). The majority of the patients (68.4%) reported to use oral hypoglycemic agents (or insulin) to treat their diabetes. More than one fifth of the participants (22.5%) reported the presence of one or more diabetes-related complications or complaints, with foot problems (10.2%) and eye problems (8.6%) being the most frequently reported. Two thirds (66.3%) of the participants reported the presence of one or more comorbid conditions, with joint problems being the most prevalent (35.3%). Patients with complications significantly differed from patients without complications regarding diabetes duration and rates of self-reported comorbid conditions.

Table 1 Demographic and illness-related characteristics of the participating T2DM patients, total and by the presence of complications.

	Total (n = 192)	Complications		p
		Present (n = 42)	Absent (n = 145)	
Gender: male (%)	55.7	50.0	55.9	.50
Age (years; mean (SD))	64.3 (10.0)	66.2 (10.0)	63.6 (10.0)	.14
Educational level (%)				.50
Low	29.0	33.3	28.0	
Middle	47.9	50.0	46.9	
High	23.2	16.7	25.2	
Married/cohabiting (%)	75.3	76.2	74.8	.86
Diabetes duration (years; mean (SD))	2.3 (0.7)	2.6 (0.8)	2.3 (0.7)	.02
Treatment: pharmacological (%)	68.4	78.6	65.5	.11
Diabetes-related complications: present (%)	22.5	100	0	-
Comorbid conditions: present (%)	66.3	82.1	62.1	.02

Illness perceptions

Mean scores on the illness perception dimensions are depicted in Table 2. The majority of the patients did not experience complaints that they attributed to (their) diabetes (71.4%). Twenty percent attributed one or two complaints to their diabetes and the remaining eight percent attributed three or more complaints to diabetes (range 3 - 8). The most frequently reported complaint attributed to T2DM was fatigue (16.4%), followed by sensitive eyes (9.5%), stiff joints (6.9%) and dizziness (6.9%).

The scores on the different illness perception dimensions indicated that, in general, patients perceived their illness as chronic but not very serious, with a low (emotional) impact on their daily life and well controllable either by self-care or medical treatment. Considering patients' ideas about the causes of their diabetes, patients predominantly thought that their diabetes has been caused by fate, followed by their own behaviour in the past, such as dietary behaviours and smoking.

Significant differences were found between the perceptions of patients with complications and patients without complications. Patients with complications experienced and attributed more symptoms to their diabetes, experienced the course and symptoms of their diabetes as more unpredictable, rated the impact of their disease on their daily life and emotional state as more serious and believed less in the controllability of their illness, either by self-care or professional treatment.

As illness perception dimensions are not unrelated, but presumed to form a coherent model, we also checked the inter-correlations between the different illness perception dimensions (data not shown). The different subscales appeared to relate in a logical manner, with cor-

Table 2 Illness perceptions of T2DM patients, total and by the presence of complications (mean (SD)).

	Total (n = 192)	Complications		t	p
		Present (n = 42)	Absent (n = 145)		
Identity (0 – 14)	0.63 (1.37)	1.21 (2.03)	0.48 (1.07)	3.12	.02
Timeline: chronic (1-5)	3.84 (0.76)	3.91 (0.63)	3.81 (0.80)	0.72	.47
Timeline: cyclical (1-5)	2.36 (0.81)	2.80 (0.81)	2.23 (0.77)	4.07	< .001
Consequences (1-5)	2.49 (0.67)	2.74 (0.82)	2.42 (0.60)	2.76	< .01
Personal control (1-5)	3.79 (0.59)	3.55 (0.57)	3.86 (0.58)	3.12	<.01
Treatment control (1-5)	3.78 (0.48)	3.63 (0.48)	3.83 (0.47)	2.33	.02
Illness coherence (1-5)	3.42 (0.75)	3.33 (0.79)	3.45 (0.75)	0.87	.39
Emotional representations (1-5)	2.17 (0.64)	2.36 (0.78)	2.12 (0.59)	2.13	.04
Cause: psychological factors (1-5)	2.20 (0.77)	2.38 (0.80)	2.16 (0.77)	1.56	.12
Cause: own behaviour (1-5)	2.49 (0.73)	2.47 (0.63)	2.49 (0.76)	0.12	.91
Cause: bad luck (1-5)	2.66 (1.16)	2.67 (1.15)	2.65 (1.18)	0.08	.94

relations ranging up to .63. Overall, beliefs on the cyclical nature of the condition and its symptoms, the possibilities for control (personal and treatment control) and the comprehensibility of the condition particularly correlated strongly with all other dimensions. In patients with complications, particularly the belief that diabetes is a chronic condition that will not go away (timeline chronic) and the feeling that one does not understand the illness (coherence) correlated negatively with feelings of control. In patients without complications, the extent to which they view their illness as (un)predictable (timeline cyclical) seemed particularly important. Patients who experienced diabetes as a more unpredictable disease with symptoms changing from day to day, were more convinced that diabetes has serious consequences, more strongly believed in fate or stress as the cause of their diabetes, and experienced less control and less understanding than patients who perceived diabetes to be more predictable.

Self-care behaviour

The extent to which T2DM patients engage in self-care behaviours is shown in Table 3. Following the recommendations for healthy eating (general diet and the recommended servings of fruit and vegetables) and non-smoking were the behaviours most often performed during the previous week. Foot care, which comprised checking one's feet and the inside of the shoes, was not commonly performed during the previous week in this recently diagnosed group. In general, self-care behaviours were performed more frequently by patients with diabetes-related complications, but only the differences in the frequency of foot care reached statistical significance.

Table 3 Self-care behaviours performed during the previous week by T2DM patients, total and by presence of complications (mean number of days (SD)).

	Total (n = 192)	Complications		t/ X^2	p
		Present (n = 42)	Absent (n = 145)		
Exercise (0 – 7)	4.44 (1.89)	4.85 (1.65)	4.33 (1.96)	1.50	.14
Foot care (0 – 7)	1.22 (1.89)	2.37 (2.37)	0.85 (1.49)	4.88	< .001
Diet: general (0 - 7)	5.16 (1.67)	5.33 (1.51)	5.15 (1.69)	0.60	.55
Diet: fruit/vegetables (0 - 7)	5.36 (1.96)	5.65 (1.83)	5.27 (2.01)	1.04	.30
Diet: low-fat (0 - 7)	4.80 (2.13)	4.61 (2.02)	4.92 (2.11)	0.83	.41
Non-smoking (%)	81.9	79.5	81.9	0.12	.73

Associations between illness perceptions and self-care

Bivariate correlations revealed significant associations between self-care behaviours and some of the illness perception dimensions, although the correlations found were generally low. Physical activity and general dietary behaviours were positively associated with stronger beliefs of personal control (r = 0.19, p < .05; r = 0.23, p < .01) and treatment control (r = 0.18, p < .05; r = 0.25, p < .01). Foot care was associated with more symptoms being attributed to diabetes (r = 0.19, p < .05), and stronger beliefs about diabetes being a chronic condition (r = 0.19, p < .05) with unpredictable symptoms (r = 0.18, p < .05) and feeling more emotionally upset by the illness (r = 0.15, p < .05). Eating the recommended servings of fruits and vegetables was negatively associated with the belief that diabetes was caused by own (risk) behaviours in the past (r = -0.23, p < .01). Not smoking was negatively associated with perceived consequences (r = -0.15, p < .05) and beliefs that diabetes was caused by psychological factors (r = -0.15, p < .05) or own behaviour (r = -0.23, p < .01).

Table 4 shows the results of the multivariate regression analyses to predict the different self-care behaviours. As might be expected on the basis of the bivariate correlations, illness perceptions appeared to contribute minimally to the explanation of the variance in self-care behaviours. Perceived personal control was significantly positively associated with physical activity and general dietary behaviours. Indicating own past behaviours as a causal factor for diabetes was negatively associated with eating the recommended servings of fruit and vegetables and non-smoking. Perceiving T2DM to be a chronic condition was positively related to foot care. Finally, the presence of self-reported complications was found to be associated with increased physical activity and foot care, independently from illness perceptions. Moderation analyses showed that some illness perception dimensions related differently to self-care in the presence of diabetes-related complications. First, a significant interaction effect was found between complications and emotional representations on foot care (p < .05), with a higher frequency of foot care being related to higher levels of emotional representations in patients with complications (β = .36, p < .01), but not in patients without complications (β

Table 4 Independent associations between illness perceptions and self-care behaviour and the role of complications; regression coefficients, odds ratios and explained variance (n = 192).

	Exercise			Foot care			Diet (general)			Diet (fruit/veg.)			Diet (low-fat)			Non-smoking		
	β	β	β	β	β	β	β	β	β	β	β	β	β	β	β	OR	OR	OR
Gender (male)	-.09	-.12	-.12	.00	.01	.01	-.11	-.14	-.14	-.14	-.10	-.10	.05	.01	.01	0.64	0.72	0.69
Age	.03	.07	.03	.03	.06	.03	.01	.09	.08	.15	.15	.14	.12	.14	.15	1.01	1.01	1.00
Treatment (pharmacol.)	-.03	-.02	-.05	.09	.06	.03	-.05	-.07	-.08	-.05	-07	-.08	-.02	-.02	-.01	0.89	0.68	0.62
Comorbidity (present)	-.14	-.12	-.15	.02	-.01	-.03	-.10	-.09	-.10	.05	.05	.05	.13	.14	.15	0.77	0.79	0.76
Diabetes duration	-.02	-.02	-.08	.05	.03	-.04	-.11	-.13	-.16	-.08	-.08	-.10	-.04	-.04	-.02	0.55*	0.55*	0.48*
Identity		.00	-.04		.14	.12		.08	.07		-.06	-.06		.11	.12		0.96	0.93
Timeline: chronic		-.04	-.04		.19*	.18*		-.09	-.08		-.04	-.04		.02	.02		0.83	0.83
Timeline: cyclical		.02	-.05		.23*	.16		.04	.01		.03	.00		.11	.13		0.93	0.87
Consequences		-.06	-.08		-.10	-.12		.04	.03		-.04	-.04		-.12	-.11		0.74	0.74
Personal control		.18	.21*		.02	.05		.18	.20*		.10	.11		.09	.08		1.06	1.10
Treatment control		.12	.13		.05	.06		.17	.17		.09	.10		-.16	-.16		0.82	0.87
Illness coherence		-.13	-.16		-.04	-.07		.02	.00		-.03	-.04		.02	.03		1.41	1.40
Emotional represent.		-.08	-.07		.09	.10		.04	.05		.04	.04		-.16	-.16		0.99	0.97
Cause: psychological		-.04	-.05		-.03	-.05		-.10	-.10		.21	.21		-.19	-.18		1.08	1.03
Cause: own behaviour		-.02	-.01		-.03	-.01		-.13	-.13		-.42**	-.41**		.22	.21		0.37*	0.38*
Cause: bad luck		.02	-.04		-.07	-.05		.06	.07		.07	.08		.04	.03		0.93	0.94
Complications (present)			.29**			.30**			.15			.10			-.09			2.23
Adjusted R²	.00	.00	.07	.00	.03	.10*	.00	.04	.05	.01	.06	.06	.00	.01	.01			
Nagelkerke R																.07	.15	.15

* Significant at 0.05 level.
** Significant at 0.01 level.

= .03, ns). In addition, the (direction of the) association between foot care and perceptions of diabetes being caused by bad luck differed significantly (p < .05) between patients with complications (β = .31, ns) and patients without complications (β = -.10, ns). Finally, an interaction was found between complications and perceived consequences on non-smoking (p < .05). Patients with complications who smoked during the previous week were found to perceive diabetes to have more serious consequences (OR = 0.10, p < .05), while in patients without complications non-smoking and consequences were only slightly negatively related to one another (OR = 0.80, ns).

DISCUSSION

Overall, participating T2DM patients perceived their illness as chronic but not very serious, with a low (emotional) impact on their daily life and well controllable either by self-care or medical treatment. In the presence of (self-reported) complications, however, T2DM was perceived as a more unpredictable illness with more consequences. In addition, patients with complications believed less in the controllability of their condition by self-care or medical treatment and also felt more emotionally upset as a result of their diabetes. These results seem to be in accordance with results of previous studies, indicating the presence of mainly optimistic perceptions regarding controllability and consequences of T2DM in the first years after diagnosis [8–10], which appear to decrease in the presence of the diabetes-related complications [19].

Performance of self-care varied over the five different behaviours assessed. Guidelines for healthy food and diet were reported to be followed for about five days per week on average. Also, the majority of the participating patients (82%) indicated to be a non-smoker. Exercise was reported somewhat less often: patients were physically active for less than 4.5 days per week on average, which is below the Dutch standard of healthy exercise behaviour [20]. These results partly support previous studies indicating lifestyle behaviours to be particularly challenging aspects in diabetes care [21–23]. Foot-care, a self-care behaviour specifically related to diabetes, was hardly performed by the majority of the participating patients during the previous week. Contrary to expectations, only a few illness perception dimensions were associated with self-care behaviours. Patients who perceived they had the ability to control their diabetes, reported to have been more physically active and to have followed the general guidelines for healthy eating and diet more often. These findings seem to support previous studies that identified control perceptions to be particularly influential on health behaviours [3,11]. In addition, our study showed that patients who more strongly believed their own risky behaviours in the past to have caused the onset of their diabetes, were less likely to have consumed the recommended amounts of fruits and vegetables and more likely to have smoked during the past week. This seems to be contrary to the general belief that patients'

awareness of unhealthy behaviours being a major cause for developing diabetes is an important condition for engaging in healthy behaviours later on. It should, however, be kept in mind that perceptions not only influence behaviours, but also vice versa. Patients who have never been smoking and do not perceive their dietary behaviours prior to diagnosis as unhealthy, will most likely not identify 'own risky behaviours' as a cause for their diabetes.

In addition to some of the illness perceptions dimensions, the presence of complications was found to be associated with certain self-care behaviours, namely physical activity and foot care. These findings seem to partly support previous studies [14,24] suggesting that the perceived urge and need to make behavioural changes primarily appear to arise in the presence of diabetes-related symptoms. Significant interaction effects found in this study seemed to partly support previous hypotheses on illness perceptions being related to self-care differently in the presence of diabetes-related complications or complaints. The importance of the perceived seriousness and experienced distress, resulting from diabetes-related complaints, for the performance of self-care appears to be supported by the finding that emotional representations were more strongly associated with checking one's feet more regularly once complications were present. On the contrary, perceptions of the seriousness (of the consequences) of diabetes were associated more strongly with smoking in the presence of complications. However, as smoking may be part of a long existing lifestyle, the heightened perceived consequences are most likely the result of experiencing complications and patients' awareness of their potential harmful smoking behaviour. The positive association between bad luck as a causal factor and foot care in patients with complications was opposite to the direction found in patients without complications, as well as the general conception that lack of awareness of own behaviours as a risk factor for diabetes negatively associates with the performance of self-care. Possibly, patients who perform foot care on a regular basis (e.g. because they are instructed to do so by their health care provider), but who also experience diabetes-related complaints might believe less in the influence of own behaviours on (the course of) their diabetes.

We believe the relatively low proportion of significant associations between illness perceptions and self-care found in this study might be explained by several factors. First, it is difficult to determine whether the self-care behaviours, with the exception of foot care, were actually performed as a part of the diabetes treatment regimen or rather as a part of an already existing lifestyle. Furthermore, the fact that we studied the effects of separate illness perception dimensions, rather than illness perception clusters, may have contributed to the relatively few associations found with self-care behaviours and lifestyle [25]; particularly considering the high perceived controllability and low perceived consequences that were generally found in this study. The low variation in self-care behaviours and illness perceptions in this group of relatively recently diagnosed T2DM patients, however, did not allow for clustering of perception dimensions.

Strengths and limitations

To our knowledge, this study is the first to examine the differences in both illness perceptions and self-care behaviours and its relationship in relatively recently diagnosed T2DM patients with and without complications. In addition, participants were recruited from a large sample of participating GPs in different regions of the Netherlands, which enhances the representativeness of the study population. However, a few factors should be kept in mind when interpreting the results. First, because of the cross-sectional design, conclusions about causality cannot be drawn in this study. In addition, data on diabetes-related complications were self-reported and may not be consistent with complications from a medical point of view. It should, however, be kept in mind that perceived health and illness are often considered to be more predictive of health behaviours and outcomes than objective, medical indicators [26,27].

Implications

This study provides insight into the self-care behaviours, illness perceptions and their relationship in patients in the first years of living with T2DM. The belief that diabetes is controllable by self-care seems to be an important indicator of physical activity and dietary behaviour. However, it remains unclear whether feelings of control give patients more confidence to engage in self-care behaviours or that self-care behaviours make that patients feel more in control. Reasoning from the CSM, both paths are likely and may be intertwined, as the model stresses the importance of concrete experience in forming illness perceptions and, in turn, guiding (coping) behaviours, including self-care behaviours, of individuals [5]. Also, the results suggest that patients are more triggered to engage in certain self-care behaviours when they experience diabetes-related complications or symptoms than when complaints are absent. Although these correlations were generally weak and the results are derived from a cross-sectional study, these findings deserve further investigation as they may have important implications for clinical practice.

Preventive action in the form of healthy behaviours is important for recently diagnosed T2DM patients to prevent complications and to slow down disease progression. Results of this study appear to support previous studies suggesting that patients are less motivated to engage in self-care in the absence of any complaints. It is a major challenge for health care providers to convince asymptomatic patients of the importance of self-care and to explain which role each of the self-care behaviours plays in the course of diabetes so that patients understand why they have to invest in self-care. For those who already experience complications, feelings of control or self-efficacy are of particular importance. Health care providers should advise and support patients, for example by providing information or teaching skills, so that patients gain the confidence to perform self-care behaviours; particularly when serious complications or comorbid conditions are present which interfere with self-care behaviours.

It would be interesting to test our findings in a longitudinal study with larger groups of patients that vary more in the presence of diabetes-related complaints and complications.

Preferably, individually recommended self-care behaviours would be the focus of the study rather than general lifestyle variables, such as healthy eating and being physically active, as was done in this study. Finally, it is important to remember that diabetes management does not only comprise self-care behaviours, but also patients' methods to adapt to living with the illness socially and emotionally. Hence, taking a broader approach of diabetes management by including psychosocial responses would be of special interest.

Acknowledgements

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3

Self-care of patients with type 2 diabetes mellitus over the course of illness: implications for tailoring support.

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ABSTRACT

Purpose

Type 2 diabetes requires patients to make lifestyle changes and perform daily self-care. To determine at what stages patients may need particular self-management support, we examined (1) whether patients' performance of self-care related to their diabetes duration, and (2) whether illness characteristics (treatment and complications) and diabetes-related distress influenced this relationship.

Methods

Data from 590 type 2 diabetes patients were analysed through regression analysis. Lifestyle and self-care behaviours were assessed by the revised Summary of Diabetes Self-Care Activities (SDSCA) measure. Diabetes duration (model 1), treatment and complications (model 2), and distress, as assessed by the Problem Areas In Diabetes (PAID) scale (model 3), were stepwise included. Sociodemographic characteristics were added to all models to account for confounding.

Results

Patients with a longer history of diabetes were less physically active, but monitored their blood glucose more frequently than more recently diagnosed patients. Experiencing complications and using insulin mediated these relationships. Patients with macrovascular complications were less physically active. Patients on insulin self-monitored their glucose levels more frequently, but were also more often smokers. Microvascular complications related to better foot care, while more distress increased the likelihood of smoking. All predictors together explained maximally 5% of the variance in self-care, except for glucose monitoring (37%) and smoking (11%).

Conclusions

Type 2 diabetes patients' self-care activity changes over the course of illness. To provide tailored self-management support, diabetes care providers should take into account patients' phase of illness, including their treatment and complications, as well as their personal characteristics and distress level.

BACKGROUND

A healthy lifestyle and adequate self-care are considered key elements of good-quality care for type 2 diabetes mellitus. Physical exercise and a healthy diet have been proven effective in reducing the risk of micro- and macrovascular complications. This also holds for regular foot and glucose checks to monitor and detect risk factors and symptoms of these complications [1]. For these reasons, medical doctors and nurses invest a lot of time in supporting patients with type 2 diabetes with self-care and making lifestyle changes. In recent years, the importance of tailoring this support to the specific needs of patients has been emphasised [2,3], as research has shown that patients' performance of self-care differs according to their sociodemographic and clinical characteristics, such as their age [4] and socioeconomic position [4,5], and the presence of physical and mental health comorbidities [4,6-8]. As patients' personal characteristics and circumstances as well as their diabetes change over time, the health behaviours they (need to) perform are also likely to change and, consequently, their need for support. However, until now, diabetes self-management support programmes pay little attention to specific support needs and challenges that may arise in different phases in the illness process. Obtaining more insight into patients' self-care behaviours over the course of illness could help determine at what stages of type 2 diabetes specific or additional support is needed. Therefore, we aimed to examine patients' lifestyle and diabetes self-care behaviours in relation to their illness duration.

Regarding the relationship between illness duration and lifestyle and self-care behaviours, we did not formulate a priori hypotheses, as we found that previous studies show inconclusive results. Some research suggests that adherence to lifestyle and self-care recommendations may improve over time, as patients with a longer illness duration are expected to have grown more accustomed to living with diabetes and its management over the years [9]. Patients with a longer illness duration are also more likely to need insulin therapy and to experience complications, both of which may cause patients to perceive their condition as more serious and consequently to attach greater value to adherence to lifestyle and self-care recommendations [10-13]. Conversely, several studies have shown a longer duration of diabetes to be associated with poor glycaemic control [4,14] and worse self-care [14]. Pharmacological treatment, and insulin therapy in particular, may negatively impact patients' perceptions of the need to exercise and adhere to a healthy diet to control glucose levels. Sasi and colleagues have also suggested that the progressive nature of type 2 diabetes may be (partially) responsible for the worse self-care behaviours that they noticed in patients with a longer illness duration, as treatment regimens often become more intensive and complicated over time and thus more challenging for patients. In addition, experiencing complications could have a detrimental effect on adherence to lifestyle and self-care recommendations, as the physical discomfort caused by complications could interfere with physical activity and other health behaviours [14]. Besides, diabetes-related distress may play a role in the relationship between illness

duration and self-care, as patients' level of distress was found to increase with increased illness duration [15], and diabetes-related distress has been shown to both negatively [16] and positively [13] associate with engagement in self-care. Finally, adherence to diabetes self-care recommendations has been reported to differ dependent on the type of self-care activity at stake, suggesting that adequate performance of a specific self-care activity does not guarantee adequate performance of other self-care activities as well [17]. Hence, the objectives of our study were to gain more insight in whether the performance of various self-care behaviours by patients with type 2 diabetes relate to their illness duration (time since diagnosis), and whether certain diabetes-related characteristics, such as diabetes treatment and complications, and the level of diabetes-related distress impact on these relationships.

METHODS

Design and setting

The design of the study was cross-sectional and used the baseline (pre-intervention) measurements from three randomized controlled trials (RCTs) of the Dutch Diacourse study. In the Diacourse study, three self-management intervention programs were developed and tested for patients with type 2 diabetes at different stages of illness: 1. an interactive group-based course for patients with a diabetes duration between one and three years ('short duration'; SD), 2. a peer support intervention for patients diagnosed more than three years ago ('longer duration', LD) and 3. a nurse-led individual intervention for patients who had recently had a first Acute Coronary Event ('Diabetes and ACE'; DA) [18-20] (see the study protocols for more details). Between October 2011 and August 2013, SD and LD patients were recruited from 134 general practices (GP's) in six regions in the Netherlands and DA patients were recruited from 13 hospitals distributed across the country.

Apart from being diagnosed with type 2 diabetes, the inclusion criteria for the SD sample were age of 18 to 85 years and an illness duration (since diagnosis) of minimally one and maximally three years. For the LD sample patients had to be aged 50 to 70 years and diagnosed with type 2 diabetes more than three years prior to inclusion. The inclusion criteria for the DA sample were age older than 35 years, a diabetes duration (since diagnosis) of at least one year and being recently (< three weeks) discharged from the hospital because of a first acute coronary event. The exclusion criteria for all three samples were not being able to sufficiently speak, read and/or understand the Dutch language and having insufficient mental or intellectual capabilities to participate in the study. For the SD and LD samples, patients were also excluded if they were receiving treatment for severe psychological or psychiatric conditions or if they were recently diagnosed with a life-threatening condition (e.g., cancer or stroke).

Measurements

Eligible patients were invited to participate in the study by their general practitioner (SD, LD) or cardiologist (DA), who provided them with written information. Patients who gave informed consent received a postal survey prior to participation in either the intervention or control group. Data were analysed from this first pre-intervention survey.

Self-care

Self-care was assessed using the Dutch version of the revised Summary of Diabetes Self-Care Activities (SDSCA) measure [21]. This instrument focuses on six aspects of diabetes self-care: exercise, glucose monitoring, foot care, general diet, specific diet and smoking. With the exception of smoking, all behaviours were assessed with two questions, which included asking the number of days on which these activities were performed during the past week (response options: 0 to 7 days). Smoking behaviour was assessed with one question, which asked whether the participant had smoked during the past week (response options: yes or no). The revised SDSCA has been validated against other measures of diet and exercise and has shown adequate internal consistency and test-retest reliability [21]. In our study, the Cronbach's alphas of the scales were all above .70, except for the specific diet scale. Therefore, we analysed the two items from this scale (intake of the recommended servings of fruit/vegetables and of a low-fat diet) separately, as suggested by Toobert and colleagues [21].

Diabetes duration

Diabetes duration (at the time of the survey) was calculated from the date of diagnosis reported by the participants (LD, DA) or retrieved from the patients' medical records (SD).

Diabetes-related characteristics

To assess the presence of microvascular complications, participants in the SD and LD studies reported whether they suffered from 1) eye problems, 2) kidney problems, 3) neurological problems, or 4) foot problems, as a result of their diabetes (response options: yes or no). The presence of macrovascular complications was assessed by asking the participants in these studies to indicate whether they suffered from cardiovascular disease. As it was impossible to determine whether the reported macrovascular conditions were related to the participants' diabetes, we decided to treat all reported macrovascular conditions as complications of diabetes in this study. In the DA study, all participants had a macrovascular complication (ACE). The presence of microvascular complications in this study was derived from hospital records.

Type of diabetes treatment (lifestyle advice only, oral hypoglycaemic agents only or insulin) and the presence of comorbid conditions (e.g., cancer, respiratory problems, joint conditions or 'other') were self-reported by the participants in the SD and LD studies and derived from hospital records in the DA study.

Diabetes-related distress

To assess diabetes-related distress, we included the Dutch version of the Problems Areas in Diabetes (PAID) scale [22]. This scale consists of 20 items with five response options, ranging from 0 (no problem) to 4 (serious problem). The scores are summed and transformed to a total score ranging between 0 and 100, with higher scores indicating greater diabetes-related distress. The PAID scale was found to have strong concurrent and discriminant validity [23].

Sociodemographic characteristics

Age, gender, education level and living with or without a partner were self-reported by the participants. Education level was categorized into low (primary school, low general secondary education, preparatory or low vocational education), mid (intermediate or advanced general secondary education or intermediate vocational education), and high (high vocational education or college).

Statistical analyses

Descriptive statistics were calculated for the total population and separately for the three samples. For normally distributed continuous variables, we calculated the means with standard deviations (SDs), and for non-normally distributed variables, we calculated the medians with interquartile ranges (IQRs). One-way analyses of variance with post hoc Bonferroni tests were used to examine differences in exercising, glucose testing, foot care and diet between the three study samples. Differences in smoking behaviour were tested using chi-square tests.

To examine whether participants' self-care behaviours were related to their illness duration, we conducted a separate regression analysis for each of the self-care behaviours. These were all linear regression analyses, except for smoking behaviour, which was analysed using logistic regression analysis. In all regression analyses, self-care behaviour was the dependent variable. We estimated a first model that included diabetes duration in years and diabetes duration in years squared (to account for potential non-linear effects) as independent variables (model 1). To examine whether the presence of micro- or macrovascular complications and the type of diabetes treatment mediated the relationship between illness duration and self-care, we added these variables to a second model (model 2). To examine the potential mediating role of distress, we analysed a third model with diabetes-related distress added as an independent variable (model 3). In all three models, we included participants' gender, age, education level and the presence of comorbid conditions as independent variables to adjust for their potential confounding effects. All analyses were performed using SPSS (version 18.0).

RESULTS

Characteristics of the study sample

The total sample of the three Diacourse studies consisted of 622 persons, 32 of whom had to be excluded because of missing data on the key variables of this study (self-care and diabetes duration), leaving data from 590 participants for analysis. The mean age of these participants was 64 years, and two thirds (64%) were male (Table 1). The median diabetes duration was almost six years. The majority used diabetes medication, either oral hypoglycaemic agents (60%) or insulin (24%). Almost half suffered from comorbid conditions (49%), with joint problems being most prevalent (28%). Microvascular complications were present in a third of the study sample, with foot problems (14%) and eye problems (12%) being most prevalent. Macrovascular complications were present in 45% of the participants.

Table 1 Sociodemographic characteristics, illness-related characteristics and self-care behaviours of the total study sample and the separate SD, LD and DA samples.

	Total sample N= 590	SD sample N= 180	LD sample N= 224	DA sample N= 186
Sociodemographic characteristics				
Gender: % male	63.6	57.2	60.7	73.1
Age, in years: mean (SD)	64.2 (8.4)	63.8	63.6	65.4
Living with a partner: %	78.4	75.1	83.9	74.7
Education level: %				
Low	31.2	29.5	22.9	42.9
Mid	47.4	48.0	49.8	44.0
High	21.4	22.5	27.4	13.0
Illness-related characteristics				
Diabetes duration, in years: median (IQR)	5.9 (2.6 -12.3)	2.3 (1.8 - 3.0)	9.5 (6.5 - 14.5)	7.8 (3.7 - 14.3)
Treatment:				
Oral hypoglycaemics: %	60.2	65.2	58.5	57.5
Insulin: %	23.6	2.2	32.1	33.9
Presence of microvascular complications: %	33.3	21.7	49.1	25.3
Presence of macrovascular complications: %	44.7	21.1	16.7	100
Presence of comorbid conditions: %	48.5	54.3	53.8	36.6
Diabetes distress (0-100): median (IQR)	7.5 (2.5-17.8)	6.3 (1.3-15.9)	9.4 (2.5-21.3)	5.0 (1.3-16.3)
Self-care				
No. of days physical exercise: mean (SD)	3.83 (2.17)	4.42 (1.90)	4.08 (1.97)	2.96 (2.38)
No. of days glucose monitoring: mean (SD)	1.45 (2.35)	0.43 (1.18)	1.70 (2.50)	2.15 (2.67)
No. of days foot care: mean (SD)	1.51 (2.10)	1.22 (1.92)	1.57 (2.15)	1.74 (2.18)
No. of days healthy diet-general: mean (SD)	4.86 (1.92)	5.14 (1.70)	4.78 (1.82)	4.68 (2.20)
No. of days sufficient fruit/vegetables intake: mean (SD)	5.37 (1.97)	5.38 (1.95)	5.56 (1.78)	5.13 (2.17)
No of days low-fat diet: mean (SD)	4.60 (2.15)	4.74 (2.16)	4.69 (2.00)	4.36 (2.32)
Non-smoking: %	85.1	81.3	85.9	87.8

On average, the participants reported having been physically active for a little less than four days per week. Significant differences between the three samples existed in this respect $(F_{(2,575)} = 24.26, p < .001)$, with the participants of the DA sample being significantly less active (M = 2.96) than the participants of the SD sample (M = 4.42). Glucose monitoring and foot care were performed for an average of one to two days (M = 1.5) per week. The frequency of foot care did not statistically differ between the three samples, but glucose monitoring did $(F_{(2, 575)} = 27.92, p < .001)$: the SD participants reported fewer days of glucose self-monitoring (M = 0.43) than the LD participants (M = 1.70) and the DA participants (M = 2.15). Recommendations for a healthy diet were followed for approximately five days per week, and the majority of the participants indicated to not have smoked during the previous week. No differences existed between the three samples regarding these behaviours.

Effects of diabetes duration, diabetes-related characteristics and distress on self-care

Tables 2, 3 and 4 show that diabetes duration was significantly associated with the number of days participants reported to be exercising and self-monitoring their glucose levels, but not with the number of days they performed foot care, ate a healthy diet or smoked. Starting with exercise, Table 2 shows that the longer participants had diabetes, the less days they were physically active. Diabetes duration had both a linear and quadratic effect, and Figure 1 (blue line, based on model 1) shows that the decline in physical activity was largest during the first years after diagnosis. Adding diabetes-related characteristics to the model (model 2) decreased the effects of diabetes duration (though they remained significant), suggesting that the presence of macrovascular complications in particular was partially responsible for the negative relationship between diabetes duration and exercise. Adding diabetes-related distress to the model (model 3) did not make a difference. The variance in time spent exercising explained by the last model remained small (5%).
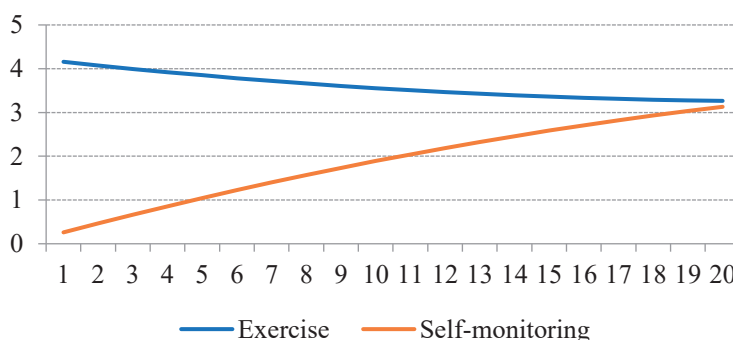
Figure 1 Illustration of the relationships between diabetes duration in years (X-axis) and the number of days per week (Y-axis) exercising (blue line) and self-monitoring (red line) (based on Table 2, model 1).

With regard to glucose self-monitoring, Table 2 shows that a longer diabetes duration increased the number of days that participants monitored their blood glucose levels. Figure 1 (red line, based on model 1) illustrates the not entirely linear relationship found between diabetes duration and the participants' self-monitoring behaviour. The effects of diabetes duration substantially decreased after adding the diabetes-related characteristics (model 2). In particular, using insulin decreased the effects of diabetes duration on self-monitoring, suggesting that this was an important mediator. In addition, the total variance explained by the model increased from 17% to 37% by adding the diabetes-related characteristics, which indicates that using insulin has an important additive effect on glucose self-monitoring (in addition to diabetes duration).

Frequency of foot care was not related to diabetes duration (Table 2), but the presence of microvascular complications increased the number of days that the participants performed foot care, although the total variance remained low (5%).

With regard to healthy eating, Table 3 shows that diabetes duration was not a significant predictor. In fact, none of the diabetes-related variables in our analyses - except for the presence of microvascular complications, which had some small, negative effects - helped explain the participants' eating behaviours. As such, the total variance in the participants' eating behaviours explained by our models was less than 2%.

The duration of diabetes was not related to the participants' smoking behaviour (Table 4); instead, the use of insulin and experiencing greater diabetes-related distress significantly decreased the likelihood of being a non-smoker. With all variables included, model 3 explained approximately 11% of the variance in smoking among the participants.

Table 2 Effects of diabetes duration, diabetes-related characteristics and distress on exercising, glucose self-monitoring and foot care; results of linear regression analyses: standardized regression coefficients (β) and explained variance (adjusted R²)†

	Exercising (N=558)			Glucose self-monitoring (N=558)			Foot care (N=559)		
	Model 1	Model 2	Model 3	Model 1	Model 2	Model 3	Model 1	Model 2	Model 3
	β	β	β	β	β	β	β	β	β
Diabetes duration									
In years	-.308**	-.229*	-.228*	.683***	.260**	.257**	.190	.019	.016
In years squared	.281**	.237*	.234*	-.319**	-.095	-.090	-.092	.000	.005
Diabetes-related characteristics									
Oral hypoglycaemics		-.111	-.110		-.045	-.046		.011	.009
Insulin		-.115	-.112		.459***	.451***		.088	.081
Microvascular complications		-.006	-.002		.050	.042		.197***	.189***
Macrovascular complications		-.182***	-.183***		.055	.056		.069	.070
Diabetes-related distress			-.027			.063			.056
Adjusted R²	.017*	.051***	.050***	.168***	.367***	.370***	.009	.048***	.049***

† All analyses adjusted for age, gender, education level and comorbid conditions.
* Significant at .05 level, ** Significant at .01 level, *** Significant at .001 level.

Table 3 Effects of diabetes duration, diabetes-related characteristics and distress on adhering to recommendations of a healthy diet; results of linear regression analyses: standardized regression coefficients (β) and explained variance (adjusted R²)†

	Healthy diet-general (N=553)			Fruit/vegetables intake (N=551)			Low-fat intake (N=554)		
	Model 1	Model 2	Model 3	Model 1	Model 2	Model 3	Model 1	Model 2	Model 3
	β	β	β	β	β	β	β	β	β
Diabetes duration									
In years	-.110	-.012	-.008	.027	.133	.136	-.054	-.042	-.041
In years squared	.148	.092	.086	.030	-.028	-.032	-.019	-.026	-.026
Diabetes-related characteristics									
Oral hypoglycaemics		-.095	-.093		-.039	-.038		.008	.008
Insulin		-.099	-.090		-.071	-.065		-.056	-.055
Microvascular complications		-.104*	-.095*		-.108*	-.102*		.064	.065
Macrovascular complications		-.039	-.040		-.077	-.078		.033	.033
Diabetes-related distress			-.069			-.048			-.006
Adjusted R²	.001	.011	.014	.004	.016*	.016*	.017*	.016*	.015

† All analyses adjusted for age, gender, education level and comorbid conditions.
* Significant at .05 level, ** Significant at .01 level, *** Significant at .001 level.

Table 4 Effects of diabetes duration, diabetes-related characteristics and distress on smoking behaviour; results of logistic regression analyses: odds ratios (OR) with 95%-confidence intervals (95%-CI) and explained variance (Nagelkerke R²)†

	Non-smoking (versus smoking) (N=556)		
	Model 1	Model 2	Model 3
	OR (95% CI)	OR (95% CI)	OR (95% CI)
Diabetes duration			
In years	1.009 (0.889 – 1.145)	1.055 (0.921 – 1.208)	1.065 (0.929 – 1.221)
In years squared	1.002 (0.997 – 1.008)	1.002 (0.996 – 1.008)	1.001 (0.995 – 1.008)
Diabetes-related characteristics			
Oral hypoglycaemics		0.718 (0.347 – 1.485)	0.729 (0.351 – 1.515)
Insulin		0.361* (0.150 – 0.872)	0.390* (0.160 – 0.950)
Microvascular complications		0.819 (0.468 – 1.434)	0.925 (0.521 – 1.643)
Macrovascular complications		1.601 (0.947 – 2.707)	1.602 (0.943 – 2.722)
Diabetes-related distress			0.979** (0.964 – 0.993)
Nagelkerke R²	.063**	.090**	.114***

† All analyses adjusted for age, gender, education level and comorbid conditions.
* Significant at .05 level, ** Significant at .01 level, *** Significant at .001 level.

DISCUSSION

In this study, we examined the relationship between lifestyle, self-care behaviours and disease duration in people with type 2 diabetes. We also explored the potential mediating roles of diabetes-related characteristics and diabetes-related distress in this relationship. Our findings show that patients with a longer illness duration were less physically active; in particular during the first years after diagnosis the level of physical activity seems to decrease. Conversely, glucose self-monitoring was performed more often as illness duration increased. Regarding the opposing associations of diabetes duration with physical exercise and self-monitoring, it is possible that patients with a longer diabetes duration experience a greater number of health problems (e.g., fatigue and headache) that are not considered diabetes-related complications but do hinder physical activity and trigger the tendency to monitor blood glucose levels more often [24,25]. Additionally, the negative association between diabetes duration and physical activity may indicate a shift in focus on the topics discussed during regular check-ups over time. These findings indicate that diabetes care providers may have to focus more on emphasizing the importance of an active lifestyle at later stages of illness progression, and on providing additional support to patients experiencing symptoms that may interfere with physical activity.

Relationships between diabetes duration and exercising or self-monitoring were partially mediated by the presence of macrovascular complications (exercising) and the use of insulin (self-monitoring). The presence of macrovascular complications had an additive, negative effect on exercise frequency. This finding that participants with macrovascular complications were less physically active could be the consequence of feelings of hesitation and uncertainty regarding physical exercise that are often experienced by individuals following an acute coronary event [26,27]. However, as our study design did not allow causal interpretation, it should be noted that low levels of physical activity could have also contributed to the occurrence of macrovascular complications [28,29]. The use of insulin was found to have additive effects on self-monitoring and smoking behaviour. The participants who used insulin monitored their blood glucose levels more frequently, but were also more often smokers. The fact that Dutch guidelines usually do not recommend regular or daily monitoring of blood glucose levels to patients not on insulin treatment [30] is most likely the main explanation for the positive association between insulin use and glucose monitoring, although diabetes duration continued to be positively related to glucose monitoring after treatment and complications had been added to the model. The relationship between insulin use and smoking may be explained by increased levels of diabetes distress, which have been found to be associated with insulin use in previous studies [31,32], and to smoking in this study.

The presence of microvascular complications was found to have a positive effect on the frequency of foot care. The presumption that microvascular complications trigger self-care is supported by the positive association found between the presence of microvascular complica-

tions and the frequency of foot care, but not by the negative association found with dietary behaviours and the lack of association with physical activity and smoking behaviour. It may be that the presence of microvascular complications particularly impacts diabetes specific self-care behaviours, such as foot care [10], rather than more generic lifestyle behaviours such as physical activity, eating and smoking. In addition, the relatively large proportion of participants with a recent acute coronary event in the study sample could have masked the significance of microvascular complications as a cue to action for patients with type 2 diabetes to exercise, as we found that microvascular complications were positively related to exercising behaviour when analysing only the data from the SD sample [33]. The presence of microvascular complications in the DA sample may have been underreported, as it is likely that not all microvascular complications experienced by these patients were reported in the records maintained by their cardiologists [34].

Diabetes-related distress was only associated with smoking behaviour. Previous findings that diabetes-related distress is related to the presence of microvascular complications and insulin use in our sample [34] might elucidate why distress itself did not explain any additional variance in the regression models. Additionally, the participants' scores on the PAID scale were generally low, which implies that they were not very concerned about their diabetes or its treatment.

Finally, it must be noted that although diabetes duration and its associated characteristics were found to be associated with the lifestyles and self-care behaviours of patients with type 2 diabetes, only a small proportion of the variance could be explained by these determinants. In other words, with the exception of glucose self-monitoring, self-care seems to be primarily influenced by other factors that were not included in this study, such as psychological characteristics, family support or other priorities.

A strength of our study is the large size of the total sample, which allowed us to examine a broad range of diabetes durations and diabetes-related characteristics. Baseline data from three RCT's were combined to obtain the study sample. Although all three samples were part of the Dutch Diacourse study, it should be noted that the data collection procedures were not exactly the same. In the SD and LD samples, several illness-related characteristics, such as diabetes treatment, complications and comorbidities, were self-reported by patients, whereas in the DA study, data on these characteristics were derived from hospital records. Self-reported complications and conditions may not fully correspond with relevant symptoms and diseases from a medical point of view. Nonetheless, they have been proven to be important determinants of health behaviours and outcomes [35,36]. Furthermore, the participants in this study may not be entirely representative of all patients with type 2 diabetes, as those included here were willing to participate in an intervention study on self-management, which may have led to an underrepresentation of patients who are less motivated to perform self-care. However, by recruiting general practices and hospitals in different regions across the Netherlands, and by covering the (travel) expenses of the participating patients, we aimed to

keep the chances on selection bias in our study population as low as possible. Furthermore, as all inhabitants in the Netherlands are obligatory registered at a general practice, no selection could have occurred beforehand.

Notwithstanding its limitations, we believe that our study provided some valuable insights to support the self-care of patients with type 2 diabetes in clinical practice. We have added to existing literature by differentiating the impact of diabetes duration in itself from the impact of illness-related characteristics on self-care, and by reporting their relationship separately for the different, independent self-care behaviours that make up the diabetes care regimen. Our study results show that diabetes duration and several diabetes-related characteristics (i.e., presence of microvascular and macrovascular complications as well as treatment type) need to be taken into account when supporting patients in making lifestyle changes and adhering to self-care recommendations. Clinicians need to be aware that patients have different support needs dependent on the type of self-care behaviour at stake as well as on the phase of illness they find themselves in. For instance, with regard to physical activity, diabetes care providers should encourage physical exercise not only in consultations with patients in the first years after diagnosis but also in consultations with patients with a much longer diabetes duration, as their physical activity seems to decline. In these consultations, special attention needs to be paid to complications or conditions that might interfere with exercise either because of their disabling nature or because of patients' fears or false beliefs that result in the avoidance of activity. In the early years of diabetes, other support may be necessary. Attention should be paid to the benefits and barriers that patients perceive with regard to adhering to lifestyle and self-care recommendations, especially in the absence of diabetes-related symptoms. Traditional patient education may not be sufficient, as it often neglects patients' personal goals and their perceptions of their illness. Therefore, innovative strategies need to be developed to provide tailored person-centered support to help patients with type 2 diabetes adopt a healthy lifestyle and perform adequate self-care in all phases of their illness.

Conclusions

Patients with type 2 diabetes with a longer illness duration are less physically active than those with a shorter illness duration, which partially relates to the higher frequency of macrovascular complications in patients with a longer illness duration. In contrast, patients with type 2 diabetes with a longer illness duration monitor their blood glucose levels more frequently, which mainly relates to their use of insulin. To help patients adopt a healthy lifestyle and improve their self-care, diabetes care providers need to tailor their support to the phase of the illness that patients find themselves in, to characteristics such as the presence of complications and the type of treatment, and to patients' personal characteristics and perceptions.

Acknowledgements

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4

Diabetes-related distress over the course of illness: results from the Diacourse study.

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ABSTRACT

Aims

To investigate the relationship between diabetes duration and diabetes-related distress and to examine the impact of micro- and macrovascular complications and blood glucose-lowering treatment on this relationship.

Methods

We conducted a cross-sectional study in people with Type 2 diabetes who participated in the Dutch Diacourse study (n = 590) and completed the Problem Areas in Diabetes questionnaire. Data on diabetes duration, micro- and macrovascular complications and blood glucose-lowering treatment were collected. Multiple linear regression analysis was used to investigate the association between diabetes duration and diabetes-related distress, and to examine whether complications and treatment could explain this association.

Results

A significant linear and quadratic association between diabetes duration and diabetes-related distress was found (duration: β = 0.27, P = 0.005; duration^2: β = -0.21, P = 0.030). The association between duration and distress could be explained by microvascular complications and insulin treatment, which were both more often present in people with a longer diabetes duration, and were associated with higher levels of diabetes-related distress (β = 0.20, P < 0.001 and β = 0.16, P = 0.006 respectively). Duration, age, gender, complications and treatment together explained 13.1% of the variance in distress.

Conclusions

Diabetes duration was associated with diabetes-related distress. This association can be explained largely by the presence of diabetes-related microvascular complications and insulin treatment. Healthcare providers should focus on distress in people with Type 2 diabetes in different stages over the course of illness, especially when complications are present or when people are on insulin treatment. As well as diabetes duration, complications and blood glucose-lowering treatment, diabetes-related distress is likely to be influenced by many other factors.

INTRODUCTION

Type 2 diabetes mellitus is a chronic condition that requires people to adhere to a healthy diet, physical activity and the daily use of medication. They need to implement these activities into their daily life and have to deal with the potential for complications. This can be burdensome and may result in diabetes-related distress, which comprises an emotional burden and concerns about access to care, disease management and support. Loss of control, feelings of failure and lowered self-efficacy might be present in people with diabetes with increased distress [1,2]. These concerns may result from the diabetes itself (e.g. occurrence of complications or disability) or from enforced lifestyle changes necessitated by the illness. Distress is related to poor self-care [3], poor medication adherence [4], and poor glycaemic control [5].

Several diabetes management guidelines recommend assessment of the emotional wellbeing of people with diabetes [6,7]; however, a study in a Dutch outpatient clinic showed that diabetes nurses only recognized distress in 20–29% of the people with diabetes with high distress scores [8]. To improve recognition of distress and to offer tailored support when needed, it is important for diabetes care providers to gain insight into who may experience increased distress.

Several factors have been reported to increase the risk of becoming distressed regarding diabetes. Female gender, younger age, low education, poor diet, higher BMI, higher HbA1c level, insulin use and complications were all associated with increased distress [9,10]. As people with a longer diabetes duration are more likely to have complications and/or are on more intensive treatment, we would also expect diabetes duration to be associated with diabetes-related distress. Most studies examining the determinants of diabetes-related distress, however, have not found a linear association between duration of Type 2 diabetes and distress [10–13]. It may be, therefore, that the association between diabetes duration and distress is non-linear. Distress may change over time as a result of adaptation to a life with diabetes, new information or progression of the disease, such as the occurrence of complications or treatment intensification. Evidence for an interacting role of diabetes treatment was found in people with screen-detected diabetes: people with intensive multifactorial treatment showed more distress in the first year after diagnosis, whereas people receiving 'usual care' reported more distress only 2 years or more after diagnosis. It is possible that intensively treated people experience distress shortly after diagnosis because they must immediately face a barrage of treatments, whereas distress in people on less intensive treatment is delayed and primarily related to illness progression [14].

There are only few examples in the literature that focus on diabetes-related distress in the different phases of the illness. We aimed to investigate diabetes-related distress over the course of illness. More specifically, we examined the relationship between diabetes duration and diabetes-related distress, taking into account the impact of complications and treatment intensity.

PATIENTS AND METHODS

The study population consisted of people with Type 2 diabetes who participated in the Dutch Diacourse study between October 2011 and August 2013 [15–17]. The Diacourse study was designed to investigate the effectiveness of three supportive interventions to improve self-management and to decrease diabetes-related distress in three samples at different stages over the course of illness. Hereafter, we refer to these samples as: the short diabetes duration group; the longer diabetes duration group; and the recent acute coronary event group. Participants were recruited via their general practitioners (the short and longer diabetes duration groups) or via their cardiologist (recent acute coronary event group). The participants in the short diabetes duration group were aged 18–85 years and had a Type 2 diabetes duration of 1–3 years, those in the longer diabetes duration group were aged 50–70 years and had a diabetes duration of ≥ 3 years, and those in the recent acute coronary event group were aged > 35 years, had a diabetes duration of ≥ 1 year and were very recently discharged from hospital after a first acute coronary event. Participants were excluded if they did not speak or understand the Dutch language; or had severe mental or intellectual limitations. For the present study we used the baseline measurements of the Diacourse study.

Measures

Diabetes-related distress
The Problem Areas in Diabetes (PAID) questionnaire was used to measure diabetes-related distress [18]. This is a widely recognized measure of diabetes distress, assessing the general emotional burden of diabetes and distress related to diabetes treatment, food choices and social support. The PAID questionnaire comprises 20 items, producing a total score ranging from 0 to 100, with higher scores representing higher distress. A score ≥ 40 on the PAID questionnaire represents high distress [19]. The Dutch PAID scale has good convergent and discriminant validity and high internal consistency [2]. The questionnaire has been shown to be a useful measure to assess diabetes-related distress, and its responsiveness has been tested, supporting its sensitivity to change over time [20].

Diabetes duration
Diabetes duration was calculated on the basis of the date of diagnosis, either self-reported (longer diabetes duration group and recent acute coronary event group) or as extracted from the electronic medical record of the general practitioner (short diabetes duration group), and date of completing the PAID questionnaire.

Demographics and clinical variables

The following personal characteristics were collected using a self-report questionnaire, which was completed by the participants: age, gender, education, living status, working status and marital status. Furthermore, participants were asked whether they currently smoked or not. Information on blood glucose-lowering treatment [no diabetes treatment/ only lifestyle advice, only oral blood glucose lowering medication or insulin (with or without oral medication)] and comorbidity (cancer, chronic respiratory diseases, joint problems, other) was self-reported (short and longer diabetes duration groups) or extracted from hospital files (recent acute coronary event group). To assess the presence of microvascular complications, the participants in the short and longer diabetes duration groups were asked to indicate whether they had 1) eye problems; 2) kidney problems; 3) neurological problems; and 4) foot problems as a result of the Type 2 diabetes. For the recent acute coronary event group information on microvascular complications was extracted from the hospital files. To assess the presence of macrovascular complications, participants in the short and longer diabetes duration groups were asked whether they had cardiovascular disease. All participants in the recent acute coronary event group had a macrovascular complication, because one of the inclusion criteria was being discharged from hospital after a first acute coronary event.

Statistical analysis

Patients with missing data on diabetes duration or missing diabetes-related distress scores were excluded from the analysis (n = 32). All analyses were performed using SPSS (version 20.0). First, descriptive statistics (frequencies of demographic characteristics and study variables) were computed. Normally distributed continuous variables were reported as means with ranges, non-normally distributed continuous variables as medians with interquartile ranges (IQRs) and categorical variables as numbers and percentages. Differences in baseline characteristics between the three study samples were examined using one-way ANOVA (for normally distributed continuous variables), Kruskal–Wallis tests (for non-normally distributed continuous variables) or chi-squared tests (for categorical variables). Log transformation was used to correct the skewed distribution of the PAID scores. In models where the dependent variable has been log transformed and the predictors have not, the interpretation of the parameter estimate is that the dependent variable changes by 100*(coefficient)% for a 1-unit increase in the independent variable, while all other variables in the model are held constant.

The association between diabetes duration as an independent variable and diabetes-related distress as a dependent variable was examined using linear regression analysis. To account for a potential non-linear effect of diabetes duration, we included diabetes duration as two independent (continuous) variables in all models: in years and in years squared. We examined whether the association between diabetes duration and diabetes-related distress (model 1) was attenuated by adding microvascular complications (model 2) or macrovascular complications (model 3) and their combined effects (model 4). Furthermore, the effect of blood glucose

lowering treatment was estimated (model 5) and the final model included the combination of micro- and macrovascular complications and blood glucose-lowering treatment in addition to the diabetes duration variables (model 6). Micro- and/or macrovascular complications were included in the models as dichotomous variables (coded as 1 if at least one of these complications was present and 0 if none). Furthermore, we examined whether the association between the presence of complications and diabetes-related distress was influenced by the duration of diabetes. We looked at the overall explained variance (R^2) in diabetes-related distress of these models and used F-tests to determine the impact of these variables on explaining distress.

A sensitivity analysis was performed to examine the impact of method of data collection of complications and blood glucose-lowering treatment (self-reported versus hospitals files) on the association of diabetes duration and diabetes-related distress. In addition, we examined whether the method of data collection acted as a moderator on the associations between microvascular complications and distress and between insulin treatment and distress.

All analyses were adjusted for age and gender given the potential for these variables to influence the outcomes. A P value of < 0.05 was considered significant.

RESULTS

The complete study sample included 590 participants [mean age 64.2 (26–86) years, 63.6% male]. The median (IQR) diabetes duration was 5.9 (2.6–12.3) years. The demographic and clinical characteristics of the participants of the three samples are shown in Table 1.

Diabetes-related distress

The median (IQR) level of diabetes-related distress in the total sample was 7.5 (2.5–18.8). Levels of diabetes-related distress differed between the three samples (P = 0.011), with higher median (IQR) levels of distress experienced by participants in the longer diabetes duration group [9.4 (2.5–21.3)], compared with those in the short diabetes duration group [6.3 (1.3–15.9); P = 0.023] and the recent acute coronary event group [5.0 (1.3–16.3); P = 0.006]. Patients with microvascular complications [PAID score 12.5 (3.8–23.8)] experienced more distress than participants without these complications [PAID score 6.3 (1.3–15.0); P < 0.001], whereas participants with macrovascular complications did not experience increased distress (P = 0.169). Participants on insulin treatment [PAID score 11.3 (5.0–25.0)] had higher levels of diabetes-related distress than participants with only oral glucose-lowering medication [PAID score 6.3 (1.2–16.3); P < 0.001] or without blood glucose-lowering treatment [6.3 (1.2–12.5); P < 0.001]. Only 7.1% of the total sample had a PAID score ≥ 40, representing high distress.

Table 1 Demographic and clinical characteristics of the total study sample and the three subsamples.

	Short diabetes duration group	Longer diabetes duration group	Recent acute coronary event group	Total
	(n = 180)	(n =224)	(n = 186)	(n = 590)
Age in years, mean (range)	63.8 (26-83)	63.6 (50-72)	65.4 (41-86)	64.2 (26-86)
Male gender, % (n/N)*	57.2 (103/180)[a]	60.7 (136/224)[a]	73.1 (136/186)[b]	63.6 (375/590)
Education				
Low, %(n/N)*	29.5 (51/173)[a]	22.9 (51/223)[a]	42.9 (79/184)[b]	30.9 (181/580)
Middle, %(n/N)	48.0 (83/173)	49.8 (111/223)	44.0 (81/184)	47.0 (275/580)
High, (%) (n/N)*	22.5 (39/173)[a, b]	27.4 (61/223)[a]	13.0 (24/184)[b]	21.2 (124/580)
Living alone,%(n/N)	22.0 (39/177)	16.1 (36/223)	20.7 (38/184)	19.3 (113/584)
Paid job,%(n/N)	29.4 (53/180)	28.3 (63/223)	22.3 (39/175)	26.8 (155/578)
Currently smoking, % (n/N)	18.4 (33/179)	11.8 (26/221)	10.9 (20/184)	13.5 (79/584)
Clinical variables				
Diabetes duration (years) (IQR)*	2.3 (1.8-3.0)[a]	9.5 (6.5-14.5)[b]	7.8 (3.7-14.3)[c]	5.9 (2.6-12.3)
Diabetes medication				
No medication/only lifestyle, %(n/N)*	32.2 (58/178)[a]	9.4 (21/224)[b]	8.6 (16/186)[b]	16.2 (95/588)
Oral blood glucose lowering medication, %(n/N)	65.2 (116/178)	58.5 (131/224)	57.5 (107/186)	60.2 (354/588)
Insulin, %(n/N)*	2.2 (4/178)[a]	33.1 (72/224)[b]	33.9 (63/186)[b]	23.6 (139/588)
Complications				
No complications,%(n/N)*	66.3 (114/175)[a]	45.2 (100/221)[b]	0 (0/186)[c]	37.0 (214/582)
Microvascular,%(n/N)*	21.7 (38/175)[a]	49.1 (110/224)[b]	25.3 (47/186)[a]	33.3 (195/585)
Eye problems,%(n/N)	8.6 (15/175)	14.7 (33/224)	12.4 (23/186)	12.1 (71/585)
Kidney problems, (n/N)*	1.1 (2/175)[a]	0.9 (2/224)[a]	10.2 (19/186)[b]	3.9 (23/585)
Neurologic problems,%(n/N)*	4.6 (8/175)[a]	11.6 (26/224)[b]	3.8 (7/186)[a]	7.0 (41/585)
Foot,%(n/N)*	9.7 (17/175)[a]	25.0 (56/224)[b]	3.2 (6/186)[c]	13.5 (79/585)
Macrovascular, %(n/N)*	21.1 (37/175)[a]	16.7 (37/221)[a]	100 (186/186)[b]	44.7 (260/582)
Comorbidity				
Cancer,%(n/N)*	2.3 (4/175)[a]	2.3 (5/221)[a]	9.1 (17/186)[b]	4.5 (26/582)
Respiratory illness,%(n/N)	13.7 (24/175)	8.6 (19/221)	11.8 (22/186)	11.2 (65/582)
Joint problems,%(n/N)*	33.7 (59/175)[a]	35.3 (78/221)[a]	12.9 (24/186)[b]	27.7 (161/582)
Other, %(n/N)	20.0 (35/175)	22.6 (50/221)	15.6 (29/186)	19.6 (114/582)

IQR, interquartile range.

Data are means (range), medians (IQR) or percentages (number/total number of patients excl. missings).
Between-group differences (P < 0.05) are indicated by *.
Each superscript ([a,b,c]) letter denotes a subset of sample categories which do not differ significantly from each other at the 0.05 level.

Diabetes duration and diabetes-related distress

The first regression model showed a significant association between diabetes duration and diabetes-related distress (P = 0.011; Table 2). This association was not only linear (β = 0.27, P = 0.04), but quadratic as well (β = -0.21, P = 0.026). In the second model, the association between diabetes duration and diabetes-related distress was attenuated by adding microvascular complications as a predictor in the model, and became non-significant (Δβ diabetes duration = 0.10; Δβ diabetes duration² = 0.05; diabetes duration P = 0.175). Macrovascular complications did not have such attenuating effects (model 3). This was confirmed in model 4 (both micro- and macrovascular complications included), where only the presence of microvascular complications was associated with increased diabetes related distress (β = 0.21, P < 0.001). The association between diabetes duration and diabetes-related distress was also attenuated by adding the use of blood glucose-lowering treatment to the model (Δβ diabetes duration = 0.13; Δβ diabetes duration² = 0.00; diabetes duration P = 0.327; β values in model 5 compared with model 1), with insulin treatment being associated with increased distress (β = 0.18, P = 0.003). In the full model, the association between diabetes duration and distress was further attenuated and both the presence of microvascular complications and the use of insulin were associated with increased diabetes-related distress (β = 0.20, P < 0.001 and β = 0.16, P = 0.006, respectively). The association between the presence of complications and distress was not influenced by diabetes duration (linear and squared, β = -0.104, P = 0.591 and β = 0.539, P = 0.590 respectively).

Table 2 Relationship between diabetes-related distress and diabetes duration, diabetes complications and blood glucose lowering treatment.

	Model 1		Model 2		Model 3		Model 4		Model 5		Model 6	
	β	P	β	P	β	P	β	P	β	P	β	P
Diabetes duration	0.27		0.17		0.27		0.17		0.14		0.06	
Diabetes duration²	-0.21		-0.16		-0.21		-0.16		-0.21		-0.10	
Duration overall		0.011		0.175		0.012		0.192		0.327		0.447
Complications												
Microvascular			0.21	<0.001			0.21	<0.001			0.20	<0.001
Macrovascular					-0.04	0.316	-0.03	0.475			-0.042	0.301
Medication												
Only oral medication									0.03	0.548	0.02	0.747
Insulin treatment									0.18	0.003	0.16	0.006
R²	0.071		0.112	<0.001	0.073	0.316	0.113	<0.001	0.092	0.002	0.131	<0.001

Analyses adjusted for age and gender. Parameter estimates are based on log-transformed scores of the PAID. P-values of the R² reflect the magnitude of changes in explained variance between the models and model 1 (reference).

Diabetes duration and duration² were included in the models as continuous variables; micro- and macrovascular complications and blood glucose lowering treatment were included as dichotomous variables (present or not).

Percentage of variance explained

Diabetes duration, adjusted for age and gender, explained a total of 7.1% of the variance in diabetes-related distress. Adding microvascular complications significantly increased the explained variance to 11.2% (P < 0.001), while adding macrovascular complications did not (R^2 = 0.073, P = 0.316). Blood glucose-lowering treatment added a small but significant 2.1% (P = 0.002) to the explained variance of diabetes-related distress. The final model explained 13.1% of the variance in diabetes-related distress.

Method of data collection

A sensitivity analysis showed that adjusting for method of data collection (self-reported vs. data from hospital files) did not considerably affect the results. The regression coefficients of diabetes duration, microvascular complications and blood glucose-lowering treatment did not substantially change after adjustment for method of data collection (data not shown). Only a change in the β value of macrovascular complications was found (β = 0.01 after adjustment vs. β = -0.04), but the association between macrovascular complications and diabetes-related distress remained non-significant (P = 0.859 vs. P = 0.301). The method of data collection had a significant moderating effect on the association between microvascular complications and diabetes-related distress (β = -2.29, P = 0.022) and on the association between insulin treatment and diabetes-related distress (β = -2.72, P = 0.007).

DISCUSSION

The present study showed that people with Type 2 diabetes in the Netherlands generally experience low levels of diabetes-related distress. Only 7.1% of the total study population reported elevated distress (PAID score ≥ 40). Diabetes duration was associated with diabetes-related distress. This association was not only linear, but quadratic as well, and could largely be explained by complications and blood glucose-lowering treatment, both being more frequently present in people with a longer diabetes duration. Diabetes duration, age and gender explained only 7.1% of the variance in distress. The explained variance increased to 13.1% by adding complications and treatment with blood glucose-lowering agents to the model.

The diabetes-related distress experienced in the present study is similar to that reported in previous studies among people with Type 2 diabetes treated in primary care in the Netherlands [21,22]. Previous studies did not find a linear association between diabetes duration and diabetes-related distress [10–13]. In contrast to these studies, we examined not only the linear association, but also included a quadratic function of diabetes duration, and we did find an association between duration and distress. Because distress may change over the course of illness and the association between duration and distress is not only linear, healthcare providers should be continuously alert to diabetes-related distress in people with Type 2 diabetes over

the course of illness as part of the regular diabetes care. As expected, the association between diabetes duration and diabetes-related distress was substantially attenuated after adjustment for complications. The presence of microvascular complications was significantly related to distress. The literature in this respect is contradictory. For example, Baek et al. [9] found no independent association between the presence of microvascular complications and diabetes-related distress, whereas others did find such an association [11]. Stoop et al. [21] found only neuropathy to be associated with diabetes-related distress, while other diabetes-related micro- and macrovascular complications were not. In the present study, we also observed that macrovascular complications were not associated with diabetes-related distress. One explanation might be that people with diabetes experience cardiovascular problems as another disease (comorbidity) rather than as a diabetes-related complication, which therefore does not increase their level of diabetes-related distress [23].

The association between diabetes duration and diabetes-related distress was also explained by the use of oral blood glucose-lowering treatment, especially insulin. The latter finding is consistent with previous literature [9,10,21,24]. Patients on insulin treatment might benefit from additional support to decrease levels of distress.

The explained variance of diabetes-related distress by diabetes duration, age and gender was only 7.1%. The explained variance of the full model was still only 13.1%, suggesting that many other factors play a role. Psychological variables such as coping styles and perceived support may have a greater influence [24]. Experienced distress may be related to diabetes and its management, but non-diabetes-related stressors such as life stressors may contribute as well, as these might exacerbate diabetes-related difficulties [25]. Furthermore, Hessler et al. [26] showed that age was associated with distress, with younger people experiencing higher distress. Age interacts with several variables resulting in associations (for example between HbA1c levels and distress) being present in younger patients, but not in older patients [26]. Likewise, it could be thought that the association between diabetes duration and distress in the present study is more pronounced in younger people than in older people. Given the scope of our study, all our analyses were adjusted for age, but the association between duration and distress remained significant; however, we agree with Hessler et al. [26] that younger people with Type 2 diabetes are in a different stage of adult life and may have specific needs and health risks and that tailored support for these people is also needed.

Guidelines recommend healthcare providers to be alert to psychosocial problems such as diabetes-related distress and depression in all people with diabetes as part of the regular diabetes care [7]. Although low levels of diabetes-related distress are experienced in people with Type 2 diabetes in the Netherlands, this does not imply that extensive structural screening for distress is required in the total population of the people with Type 2 diabetes within primary care. We would suggest that healthcare providers remain aware of any diabetes-related distress in their patients with diabetes, but pay more structural attention to screening for diabetes-related distress in those people with microvascular complications or on insulin

treatment (independent of their diabetes duration). Being alert for distress is important because of the possible negative impact of distress on self-care [3], medication adherence [4] and glycaemic control [5]. This could be incorporated into patients' regular diabetes appointments. In the present study, we did not have data on the time of the occurrence of the complications or the time of the start of insulin treatment. Because diabetes-related distress is, 'an expected response to people's perceptions of health threats balanced against an appraisal of available coping resources which is mostly related to diabetes and its management', it is reasonable to assume that the risk of increased distress is the highest in the period after major events in the course of the illness (e.g. after diagnosis, after the occurrence of complications) or shortly after the start of a new treatment, when a patient cannot appraise accurately how he/she can cope with the new situation [25]. Longitudinal studies could provide further insight into whether distress is indeed highest directly after the occurrence of events in the course of illness.

The present study has several strengths. The data on participants of the three sub-studies of the Diacourse Study were combined, which resulted in a study population covering a broad range of people with Type 2 diabetes regarding diabetes duration, type of treatment and complications in the Netherlands.

The study has also several limitations. Because data from three different sub-samples were combined, differences in data collection between the samples might have influenced the results. Both self-reported and medical record-based data have advantages and disadvantages and, to the best of our knowledge, there is no consensus as to which one is more valid. For participants in the recent acute coronary event group it is likely that not all microvascular complications were reported in the files from the cardiologist, which might have resulted in the under-reporting of these complications; however, the impact of the different methods of data collection was minimal, as the sensitivity analysis showed. Examination of the (moderating) effect of method of data collection (self-reported vs. medical records) was necessary, because complications were self-reported in the short and longer diabetes duration groups and obtained from the medical records in the recent acute coronary event group. A moderating effect of method of data collection was found for microvascular complications, but this does not necessarily reflect the effect of method of data collection; it could reflect the fact that participants from the recent acute coronary event group differ in several other aspects from the short and longer diabetes duration groups. All participants in the recent acute coronary event group were recently hospitalized with this acute coronary event and participated in an individual intervention instead of group sessions. The discrepancy between the two data collection methods should be much smaller for insulin treatment, because people will know they are on insulin treatment and insulin treatment will be mentioned in the medical records. Logically, because we found the method of measurement for insulin treatment to be a moderator as well, it seems plausible that this was caused by other factors than method of data collection, most likely by other specific characteristics of the recent acute coronary event

group. As it is difficult to determine whether cardiovascular disease is a complication of diabetes or a comorbidity, we used cardiovascular disease as an indicator of macrovascular complications. Although physicians often consider cardiovascular disease as a complication of Type 2 diabetes, we have indications that people with diabetes experience it rather as another disease (comorbidity); therefore, it is possible that cardiovascular disease, whether or not a complication of the Type 2 diabetes, has minimal impact on diabetes-related distress. In addition, it should be noted that our findings may not necessarily be replicated in other countries with a different healthcare system, food culture and ethnic population.

To conclude, diabetes duration was associated with diabetes-related distress, with both a linear and quadratic association. These associations can largely be explained by the presence of diabetes-related microvascular complications and insulin treatment. Healthcare providers should focus on diabetes-related distress at different stages over the course of illness, especially in people with Type 2 diabetes and with microvascular complications or who need to start, or are already on, insulin treatment. It should be taken into account that, in addition to diabetes duration, complications and blood glucose-lowering treatment, many other factors are likely to have an impact on diabetes-related distress.

Acknowledgements

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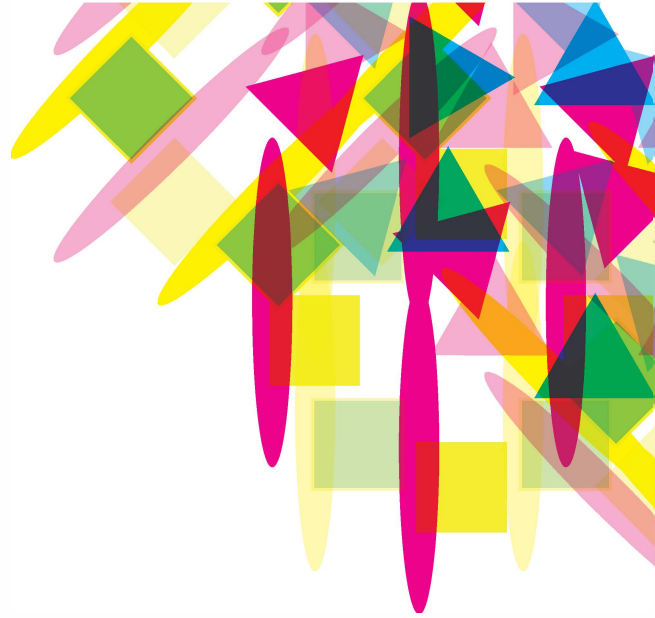
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Living with diabetes: a group-based self-management support programme for T2DM patients in the early phases of illness and their partners, study protocol of a randomised controlled trial.

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ABSTRACT

Background

The present article presents the protocol for a randomised controlled trial to test the effectiveness of a group-based self-management support programme for recently diagnosed type 2 diabetes mellitus (T2DM) patients (one to three years post-diagnosis) and their partners. The course aims to support T2DM patients and their partners in successfully integrating diabetes care into their daily lives and hereby enhance self-management and diabetes-specific health-related quality of life. The content of the course is based on the Common-Sense Model of Self-Regulation (CSM). Furthermore, principles from the Social Cognitive Theory (SCT) and social support theories are integrated.

Methods/Design

We aim to recruit 160 recently diagnosed T2DM patients and their partners from general practices in six different regions in the Netherlands. Patients need to be diagnosed with T2DM for one to three years and have to experience some degree of diabetes-related difficulties, as measured with a three-item screener. Participating patients and their partners are randomly allocated to the intervention or control condition. Participants in the intervention condition receive three monthly group sessions and a booster session three months later. Participants in the control condition receive a single information meeting. Data will be collected at baseline (T0), directly after the programme (T1) and six months post-programme (T2), including: self-management, diabetes-specific health-related quality of life, illness perceptions, attitudes, social support and empowerment. A three-level multilevel model will be used to compare change-scores between the conditions (intervention/control) on each outcome.

Discussion

Our study will be the first to determine whether a group-based support programme based on the CSM is effective in enhancing self-management and diabetes-specific health-related quality of life in recently diagnosed T2DM patients. The important role of patients' partners in effective diabetes care is also acknowledged in the study.

Trial registration

Netherlands National Trial Register (NTR) NTR3302.

BACKGROUND

The prevalence of type 2 diabetes mellitus (T2DM) is increasing to epidemic proportions. Worldwide, more than 300 million people are diagnosed with T2DM and this number is expected to increase with 50% over the next 20 years [1]. Although T2DM usually starts as a mild condition, its chronic and progressive nature, the necessity for considerable lifelong lifestyle changes and serious long-term complications can place a major burden on individuals and their families [2, 3], as well as health care systems [4].

Effective diabetes management by patients has been proven to reduce the chances of serious adverse events [5] and, consequently, maintain quality of life [6, 7] and keep health care costs manageable [8]. However, this does require patients to adopt a complex, multifaceted behavioural regimen, comprising the management of symptoms, treatment and lifestyle changes, as well as dealing with the psychological and psychosocial consequences related to the illness. Moreover, these behaviours need to be embedded within existing lifestyles, goals and priorities. Not surprisingly, a fair proportion of T2DM patients perceives the daily management of diabetes to be challenging or even burdensome and experiences difficulties in adequately engaging in self-care activities [9, 10], which might consequently impact on quality of life [7].

Recognition of the comprehensiveness of diabetes management has led to the development of many self-management support programmes [11, 12]. However, few have taken the specific challenges that may arise during the early phases of living with T2DM into account. Directly from the onset, T2DM patients are required to make lifestyle changes and adhere to treatment recommendations, mostly in the absence of diabetes-related symptoms or complaints. Hence, patients' motivation to engage in self-management should therefore primarily result from their beliefs on the likelihood of adverse events occurring, as well as beliefs on personal control and effectiveness of treatment in order to prevent these serious undesirable events [13]. However, according to a review by Thoolen et al., [14], recently diagnosed patients tend to downplay the seriousness of their own condition. In addition, patients seem to be primarily concerned with the day-to-day hassles in diabetes management, rather than the possibility of serious complications in the long term. These attitudes and perceptions are likely to contribute to the finding that relatively few patients appear to be adequately engaged in the recommended (changes in) lifestyle behaviours within the first year after diagnosis [14].

In the past decades, patients' perceptions on illness and treatment were identified to be important precursors for health behaviour change [15]. According to the Common-Sense Model of Self-Regulation (CSM) [16, 17], illness perceptions act as a framework for the coping strategies chosen by patients to deal with the illness and are closely related to behavioural adaption, physical recovery and psychological well-being in various chronic illnesses [18]. Moreover, previous studies have shown that illness perceptions and, consequently, health

related behaviours and outcomes can be successfully changed by short interventions based on CSM principles [19, 20, 21].

Accumulating evidence shows that not just the patients' illness perceptions, but also the perceptions of partners are of great importance for understanding how patients respond to a chronic illness [22]. Illness perceptions held by partners guide their coping responses to the patients' illness, including the way to give support to patients. Previous studies in T2DM have shown that social support can enhance as well as hinder self-management behaviours in patients, particularly dietary and exercise behaviours [22, 23]. A small number of studies even suggested that partners' illness perceptions can influence disease outcomes, with negative or incongruent perceptions being associated with worse physical, psychological and social functioning [24, 25]. Hence, even though patients themselves are primarily responsible for managing their illness, it seems important that partners are structurally involved in diabetes care.

Given the importance to intervene at an early stage in T2DM and the promising results of previous studies based on the CSM, we developed the 'Living with diabetes' course: a group-based self-management support programme specifically tailored to T2DM patients and their partners in the first years of living with diabetes. With this new course, we aim to support both patients and partners in successfully integrating diabetes (care) into their daily lives and, hereby, enhancing self-management and diabetes-specific health-related quality of life in T2DM patients. Psychological and social aspects, including perceptions and attitudes, empowerment and social support, are integrated in the course because of their known important role in behaviour change [26] (Figure 1). A more detailed description of the content and underlying theories of the course can be found elsewhere (van Puffelen et al., 2013 submitted).
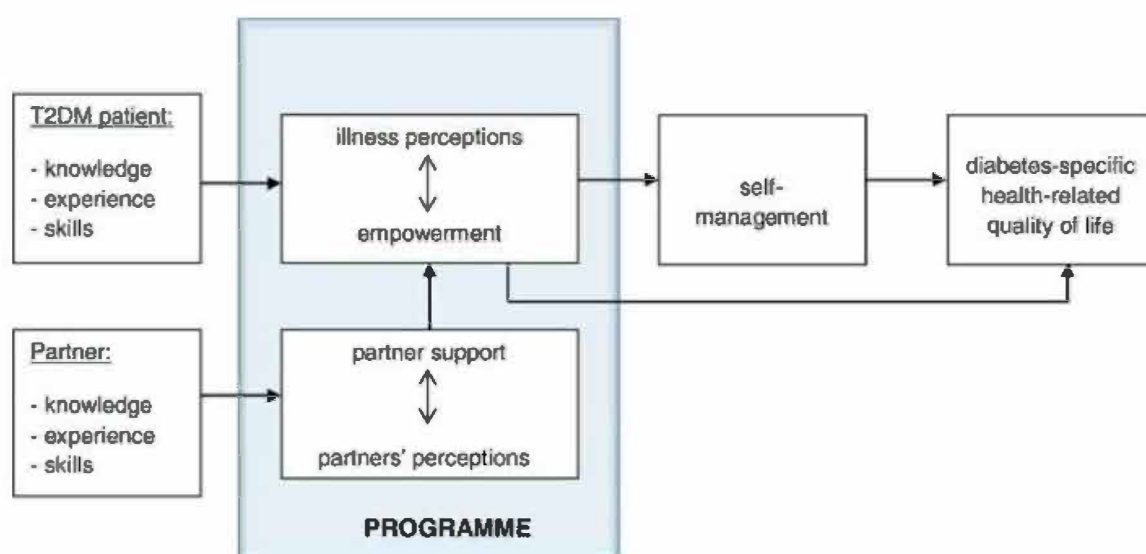
Figure 1 Theoretical model of the programme.

Aims and hypotheses

The primary aim of this study is to test the effectiveness of the 'Living with diabetes' course on enhancing self-management behaviours and diabetes-specific health-related quality of life in T2DM patients (one to three years post- diagnosis), compared to an attention control condition.

It is hypothesised that participation of T2DM patients in the group-based self-management support programme will result in:

a) Enhanced self-management and diabetes-specific health-related quality of life directly after the programme and at six months post-programme, as compared to an attention control condition.

Furthermore, we hypothesise that participation in the group-based self-management support programme will result in patients:

b) Holding more adaptive illness perceptions and attitudes towards T2DM;
c) Experiencing more activating partner support;
d) Feeling more empowered to manage their condition

Directly after the programme and at six months post-programme, as compared to an attention control condition.

METHODS/DESIGN

Study design

The effectiveness of the programme will be evaluated by a randomised controlled trial with two follow-up measurements: immediately after the programme (T1) and six months after T1 (T2) (Figure 2).

Study population

Patients will be recruited via general practitioners (GPs) who are willing to invite eligible patients to participate in the study. In the Netherlands, all inhabitants are registered in a general practice. Therefore, a representative sample can be drawn.

Inclusion criteria
Being diagnosed with T2DM for one to three years, as recorded by their GP.

Exclusion criteria
•   Not being able to speak, read and/or understand the Dutch language sufficiently according to their GP;
•   Having insufficient mental or intellectual capabilities to participate in the study, according to their GP;

- Currently receiving treatment for severe psychological or psychiatric conditions, according to their GP;
- Recently diagnosed with a severe or life-threatening comorbid condition (e.g. cancer, CVA);
- Not experiencing any degree of diabetes-related difficulty or uncertainty, as assessed with a three-item screening questionnaire.
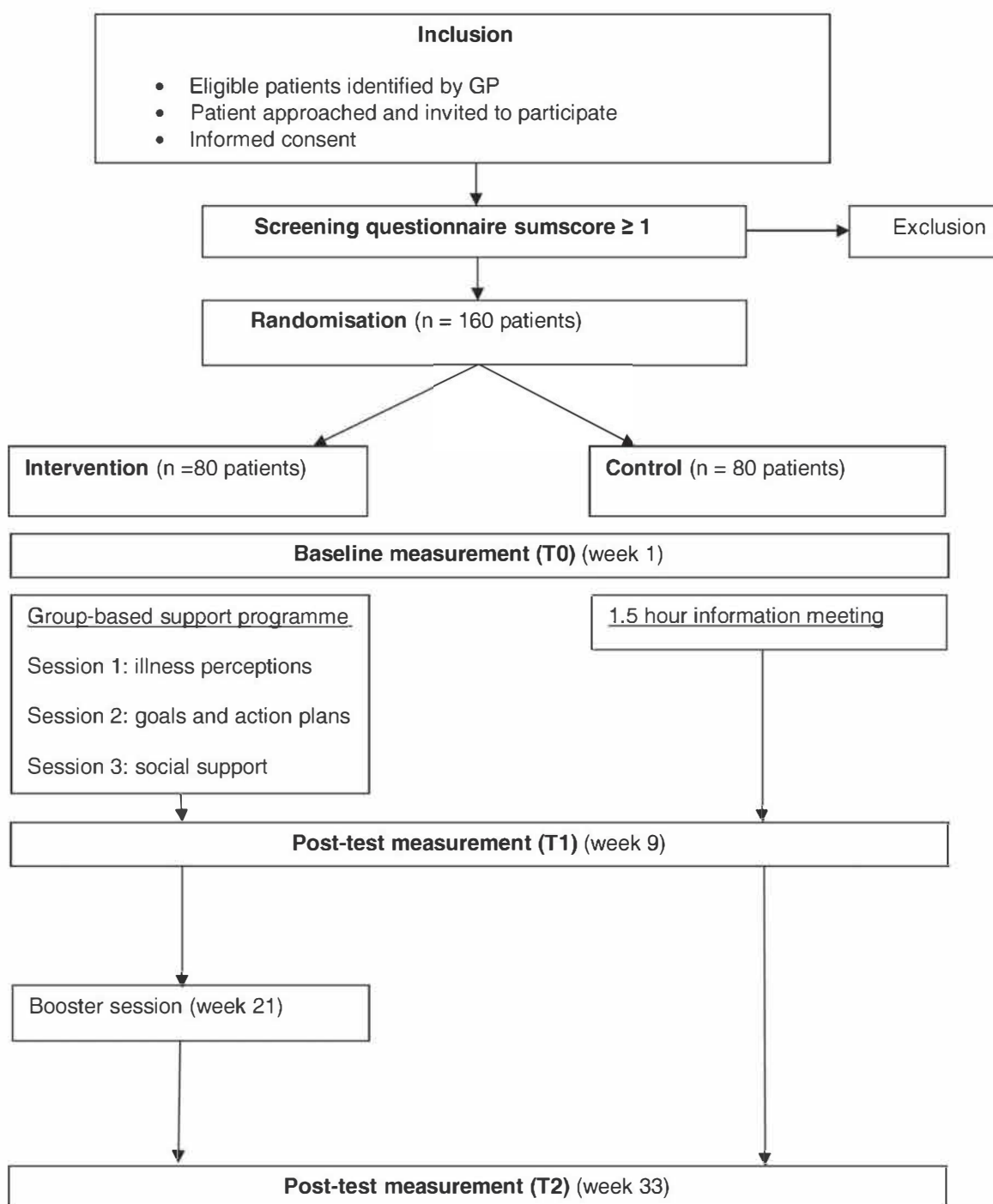
Figure 2 Flow of participants

Recruitment

The study population will be recruited from participating general practices in different regions in the Netherlands (North, West, Southwest and center). Eligible patients are selected from the medical records of the participating general practices and receive a written invitation for participation via their GP. Patients fill in an informed consent form as well as a short screening questionnaire, developed to identify patients who experience at least some degree of difficulty or challenge regarding their T2DM self-management. The questionnaire includes two questions of the Appraisal of Diabetes Scale (ADS) [27] and one statement of the Revised Illness Perception Questionnaire (IPQ-R) [28], assessing diabetes-related uncertainty, coping with diabetes and perceived consequences of diabetes on life. Patients with a total sum score of zero, indicating that they do not experience any difficulties or challenges regarding their diabetes management, are excluded from the study (see Table 1).

Table 1 Screening questionnaire

1. How much uncertainty do you currently experience in your life as a result of being diabetic?				
None at all (0)	Slight amount (1)	Moderate amount (1)	Large amount (1)	Extremely large amount (1)
2. How effective are you in coping with your diabetes?				
Not at all (1)	Slightly effective (1)	Moderately effective (1)	Very effective (0)	Extremely effective (0)
3. My diabetes has major consequences on my life.				
Strongly disagree (0)	Disagree (1)	Neither agree not disagree (1)	Agree (1)	Strongly agree (1)

Allocation to conditions

After obtaining the signed informed consent form, patients will be randomly allocated to the intervention or control condition. Randomisation will be conducted electronically by a researcher who is not involved in the study.

Intervention

Participants allocated to the intervention group are invited to take part in the group-based self-management support programme, together with their partner. Patients who do not have a partner, are instructed to bring a close friend or relative instead. Each course group consists of six to ten patients, accompanied by their partner (or close friend/relative). The course consists of three two-hour monthly meetings and one follow-up meeting ('booster session') after three months. The group sessions are led by two trained diabetes nurses or practice nurses and are delivered in medical and community centers in the different regions.

Framework

The 'Living with diabetes' course is based on the Common-sense Model of Self-Regulation [16, 17], the Social Cognitive Theory [29, 30] and principles of social support theories [31, 32, 33]. Content of the course is derived from previous psychosocial interventions focusing on illness perceptions [19, 20, 34]. The emphasis of the course is on stimulating beneficial illness perceptions and challenging misconceptions of T2DM in patients and partners. Another important aspect of the course is the enhancement of activating partner support for patients, by exploring patients' needs for support and discussing supportive interactions with patients and partners. Goal setting and action plan development are used as techniques to improve patients' empowerment and elicit self-management behaviour change. All sessions are group-based, providing the opportunity for peer modeling, social reinforcement, motivation and emotional support.

Materials

Participants receive a handbook with (homework) assignments, and practical and theoretical information about the topics discussed during the sessions. In addition, basic information about diabetes and its treatment is provided in the handbook. For the diabetes or practice nurses who guide the course sessions, a detailed manual has been developed.

Pilot

The course was pilot-tested on feasibility and acceptability in November and December 2011. Sixteen T2DM patients and eight partners from a general practice in the region of Utrecht participated in the pilot-study (attrition rate 21.6%). During the pilot, all course sessions were led by a health psychologist in order to evaluate whether the correct psychological models and techniques were used. During the first session, a practice nurse was also present to provide medical information on T2DM. Feasibility and acceptability of the course were explored by means of an evaluation form at the end of the course and by feedback of the participants during the course sessions. Based on the evaluation of the pilot, the manual was adapted and a screening questionnaire was developed for the RCT to ensure that only T2DM patients who experience some degree of difficulties or uncertainties will participate.

Training

Prior to the course, the participating nurses receive a four-hour training, led by a health psychologist who was also involved in the development of the course (MH). During this training, the nurses receive information on the underlying theories on which the course is based. Furthermore, the nurses are instructed on how to use the workbook and manual of the course. Assignments of the course are explained in detail and tips and tricks on how to execute these assignments provided. Lastly, first experiences of the pilot and resulting important topics of interest are discussed.

Attention control condition

Participants in the attention control condition are invited to a single 1.5 – hour information meeting, together with their partner (or close friend/relative). During this meeting, patients and their partners receive medical information about diabetes (e.g. causes, complications, treatment) from a professor in general practice and diabetes care. The information meeting serves as an attention control condition to control for the attention paid to being diagnosed with T2DM when participating in this study. Hence, the information that patients and partners receive during the information meeting is provided according to the classical didactic method; i.e. providing information that is important from a medical point of view, but not tailored to the specific and more comprehensive needs of the patients.

Measures

Patients fill in a questionnaire at baseline (T0), immediately after the programme (T1) and six months post-programme (T2) to assess the effectiveness of the programme on the longer term. The primary outcome measures are self-management and diabetes-specific health-related quality of life. Secondary outcomes are illness perceptions, attitudes towards diabetes, partner support and empowerment.

Primary outcome measures

Self-management is measured by using the revised Summary of Diabetes Self-Care Activities measure (SDSCA) [35]. The revised SDSCA contains 11 items, measuring six separate domains: general diet (2 items), specific diet (2 items), exercise behaviours (2 items), glucose monitoring (2 items), foot care (2 items) and smoking (1 item). Ten items are rated on an eight-point Likert scale, measuring the number of days a certain self-care behaviour is performed during the last week (0–7 days). The 11th item measures smoking (yes/no) and the number of cigarettes smoked. Each of the domains is measured separately. The revised SDSCA shows an adequate internal consistency and test-retest reliability and is sensitive to change. The measure has been validated against other measures of diet and exercise [35].

Diabetes-specific health-related quality of life is assessed by the Problem Areas in Diabetes scale (PAID) [36], measuring diabetes-related emotional distress. The PAID consists of 20 items on a five -point Likert scale, ranging from 0 (not a problem) to 4 (a serious problem). Scores are transformed into a 0–100 scale for interpretation, with higher scores indicating greater diabetes-related emotional distress. The PAID has a strong concurrent and discriminant validity [37], has been proven to be responsive to change [38] and has been validated for Dutch T2DM patients [36, 37].

Secondary outcome measures

Cognitive and emotional illness perceptions are assessed with the IPQ-R [28]. The first section of the IPQ-R measures different symptoms experienced by patients and whether they

believe these symptoms are caused by their diabetes (identity scale; 14 items). The second section of the IPQ-R consists of seven subscales, measuring 'time-line acute/chronic' (6 items); 'time-line cyclical' (4 items); 'consequences' (6 items); 'personal control' (6 items); 'treatment control' (5 items); 'coherence' (understanding of T2DM, 5 items) and 'emotional representation' (6 items). In the third section, patients' causal believes (18 items) are measured. The 'identity scale' is measured dichotomously (yes/no). All other items are measured on a five-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). The subscales of the IPQ-R have a good internal consistency and an acceptable test-retest stability [28].

Attitudes towards diabetes are measured with the Diabetes Attitude Scale (DAS-3) [39]. The DAS-3 consists of five subscales, measuring perceived seriousness (7 items); psychosocial impact (6 items); patient autonomy (8 items); value of tight control (7 items) and need for special training (5 items). The items are measured on a five-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). The DAS-3 is considered a reliable and valid general measure of diabetes-related attitudes across different groups of patients and health care professionals [39].

Patients' perceptions of partner support are assessed by using a questionnaire developed by Buunk, Sanderman, and Nieuwland [40], which measures three different dimensions of partner support; active engagement (5 items); protective buffering (8 items) and overprotection (6 items). The items are measured on a five-point Likert scale ranging from 1 (never) to 5 (always). The three subscales have a moderate to good internal consistency [40].

Patient empowerment is assessed by the Dutch Diabetes Empowerment Scale (Dutch DES-20) [41]. The questionnaire consists of five subscales, assessing dissatisfaction and goal achievement (6 items), coping and motivation (4 items), obtaining support (3 items), overcoming barriers (4 items) and determining suitable methods (3 items) in a five-point Likert scale, ranging from 1 (totally disagree) to 5 (totally agree). The Dutch DES-20 was found to be a reliable and valid instrument [41].

Sample size

The sample size calculation is based on detecting a clinically relevant change on the PAID, as a result of the programme. Since there is no consensus on the minimal important difference (MID) on the PAID, we decided to set the MID at half a standard deviation (SD); a commonly used solution when scores have no direct interpretation and no clinical results exist to determine a relevant percentage [42]. In Dutch T2DM patients, the SD found on the PAID was 20, with a mean score of 22.5 points (scale 0–100) [36]. To establish a 10-point difference with the power set at 80% and the α at .05 (two-sided), 63 patients are needed in each condition (intervention/control). However, taking the clustering of patients within groups into account, an oversampling of 15% is needed to conduct multi-level analyses. When accounting for an additional drop-out of 10%, 2×80 patients will have to be recruited.

Statistical analysis

The study is a two-arm randomised controlled trial with repeated measures over time and continuous outcome variables. Descriptive statistics (mean values and frequencies) will be calculated to evaluate the scores on primary and secondary outcome measures on T0, T1 and T2 separately. The effectiveness of the programme will be analysed by a three-level multilevel model: groups, patients and measurements (T0, T1, and T2). This type of analysis allows us to both test the main effectiveness of the condition, its effectiveness over time, as well as the interaction effects of condition (intervention/control) × time. By including groups as a separate level in the analysis, possible effects of the different regions, course leaders and group climate are corrected for. Data will be analysed according to the intention-to-treat principle. All analyses will be performed using MLwiN.

Ethical approval

The protocol, information letters and informed consent form of the study were approved by the Medical Ethical Committee of the VU University Medical Center Amsterdam.

DISCUSSION

This article describes the design of the 'Living with diabetes' study: a study testing the effectiveness of a group-based self-management support programme for people known to be diagnosed with T2DM for one to three years and their partners. The content of the course is based on principles of the CSM, SCT and social supportive theories and is specifically designed to build more adaptive (activating) illness perceptions and attitudes, increase empowerment, stimulate activating social support and, consequently, enhance self-management and diabetes specific health-related quality of life in recently diagnosed T2DM patients.

Previous research already emphasised the importance of the integration of patients' and partners' illness perceptions in self-management interventions, because of their ability to change and their close link to health behaviours and outcomes [15, 19, 20, 21]. With this study, we will contribute to the literature by providing insight into the effectiveness of a group-based method to build and alter illness perceptions in patients with chronic illness, rather than an individual programme. Furthermore, to our knowledge, we are the first to conduct such programme in T2DM patients and partners in the first years of living with T2DM.

A particular strength of the study is that the programme 'Living with diabetes' is well grounded in theory. Major psychological models on behaviour change, such as Leventhal's Common Sense Model [16, 17] and Bandura's Social Cognitive Theory [29, 30] provide the framework for the course. By incorporating social support theories and actively involving the patients' partners, we account for the influence of social support on self-management behaviours in patients. Group discussions provide patients with the opportunity to share experi-

ences and learn from others through peer modelling and peer support [43]. Consequently, the course goes beyond the mere provision of information and skills training and starts explicitly from both patients' and partners' experiences, needs and concerns. In addition, this study specifically focusses on patient important outcomes rather than solely medical outcomes (e.g. HbA1c), comprising emotional, cognitive and behavioural outcomes.

The current study also poses a number of challenges and drawbacks. We foresee a few potential threats to reliability and generalisability of the study. First, a selection of participating patients in the study is expected, as a result of a selective non-response of patients of older age and patients from the non-western origin. Consequently, specific target groups might be missed and generalisability of the results of this study limited. Furthermore, a possible selection bias might also be found among the GPs in the study. Participating GPs will probably represent a group more open to research and innovation and may also be more motivated to improve diabetes care. Consequently, their patients might already receive various educational or support programmes which may negatively impact on participation willingness. In order to keep non-response and drop-out rates as low as possible, personalised invitation letters from GPs and reminders to initial non-responders will be sent. Furthermore, the course sessions and information meetings will be organised in easily accessible locations in the area of the participating patients and GPs. Finally, a practical challenge is also foreseen in the group-based format of the course. In spite of the fact that group-based sessions pose many advantages, they are more difficult to organise and cannot be completely adapted to individuals needs and preferences (e.g. time, location, topics discussed), which may result in increased (selective) drop-out. Furthermore, we emphasise the importance of creating and keeping a positive and stimulating group climate during the course sessions. Dominant and/ or negative group members can negatively influence the group climate and interactions, and consequently, the effectiveness of the programme. Therefore, we will recruit diabetes nurses and practice nurses who already have experience in leading group-based courses and extra attention will be paid on how to deal with dominant group members during the training.

The results of this RCT will provide valuable information on the effectiveness and feasibility of group-based self-management support programmes, focusing on illness perceptions and social support. The course is well suited for implementation in a primary health care setting. The course is fully manualised and supported by a training to ensure the possibility of replication. Furthermore, the group-based setting of the course is less time and money consuming than individual support programmes. Hence, if proven effective, the course can be utilised by general practices and diabetes care groups as an addition to the individual patient education provided by health care professionals and already available patient education programmes in T2DM. First results of the study are expected in the spring of 2014.

Acknowledgements

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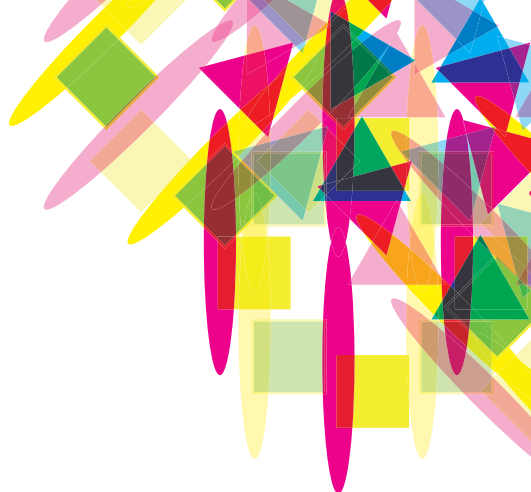
6

Improving self-management of people with type 2 diabetes in the first years after diagnosis: development and pilot of a theory-based interactive group intervention.

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ABSTRACT

Objectives

To describe how principles of self-regulation and social support could be integrated in a group intervention to improve self-management of people with type 2 diabetes mellitus in the early phase of illness and to pilot its suitability in a primary care setting.

Methods

Principles of the Common-Sense Model of Self-Regulation, Social Cognitive Theory of Self-Regulation and social support theories were integrated in the intervention. Based on this, a three-session group course was developed to challenge illness perceptions of participants that discourage adequate self-management, to practice goal-setting and behavioural actions and to create a supportive environment. The intervention was piloted with persons with early-stage (1–3 years post diagnosis) type 2 diabetes mellitus selected in general practice in the Netherlands. Data about the suitability of the intervention were retrieved by means of observation and audio-recording of the sessions, an evaluation form filled in by the participants and an evaluation meeting with the group leaders.

Results

In total, 16 type 2 diabetes mellitus patients participated in the pilot, who were divided into a group of single participants (N = 8) and a group (N = 8) who participated with their partner. Discrepancies between perceptions of one's own condition and type 2 diabetes mellitus in general were observed. Goal-setting and developing action plans appeared to be difficult tasks for many participants, whereas others felt these exercises were not useful as they did not feel a need to make changes in living with diabetes. The group-based format was appreciated as was the participation of partners.

Conclusion

Challenging the illness perceptions of persons with early-stage type 2 diabetes mellitus by a brief interactive group course is feasible and important, as many of these people tend to underestimate the seriousness of their diabetes. However, motivating persons with early-stage type 2 diabetes mellitus to participate in self-management interventions remains a challenge. Offering the intervention as an integral part of type 2 diabetes mellitus management in primary care is desirable.

INTRODUCTION

Over the past decades, many interventions have been developed to support people with type 2 diabetes mellitus (T2DM) in the important, yet challenging task of managing their condition. Reviews on the effectiveness of these self-management interventions have demonstrated positive but predominantly modest and short-term effects on behavioural and psychological outcomes [1–4]. Effectiveness of self-management interventions may increase when the provided support is tailored to the specific needs and challenges that arise in the different phases of living with T2DM. The Dutch Diabetes Foundation therefore funded the Diacourse study, which aimed to develop and test three interventions to support self-management and improve the quality of life of people with T2DM belonging to three different target groups: (1) persons with a diabetes duration of 1–3 years, (2) persons with a diabetes duration of more than 3 years and (3) persons with T2DM who have recently been confronted with an acute coronary event (see Van Puffelen et al.,[5] De Vries et al.[6] and Kasteleyn et al.[7] for the study protocols). The Diacourse study was approved by the Medical Ethical Committee of the VU University Medical Center Amsterdam.

This article describes the development and pilot of the self-management intervention targeting the first group: people with T2DM who are in an early phase of living with diabetes. Our research questions are as follows:

1. Which theoretical principles of self-regulation and social support are relevant for improving self-management of persons with T2DM in the early phase of illness, and how can these principles be integrated in a group intervention?
2. How suitable is the developed intervention for persons with early-stage T2DM managed by general practitioners in primary care?

Relevant theoretical principles

The Common-Sense Model (CSM) of Self-Regulation [8,9] posits that people have cognitive and emotional perceptions of a health threat, which act as a framework for their actions to respond to the threat. With regard to T2DM, its perceived seriousness and controllability are considered most influential to guide self-management: perceived control, either by one's own behaviour or by medical treatment, predicts a more or less healthy lifestyle, whereas the perceived seriousness and impact of the illness relate to people's emotional responses [10,11]. Many people with T2DM do not experience diabetes-related symptoms or complications during the first years after diagnosis. This could lead to underestimation of the seriousness of T2DM and, consequently, of the necessity to engage in self-management directly from diagnosis [12]. As the intention to behavioural change starts with creating awareness of the need to take action [13] we chose illness perceptions as the central concept to intervene on in this target population of people with early-stage T2DM.

Other interventions to support self-management of T2DM − not specifically targeting persons in the early phase of illness − have focused on self-efficacy [14]. Self-efficacy is a central concept of the Social Cognitive Theory (SCT) of Self-Regulation [15,16] and has been proven an important determinant of T2DM self-management [14,17]. Based on this theory, it could be expected that individuals with T2DM engage in self-management if they believe that (1) adequate self-management will result in outcomes that are beneficial to them and (2) they are able to self-manage their condition successfully. In addition, goal-setting – and its link with self-efficacy – is believed to be an important source of motivation for behavioural change in the SCT. Having individuals setting realistic, manageable and proactive goals in a stepwise manner can increase motivation for health behaviours, in addition to individuals' perceived self-efficacy to achieve these required and/or desired changes. Therefore, we integrated goal-setting and action plan development in our intervention, in addition to exploring and challenging personal illness perceptions.

Finally, we integrated insights from social support theories [18,19] in the intervention, as a person's close others could play an important role in overcoming barriers in maintaining a healthy lifestyle and provide support in coping with T2DM [20–22].

Description of the intervention

Considering that many people we aimed to reach with the intervention would not experience severe symptoms or activity limitations as a consequence of T2DM, and as we did not want to discourage these people or make them think they did not belong to the target population, we developed an intervention that was easily accessible, brief, interactive and course-like. This interactive group course consisted of three 2-h monthly sessions and a booster session 3 months after the last session. Group size was set at 5–10 persons with T2DM. Participants were encouraged to bring their partner (or a close friend or relative), but this was not required. The sessions were designed to be guided by two course leaders. Diabetes or practice nurses who participated in a 4-h training prior to the start of the intervention were eligible to lead the sessions. To guide the sessions, we developed a manual for the course leaders and a workbook for the participants, including assignments and practical and theoretical information about the topics discussed during the sessions. Box 1 provides an outline of the course sessions.

Description of the course sessions

Session 1 focuses on participants' (and partners') illness perceptions. The aim of the session is to create awareness of own personal beliefs of T2DM and how these influence coping with the illness in daily life. Participants are asked to share their perceptions of the seriousness of their (partners') diabetes, feelings of control, worries and concerns and perceived consequences of the illness on their lives. Maladaptive perceptions are challenged and adaptive perceptions strengthened through the provision of (medical) information and positive practical examples from other participants. The group discussion aims to focus on the seriousness of T2DM and

its controllability by one's own actions and medical treatment. As a homework assignment, participants are asked to keep a record of the difficulties and challenges they encounter in living with diabetes during the following month. Participants are asked to indicate (1) which aspects or situations in living with diabetes they perceive to be challenging, (2) when these situations occur and (3) how they usually react to these situations as a preparation for the second session.

Box 1 Outline of the course sessions

	Aim	Methodology
Session 1		
Illness perceptions/ attitudes towards diabetes and self-management	Creating awareness of differences in illness perceptions and their link with behaviours.	Group discussion of participants' different perceptions on the seriousness, controllability and consequences of diabetes, mediated by the course leaders.
	Increasing positive outcome expectancies of diabetes self-management and treatment by confirming perceptions of seriousness and controllability.	Challenging maladaptive perceptions in the group through the provision of medical information about diabetes and its treatment.
Session 2		
Self-efficacy/ empowerment	Increasing self-efficacy beliefs and empowerment through working on feasible and specific goals for behaviour change.	Group discussion of the homework assignment on diabetes-related challenges. Development of personal diabetes-related goals and action plans to overcome these challenges, guided by the course leaders.
Session 3		
Social support	Creating awareness of (un)helpful ways of support and the possible gap between wanted and received support.	Group discussion on achievements and challenges encountered in the pursuit of personal goals and action plans. Group discussion on partner support that is perceived helpful and whether received support is in line with or deviates from what is perceived helpful, mediated by the course leaders.
	Overcoming barriers in behaviour change by (asking) support from others.	Integrating help or support from others to overcome the experienced barriers in goal and action plan attainment, guided by the course leaders.
Booster session	Providing a reminder of the techniques learned during the course.	Group discussion on the experiences on achieving the personal goals/actions specified in the action plans and on the questions or challenges that have arisen during the past 3 months, mediated by the course leaders.

In session 2, goals and action plans are developed and discussed. The aim of the session is to support the participants in setting realistic, short-term goals and using stepwise plans to reach these goals. At the start of the session, the homework assignment on the encountered challenges is discussed and used as input to discuss the relationship between thoughts, feelings and behaviours. It is also used as a starting point for participants to set their own goals for

the short term and develop action plans on how to achieve them. Participants are encouraged to set a goal that they consider personally important and feel capable of achieving within the timeframe of the course. Long-term goals are translated into short-term intermediate goals and action plans, using principles of implementation intentions: (1) What do you plan to do? (2) How much or how often do you plan to do this? and (3) When exactly will you do this? At the end of the session, the participants are instructed to implement their action plan for the next month.

Session 3 focuses on discussing ways to ask for support and (un)helpful supportive interactions. Special attention is given to providing and receiving helpful and desired support from one's close environment. At the start of the session, participants are asked to share whether they had achieved the goals of their action plan (formulated in session 2) and the helping and hindering factors they experienced. Next, (un) helpful and (un)desired ways of providing and receiving social support are discussed: which types of support do people with T2DM receive and is this in line with what they want/need. Furthermore, the role of the partner in overcoming barriers to achieve future goals is explored. Finally, participants are asked to develop a new action plan for the next 3 months, including their partners' support to overcome potential barriers.

During the booster session, the course leaders and participants evaluate the course and discuss the (non)achievement of the goals set during the third course session. Questions and needs that have arisen during the 3 months since the third session are also being discussed.

PILOT OF THE INTERVENTION

To examine the suitability of the intervention for persons with early-stage T2DM (research question 2), we piloted three sessions guided by the following questions:

2.1 How many persons with early-stage T2DM registered in general practice are willing to participate in the intervention?

2.2 How are the format and content of each of the sessions evaluated by the participants and group leader(s)?

2.3 Do participants consider the intervention useful, irrespective of whether or not they experience diabetes complications?

2.4 How does the participation of partners (or close others) influence the sessions?

Methods

Setting and selection of participants
Potential participants were selected by a practice nurse from a general practice in the Netherlands. Inclusion criteria were (1) a diagnosis of T2DM and (2) an illness duration between

1 and 3 years after diagnosis of T2DM. Exclusion criteria were (1) unable to speak or understand the Dutch language, (2) cognitively unable to participate and (3) receiving treatment for severe psychological or psychiatric problems. Eligible persons received a written invitation to participate; those who decided to participate gave informed consent. Sociodemographic and illness- related characteristics from the selected patients were retrieved from the general practice's medical records.

Delivery of the intervention

Although the intervention was designed to be guided by trained nurses, we wanted a health psychologist to guide the sessions during the pilot, to ensure that psychological principles could be evaluated properly. During the first session, a practice nurse was also present to respond to questions about T2DM and its treatment. As the pilot would take too long when organising the sessions monthly, they were organised fortnightly. Given the purpose of the pilot and the questions we wanted to answer, we felt this approach was acceptable.

Data collection and analyses

To examine how many persons with early-stage T2DM are willing to participate in the intervention (2.1), we counted the number of invited persons who gave informed consent, and we tested for differences between the participants and non-participants in gender and age distribution, diabetes treatment and presence of diabetes complications.

To examine how the format and content of the sessions are evaluated by the participants and group leader(s) (2.2), whether the participants consider the intervention to be useful (2.3) and how the participation of partners, or close others, influences the sessions (2.4), data were collected by the following:

- Observation and audio-recording of the sessions. A researcher was present during all sessions and took notes. Each session was audio-recorded and each recording was listened to by two researchers.
- Debriefing of all sessions with the health psychologist guiding the sessions, and an oral review after the intervention with the practice nurse involved in recruitment of the participants and the first session.
- An evaluation form filled in by participants with T2DM after the third session. The evaluation form addressed the following aspects of the intervention: appreciation of the format and content of the intervention, perceived usefulness of the intervention, intention to make changes related to T2DM self-management, overall grade and recommendation of the course to others.

The notes that were made by the researchers during the course sessions, after listening to the audio-recordings and debriefing with the health psychologist and the oral review with the practice nurse, were discussed within the core research team during biweekly meetings. Observations and experiences of the researchers involved were exchanged and discussed, in

order to reach consensus on the interpretation of the qualitative data from various resources. Data collected by the written evaluation forms were analysed by descriptive quantitative analyses; additional written comments were added to the researchers' notes and discussed during the meetings of the core research team.

Results

Willingness to participate

Of the 74 eligible people with T2DM who received a written invitation, 16 agreed to participate (22%). Reported reasons for non-participation were not being interested (n = 25), not being able to attend the sessions (n = 12), not having a partner to attend the sessions with (n = 5) and being satisfied with usual care provided by diabetes care professionals (n = 3). Table 1 shows the demographic and diabetes-related characteristics of the participants with T2DM. No significant differences (p < .05) were found between participants and non-participants in age, gender, marital status, type of diabetes treatment and the presence of diabetes complications.

The 16 participants were divided into two groups: one group (n = 8) participating with their partner and one group (n = 8) attending the sessions alone. Participants in this latter group indicated that they did not have a partner or close other to bring with or reported that their partner was not willing or unable to attend the sessions.

Table 1 Sociodemographic and diabetes-related characteristics of persons with T2DM participating in the pilot (N = 16).

Characteristic	n	%	Mean	SD
Age, in years			68.0	8.4
Gender: male	8	50		
Married or cohabiting	10	63		
Diabetes duration, in years			2.0	0.9
Diabetes treatment:				
Lifestyle advice only	7	44		
Oral hypoglycaemics	9	56		
Insulin	0	0		
Diabetes complications: present	2	13		

Evaluation of the format and content of the sessions

Of the 16 participants, 13 with T2DM returned the evaluation form. Also, two partners filled in the form. Since these persons with T2DM and partners provided similar feedback, their data were combined for analysis (N = 15).

Based on our observations, the group-based setting seemed to work well in terms of sharing experiences and discussion. Participants interacted constructively and showed much inter-

est in how others experienced living with diabetes. In the group with persons with T2DM and partners − which was obviously twice the size of the other group − participants had the tendency to start talking in smaller subgroups, which was considered disruptive at times and made it more difficult for the course leader to guide the discussion. The majority of the responding participants were happy with the frequency, duration and time of the sessions. Three respondents felt that the number of sessions was too high, while two others preferred more sessions.

The first session was rated as (very) useful by nine respondents; five rated this session as fairly useful and one as not useful. One person described that hearing how others think about and deal with their diabetes was very useful. Similar comments were made by others. A notable observation was that persons with T2DM attending this session perceived T2DM to be a serious disease, but considered their own condition as less serious. Moreover, although participants generally stated they considered T2DM to be a (very) controllable condition, several barriers and challenges in managing their diabetes were expressed.

The second session was rated as (very) useful by seven respondents; two rated this session as fairly useful, five as not useful and one did not answer the question. During this session, it was observed that setting relevant goals and developing realistic and specific action plans were rather difficult tasks. For instance, all participants set goals to improve their eating habits or exercising, while stating at the same time that there was not much room for improvement in these domains. Moreover, these goals were not in accordance with the difficulties they reported in managing their diabetes, which were predominantly in the psychological domain of coping with the illness. The accompanying action plans were often not specific enough (e.g. 'My plan for next week is to be more physically active'). One-third of the respondents on the evaluation form rated action planning as not useful for them. Some explained their answer by stating that they did not experience difficulties in managing their diabetes and therefore did not need an action plan. Others felt that they were able to make thedesired changes without the use of action plans.

Of the 15 respondents on the evaluation form, 8 rated the third session as (very) useful, 6 as fairly useful and 1 as not useful. According to participants' verbal feedback after the session, this last session was appreciated by most participants with T2DM as well as partners. The focus of this session was on being supported by one's significant others in dealing with T2DM. One person attending the group without a partner or significant other commented that after all, you are still the one who has to deal with the illness. In the group of persons participating with their partner, none of the participants with T2DM reported insufficient or unhelpful partner support. However, it was noticed that one couple did not agree on the support provided by the partner, but decided not to share this with the group.

Overall evaluation of the intervention

Respondents evaluated the total course, on a scale from 1 to 10, on average with 7.4 (range: 6–10). Nine respondents indicated to probably or definitely apply the information and skills learned during the course in the near future. Seven participants reported that they had already made changes in their personal lives thanks to the course. In alignment with the intentions expressed, these changes were predominantly related to healthy eating, exercise and weight control.

Nine respondents would probably or definitely recommend the course to other people with T2DM, because you always may learn something new. One person, however, would recommend the course only to people with T2DM in a more advanced stage of the illness. Some persons who were not certain whether they would recommend the course to others expressed doubts about the usefulness of the course in the absence of experiencing problems in living with diabetes. The comment of another hesitating person that the success of the course depends too much on the motivation of other participants may point into the same direction.

Influence of partners on the sessions

We observed that all partners who attended the sessions worked together with their partner with T2DM on the assignments and actively participated in the plenary discussions. However, it also came to fore that the presence of partners may have its influence on the extent to which people with T2DM feel the ability to freely discuss (un)helpful ways of partner support.

DISCUSSION

In this article, we described relevant theoretical principles of self-regulation and social support for developing self-management interventions for persons with early-stage T2DM and assessed the suitability of a group-based interactive course based on these principles.

Relevance of theoretical principles

Our decision to focus on illness perceptions as the central theoretical concept to activate people with early-stage T2DM for self-management appears to be supported by the experiences of participants and course leaders and our observations during the pilot. It was noticed that many participants with T2DM in our pilot considered their own condition to be less serious than T2DM in general, which could be due to the fact that most did not experience any diabetes-related symptoms or complications yet. Challenging people's illness perceptions is therefore of utmost importance, since the patient activation starts with a firm belief in one's own role and need to take action [13,23]. Without this belief, as shown during the pilot, people will not be motivated to set personal goals for behavioural change and make concrete action plans accordingly.

Self-efficacy is widely known to be an important determinant of diabetes self-management [14,17]. However, whether a brief group intervention is suitable for all persons with T2DM to improve their self-efficacy of T2DM self-management is less clear. During the pilot and its evaluation, many participants indicated to have made some improvements in their lifestyle and self-care behaviours, which were in line with the action plans they had developed. Notwithstanding that, we also observed during the second and third sessions that setting relevant and concrete goals and developing corresponding action plans were rather difficult for many participants. Moreover, they indicated during the evaluation that they encountered many barriers in achieving their goals and plans. Based on these experiences, we believe that goal-setting and action planning only makes sense if patients are convinced that they need to alter certain aspects of their lifestyle or health behaviours and that these activities need to be exercised, stimulated and continuously monitored over time. Hence, introducing goal-setting and action planning to patients as part of a brief group intervention may be useful, if follow-up is ensured by integration in T2DM management.

Finally, the importance of partners in the daily self-management of T2DM (e.g. exercising together, cooking healthy meals, joining at appointments with health care providers) came to the fore during the group discussions. Also, partners were involved to provide support in the development and execution of the action plans of people with T2DM, for instance, in helping them overcome barriers by joining them on their planned walks or taking into account their diets during grocery shopping. Our experiences confirm the important role of partners in the management of diabetes, which mainly takes place in the context of family life, and also underline the importance of having partners participate in self-management support interventions [24–26]. Even though we did not observe substantial differences in the perceptions of patients and their partners during the pilot, other studies have shown such differences, with partners generally perceiving T2DM as a more serious disease [25,26] and showing a better understanding of the condition than people with diabetes themselves [24]. Considering this, we believe that involving partners in T2DM self-management interventions may be helpful to counteract underestimation of T2DM in patients.

Suitability of the intervention

Overall, the group-based interactive course we developed seemed to meet the needs of the participants. The group-based format was appreciated by both course leaders and participants and supported the notion that group discussion can be a valuable element of self-management support [27]. Group discussion enables patients to collaboratively work on self-management in an environment in which they are surrounded by individuals facing similar tasks and challenges and where they can mirror themselves against others, share experiences and exchange helpful ways to integrate T2DM self-management within other goals and priorities. Previous studies have demonstrated that group support can have positive effects on health behaviours and psychosocial and clinical outcomes in patients with diabetes [27–30].

Inclusion of partners was appreciated by both persons with T2DM and partners. Discussing (un)helpful ways of support was generally perceived useful by the participants, also in the group attending without a partner or significant other. Hence, delivering the course was feasible and participation was considered valuable, irrespective of whether partners participated or not. Nevertheless, we believe that it is important to encourage persons with T2DM to participate in self-management interventions together with a partner or close other, considering the impact that social support can have on the daily management of diabetes [20–22].

The evaluation of the total course and the three sessions was generally positive and the vast majority of the participants who filled in the evaluation form stated they would recommend the course to other persons with T2DM. The main concern is the low participation rate: only 22% of the people with T2DM invited to participate in the course actually did. We had already limited the number of course sessions to three, as we expected people with T2DM who do not experience substantial symptoms or complications to be not interested in a more comprehensive intervention. Nevertheless, the low participation rate suggests that reaching people with early-stage T2DM remains a challenge. Indicated reasons for non-participation, such as the diabetes being 'still mild', not needing to take medication or experiencing complaints, point to underestimation of T2DM. To encourage persons with early-stage T2DM to participate in a self-management intervention, primary care physicians and nurses could discuss and agree with each patient how he/she will develop self-management knowledge, skills and behaviours as an integral part of the patient's individual care plan.

Limitations

Although the number of participants in the pilot was sufficient to evaluate the intervention process, it did not allow to draw firm conclusions regarding the influence of partners on the group process. As described earlier, delivering the course with and without partners worked well, and inclusion of partners was appreciated by both persons with T2DM and partners. However, whether and how partners influence the intervention process remains unknown.

Furthermore, we cannot reflect on the ability of the future course leaders (diabetes and practice nurses) to deliver the course, since we had chosen to have a health psychologist guide the pilot sessions. It should be noted that the training of the future course leaders will be provided by the same health psychologist who guided the pilot sessions. In this way, experiences from the pilot will be directly integrated in this training.

Implications for intervention development

The lessons learned from the pilot call for some adaptations in the content and delivery of the intervention. Our experience with the second session suggests that people need to perceive some difficulties in the way they emotionally or behaviourally manage their diabetes, in order to benefit from training in goal-setting and action planning. Persons with T2DM who do not perceive any difficulties or challenges managing their diabetes might benefit more

from paying extra attention to their illness perceptions, instead of asking them to set goals and develop action plans they consider unnecessary. Persons who do perceive difficulties or challenges in managing their illness are more likely to benefit from goal-setting and action planning exercises, as these people will feel a need to make changes. Assessing diabetes-related uncertainty, coping and its perceived impact during the recruitment phase by a short screener may help to identify the two groups and offer them a second session focusing either on challenging illness perceptions or on goal-setting and action planning.

Furthermore, we suggest to let participants work on the course assignments during the sessions in guided subgroups, instead of individually or alone with the partner. By working in guided subgroups, participants could inspire each other setting relevant and realistic goals and developing concrete action plans. Moreover, as discussing partner support in the presence of the partner could be delicate, this may be better discussed in guided subgroups for people with T2DM and partners separately. Finally, we expect that working in smaller subgroups on the assignments will decrease the chances of 'disruptive' talk during the sessions.

Conclusion

Challenging the illness perceptions of persons with early stage T2DM by a brief interactive group intervention is feasible and important, as many of these people tend to underestimate the seriousness of their diabetes. However, motivating persons with early-stage T2DM to participate in self-management interventions remains a challenge. To encourage persons with early-stage T2DM to participate in a self-management intervention, primary care physicians and nurses could discuss and agree with each patient how he/she will develop self-management knowledge, skills and behaviours as an integral part of the patient's individual care plan.

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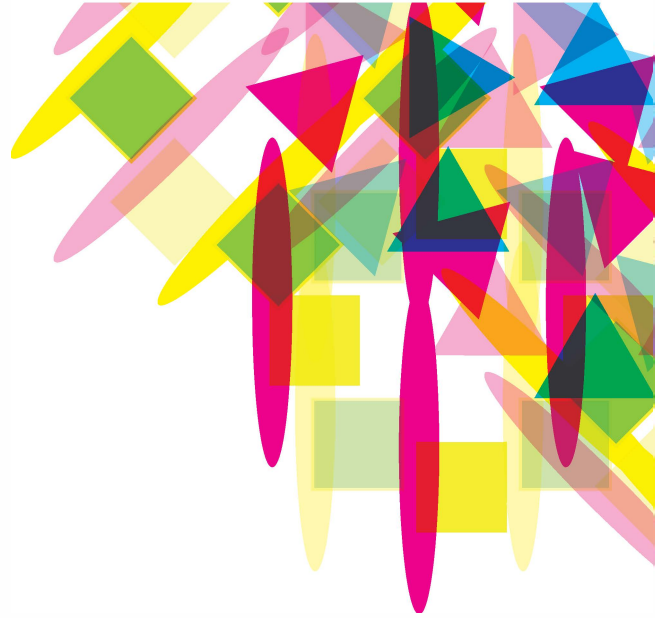
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Effectiveness of a self-management support program for type 2 diabetes patients in the first years of illness: results from a randomized controlled trial.

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ABSTRACT

Aims

To evaluate the immediate and six-month effectiveness of a group-based self-management support program for people diagnosed with type 2 diabetes (1–3 years post diagnosis) on diabetes self-care, distress and cognitions.

Methods

People with type 2 diabetes were randomized into the intervention (four group-based interactive sessions) or the control group (a single educational lecture) with their partners. Outcomes were measured at baseline, immediately after the third course session and six months later using validated questionnaires on diabetes self-care, distress, illness perceptions, diabetes-related attitudes, empowerment and partner support. Multilevel analyses were conducted according to the intention-to-treat principle using the data from 82 intervention and 86 control group participants, to test for differences in changes over time between the two groups.

Results

The intervention group showed a significantly higher increase in physical activity and fruit and vegetable intake immediately after the program, whereas the low baseline levels of diabetes distress remained unaffected. Furthermore, the intervention group believed their illness to be more likely to be caused by chance/bad luck, but also felt more empowered to handle their condition and its treatment immediately after the program compared with the control group. Six months later, only the differences in empowerment had persisted.

Conclusions

Group-based self-management support results in favorable short-term behavioral changes and more persistent alterations in (perceived) empowerment in people living in the first years of type 2 diabetes. In order to achieve more sustainable behavioral changes, more prolonged support is necessary. This could be achieved by integrating attention to patients' illness perceptions and continuous self-management support in regular diabetes care.

NTR: NL3158

INTRODUCTION

People with type 2 diabetes (T2DM) face the challenge of adapting to living with a chronic and progressive condition on a daily basis. From diagnosis, people with type 2 diabetes need to adopt a multifaceted behavioral treatment regimen, to diminish the risk of developing and/or deteriorating diabetes-related complications [1] and, consequently, to maintain adequate functioning and a satisfactory quality of life [2–4]. However, the day-to-day management of chronic illness is often considered challenging, and half of the people with chronic conditions in the Netherlands appears to struggle with making the recommended behavioral changes [5]. Moreover, in the absence of symptoms, people with type 2 diabetes generally underestimate the (potential) seriousness of their condition and, consequently, the importance of engaging in self-care [6]. Support focusing on successful strategies to incorporate diabetes self-management within daily life might therefore be particularly warranted during the first years after diagnosis.

Previous studies on diabetes self-management support have emphasized the importance of focusing on illness perceptions and one's social environment, in addition to self-efficacy, as important determinants for health behaviors and outcomes [7–9]. With this in mind, we developed a self-management support program based on the Common-Sense Model of self-regulation (CSM) [10,11], while also incorporating principles from Social Cognitive Theory (SCT) [12,13] and social support theories [14–16]. According to the CSM, individuals make sense out of their condition by forming personal models about the illness and its treatment, which determine their coping responses and, consequently, influence health-related outcomes. Such personal models comprise several cognitive and emotional dimensions, with 'perceived seriousness' and 'perceived control' being the most influential on behavioral and emotional management [7,17]. In a rather similar way, the SCT states that behavior change will only be elicited when the outcomes are deemed beneficial and important by the individual (outcome expectancies), and (s)he is confident in his or her ability to perform these behaviors (self-efficacy). Providing medical and practical information, sharing experiences in diabetes management, and teaching individuals how to set realistic and manageable goals and develop action plans are therefore considered effective strategies in diabetes self-management support [18]. Furthermore, as social support theories state that support from partners (or other close friends and relatives) can both activate and inactivate patients' behavioral and emotional management [19–21], it is of great importance that patients' "important others" are involved in self-management support programs. Hence, by addressing patients' and partners' illness perceptions, setting realistic goals and developing concrete action plans, and by stimulating activating support from partners or significant others, we aimed to improve type 2 patients' self-management and quality of life in the first years of living with the disease.

So far, comparable support programs have mainly targeted participants' self-efficacy in their efforts to improve self-management in T2DM; a strategy that appears to yield positive,

yet primarily modest and short-term results [22–25]. Considering the important role of illness and treatment perceptions in patients' willingness and (perceived) ability to engage in health behaviors [6,7,17], we believe that these personal beliefs should be the main focus and starting point of our intervention. In addition, tailoring the intervention to the specific needs and challenges that are inherent to the different phases in living with diabetes might increase and prolong its (potential) effects. Two studies previously tested the effectiveness of CSM-based support programs in type 2 diabetes patients, one directly after diagnosis [26,27] and the other in patients with poor glycemic control [9]. The program we developed specifically targeted patients who had been diagnosed one to three years ago; a phase in the illness process where the initial attention paid to patient education and support often fades away - especially in the absence of diabetes-related problems or complications - and where many patients have already been confronted with barriers that impede making and maintaining behavioral changes [6,28]. Self-management is a broad concept, comprising cognitive, behavioral and emotional aspects of living with a (chronic) condition [29,30]. For the purpose of this study, we chose to focus on the behavioral component of self-management, being the self-care behaviors and lifestyle recommendations that are part of the diabetes treatment regimen. In addition, our study focused on diabetes distress being an important diabetes-related aspect of health-related quality of life.

The present article reports the effectiveness of this support program on patients' diabetes self-care and distress as primary outcomes, both immediately after the intervention and at six months follow-up. We also assessed the immediate and follow-up effects of the intervention on more proximal secondary outcomes, including diabetes-related perceptions and attitudes, empowerment and perceived partner support, which enabled us to gain more insight in the presumed working mechanisms of the intervention. We hypothesized that the group-based self-management support program would result in participants: (a) performing more (appropriate) diabetes self-care (including healthy behaviors/lifestyle aspects) and (b) experiencing lower levels of diabetes-related distress immediately after the program and six months later, as compared to a control group. Furthermore, we hypothesized that the group-based self-management support program would result in participants: (a) holding more adaptive illness perceptions and attitudes towards their condition; (b) feeling more empowered to manage their condition, and c) experiencing more activating partner support, immediately after the program and six months later, as compared to a control group. Although it cannot be stated that certain illness beliefs are always adaptive (or maladaptive), perceiving diabetes to be a serious condition, while also perceiving its course and consequences to be (to a certain extent) controllable by a healthy lifestyle, appropriate self-care and medical treatment is generally considered an adaptive personal model of T2DM. A sense of understanding the illness may also contribute to adaptive health and illness behaviors [7,17]. Similarly, active engagement of partners in helping patients use constructive problem solving skills is generally found to be

adaptive, whereas protective buffering and overprotection by partners may negatively impact their (psychological) health and illness behaviors [20,31,32].

MATERIALS AND METHODS

A randomized controlled trial (RCT) was carried out, comparing the effects in an intervention group to a control group. Outcome measures were assessed at baseline, immediately after the intervention program (two months from baseline) and at six months follow-up (eight months from baseline). Written informed consent was obtained from participating patients prior to the start of the study. The study was approved by the Medical Ethical Committee of the VU University Medical Center Amsterdam (VUmc) and registered in the Dutch trial register [NL3158]. The protocol of the study has been published previously [33].

Participants

People with type 2 diabetes and an illness duration between one and three years post-diagnosis who received diabetes care from general practices (GPs) in six regions of the Netherlands were included in the study between the summer of 2012 and the summer of 2013. Almost all GPs in the Netherlands are organized in diabetes care groups, which may consist of 50 to more than 200 GPs who together agree upon a diabetes management program that is contracted by health insurers. For this study, we approached nine diabetes care groups of which six eventually participated and distributed information about the study and a request for participation to all their affiliated GPs. GPs willing to participate signed up for the study directly with the researchers. Subsequently, patients registered with these GPs, who had been diagnosed between one and three years ago, were selected. First, an electronic selection of all T2DM patients in the participating GP's was performed, based on ICPC code (T90.02). From there, all further data were selected by manual abstraction of the electronic medical records. People were excluded if they were 1) over the age of 85, 2) unable to speak, read and/or understand the Dutch language sufficiently, 3) mentally or intellectually incapable to participate, or 4) suffering from a severe life-threatening condition (e.g., specific types of cancer) or currently receiving (psycho)therapy for severe psychological or psychiatric problems, as reported by their GP or practice nurse.

Eligible people received a written invitation for participation, a generic participation recommendation letter from their GP, and an answer form to indicate on whether or not they agreed to participate. Invited people were also asked to complete a three-item screening questionnaire, assessing diabetes-related uncertainty, coping with diabetes and perceived consequences of diabetes (see S1 Table). Patients with a total sum score of 0, indicating that they did not experience any uncertainty or problems in coping with their illness nor perceived any negative consequences of diabetes at that moment were considered as non-eligible, as

they were not expected to benefit from the program. Hence, these people were excluded from the study before randomization.

Intervention and control condition

Randomization to the intervention and control condition was electronically performed at patient level, stratified per region, by a researcher who was not involved in the study. All participants were actively encouraged to bring their partner or, when a partner was absent, a close friend or relative to the course sessions (intervention) or information meeting (control condition).

Intervention

Participants in the intervention group were invited to a group-based self-management support program, consisting of three monthly 2-hour interactive sessions and one booster session three months after the last session. All sessions were led by two diabetes nurses or practice nurses who received a four-hour training, and a detailed manual describing the content of the program and its underlying theories to be used during the sessions. Participating patients and their partners received a workbook which contained basic information about diabetes, (homework) assignments, and theoretical and practical information about the topics discussed during the course (both books are available in Dutch from the corresponding author).

The content and method of delivery of the course were first derived from literature study and the results from a focus group. Subsequently, the manual for the (future) course leaders and the work book for the participants were developed and pilot tested in two groups. The experiences with the intervention during the pilot were used to adapt the content and method of delivery of the sessions, and served as input for the training of the future course leaders. Finally, the researcher and health psychologist that observed and guided the pilot trained the diabetes nurses and practice nurses to deliver the intervention during the RCT. The content of the three course sessions and the booster session is outlined in Table 1.

Control condition

Participants in the control group were invited to a single 2-hour educational lecture, in which they received information about living with diabetes from a medical perspective. A professor in general practice and diabetes care provided information on the course of diabetes (including treatment options and potential complications) and the latest developments in diabetes research, according to the classical didactical method.

Table 1 Outline of the Living with diabetes course.

	Aim	Activity	Main related outcome
Session 1			Perceptions/attitudes
Discussing illness perceptions.	Creating awareness on differences in perceptions and their link with behaviors.	Discussing the different perceptions on seriousness, controllability and consequences of diabetes.	
Challenging maladaptive illness perceptions.	Increasing outcome expectancies for self-management and diabetes treatment by increasing perceptions of seriousness and controllability.	Providing medical information to change maladaptive illness perceptions, primarily focusing on the seriousness and controllability of the illness.	
Session 2			Empowerment
Exploring goals and developing personalized action plans	Increasing feelings of self-efficacy and empowerment through working on feasible and specific formulated goals for behavior change.	Sharing personal diabetes-related goals. Developing step-wised, specific action plans for these goals in subgroups.	
Session 3			Social support
Exploring and discussing (un)helpful ways of support.	Creating awareness on (un)helpful ways of support and the possible gap between wanted and received support.	Discussing ways of support that is perceived helpful and which ways of support are currently received.	
Developing personalized pro-active action plans	Overcoming barriers in behavior change by (asking) support from others.	Integrating help or support from others in the action plan.	
Booster session			
Reflections	Providing a reminder of the techniques learned during the course.	Sharing experiences on achieving the goals and action plans during the last three months. Questions or challenges that have arisen during the three months after the 3rd course session are discussed .	

Measurements and measures

Questionnaires were administered at baseline, immediately after the intervention program (two months after baseline), and six months after the intervention (eight months after baseline). Participants in the control group also received a questionnaire at two months and at eight months after the baseline measurement.

Primary outcome measures

Self-care was assessed with the revised Summary of Diabetes Self-Care Activities measure (SDSCA) [34], assessing six separate self-care domains: exercise behaviors (2 items, Cronbach's $\alpha = .75$), glucose monitoring (2 items $\alpha = .50$), foot care (2 items $\alpha = .68$), general diet (2 items, $\alpha = .83$), specific diet (2 items, $\alpha = .08$), and smoking (1 item). With the exception of smoking, the self-care behaviors were rated on a 8-point scale, assessing the average number of days self-care was performed during the previous week (0–7 days). Because of the low internal reliability of the specific diet scale, the two items (fruit/vegetable intake and low-fat diet) were analyzed separately, as also suggested by Toobert et al. [34]. Smoking was assessed dichotomously (yes/no).

Diabetes-related distress was measured with the Problem Areas in Diabetes scale (PAID) [35]. The 20 items of the PAID assess experienced levels of diabetes-related emotional distress or problems on a 5-point Likert scale ranging from 0 (no problem) to 4 (a serious problem). The sum of the 20 items were transformed into an overall score between 0 and 100 ($\alpha = .95$) by multiplying them by 1.25.

Proximal effect measures

Illness perceptions were measured with the revised Illness Perceptions Questionnaire (IPQ-R) [36]. In the first section of this questionnaire, participants indicate whether or not they experience 14 different symptoms (yes/no) and whether they attribute these to their diabetes (yes/no). The sum of the yes-rated items that were attributed to diabetes formed the 'identity' subscale (range: 0–14).

The second section of the IPQ-R (see S1 Box) assesses seven illness perception dimensions: 'time-line acute/chronic' (6 items, e.g. "My diabetes will last for a long time",$\alpha = .86$); 'time-line cyclical' (4 items, e.g. "My diabetes is very unpredictable", $\alpha = .89$); 'consequences' (6 items, e.g. "My diabetes is a serious condition", $\alpha = .75$); 'personal control' (6 items, "The course of my diabetes depends on me", $\alpha = .72$); 'treatment control' (5 items, "My treatment can control my diabetes", $\alpha = .53$); 'coherence' or understanding of diabetes (5 items, "My diabetes doesn't make any sense to me", $\alpha = .80$) and 'emotional representation' (6 items, "When I think about my diabetes I get upset", $\alpha = .83$). The third section assesses causal beliefs (18 items) divided in three scales, based on factor analyses and as suggested by Moss-Morris et al [22]: own behavior in the past (6 items, e.g. "Diet or eating habits", $\alpha = .83$), psychological cause (5 items, e.g. "Stress or worries", $\alpha = .72$), and chance/bad luck (1 item). Apart from the 'identity' scale, which was measured dichotomously, the items of the IPQ-R were measured on a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree) and calculated into a mean score for each subscale.

Attitudes towards diabetes were measured with the Diabetes Attitude Scale (DAS-3) [37] (see S1 Box), consisting of five subscales: need for special training (5 items $\alpha = .73$); perceived seriousness (7 items $\alpha = .73$); value of tight control (7 items $\alpha = .56$); psychosocial

impact (6 items α = .66); and patient autonomy (8 items α = .65). The items are scored on a five-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree) and calculated into a mean score for each subscale.

Perceptions of partner support were assessed by the questionnaire developed by Buunk et al. [38] (see S1 Box), measuring three dimensions of partner support: active engagement (5 items α = .91); protective buffering (8 items α = .73) and overprotection (6 items α = .74). The items were measured on a 5-point Likert scale ranging from 1 (never) to 5 (always) and calculated into a mean score for each subscale.

Empowerment was assessed by the Dutch Diabetes Empowerment Scale (Dutch DES-20) [39]; a Dutch version of Anderson's Diabetes Empowerment Scale (DES) [40]. The Dutch-DES-20 consists of 20 items with a five-point Likert scale, ranging from 1 (totally disagree) to 5 (totally agree), and results in an overall empowerment mean score (α = .94).

Sociodemographic and clinical characteristics

Age, gender and diabetes duration were derived from patients' health records kept by the GPs. All other sociodemographic and clinical characteristics were self-reported by the patients. Level of education was categorized into low (no education, primary school or low vocational training), middle (high school or middle vocational training) and high (college or university), based on the reported highest type of education completed. Marital status was dichotomized into 'married or cohabiting' and 'other' (single, divorced, widowed, other). Diabetes treatment was categorized into 1) lifestyle advice only, 2) oral hypoglycemic agents, and 3) insulin. To assess diabetes-related microvascular complications, patients were asked to indicate whether they suffered from 1) eye problems: retina problems (retinopathy), 2) kidney-problems: proteinuria or dialysis (nephropathy), 3) nerve damage (neuropathy), and 4) foot problems (wounds, amputation, need for adapted shoes). The presence of comorbidity was assessed by asking patients to indicate whether they suffered from 1) heart and vessel disease (e.g. serious heart condition or infarction), 2) cancer, 3) respiratory problems (asthma, chronic obstructive pulmonary disease (COPD), 4) joint conditions (neck and back problems, osteoporosis, arthrosis, rheumatoid arthritis) or 5) 'other'.

Statistical analysis

Participants' characteristics are reported for the intervention group and control group separately. Differences in baseline characteristics between drop-outs and non-drop outs were tested with Student's t-tests, and Chi-square or Fishers' Exact tests. Multilevel analyses (MLA) were performed to test the effectiveness of the intervention over time, taking the dependency of the three measurements within participants into account. Analyses were performed according to the intention-to-treat-principle.

All outcome measures were analyzed separately as dependent continuous variables in two level (patient and measurement) multivariate regression models. Condition (intervention or

control group) and measurement (baseline, immediately after the intervention and after six months follow-up; dichotomous) and their interaction term (condition*measurement) were included in the analyses to examine the differences in effect between the groups over time. All analyses were adjusted for gender and age. All outcome measures were analyzed by linear regression models, except for smoking which was analyzed by a logistic regression model. Mixed effect models were used to calculate the intevention's effect over time, with individual level being estimated as a random effect, and all other variables (age, sex and measurement*condition) as fixed effects.

Intervention effects were tested two-tailed and the significance level was set at $p < .05$. All analyses were performed with STATA 13.

RESULTS

Data were available from 168 participants in the study, with 82 participants in the intervention group and 86 participants in the control group (Fig 1). Even though the intervention and control group seem to somewhat differ in their sociodemographic and clinical characteristics (Table 2), these differences were not significant. Participants did not significantly differ from non-participants, with the exception of education level, which was higher among participants [41]. Thirty-one patients (18%) were lost during follow-up, with higher dropout rates in the intervention group (24%; n = 20) than in the control group (13%; n = 11). Non-response analyses showed that those lost to follow-up had a shorter diabetes duration (mean 2.1 vs. 2.5 years, $p < 0.01$) than those who completed the study. Furthermore, lower baseline scores on general dietary behaviors (mean 4.6 vs 5.3, $p = 0.04$), and psychological impact of type 2 diabetes (mean 2.8 vs. 3.1, $p = 0.02$) were found among dropouts, compared to participants with complete follow-up. In total, nine course groups were organized with an average of 8-9 participating patients per group. A little over half of the participants in the intervention group (54%) brought a partner to the course sessions.
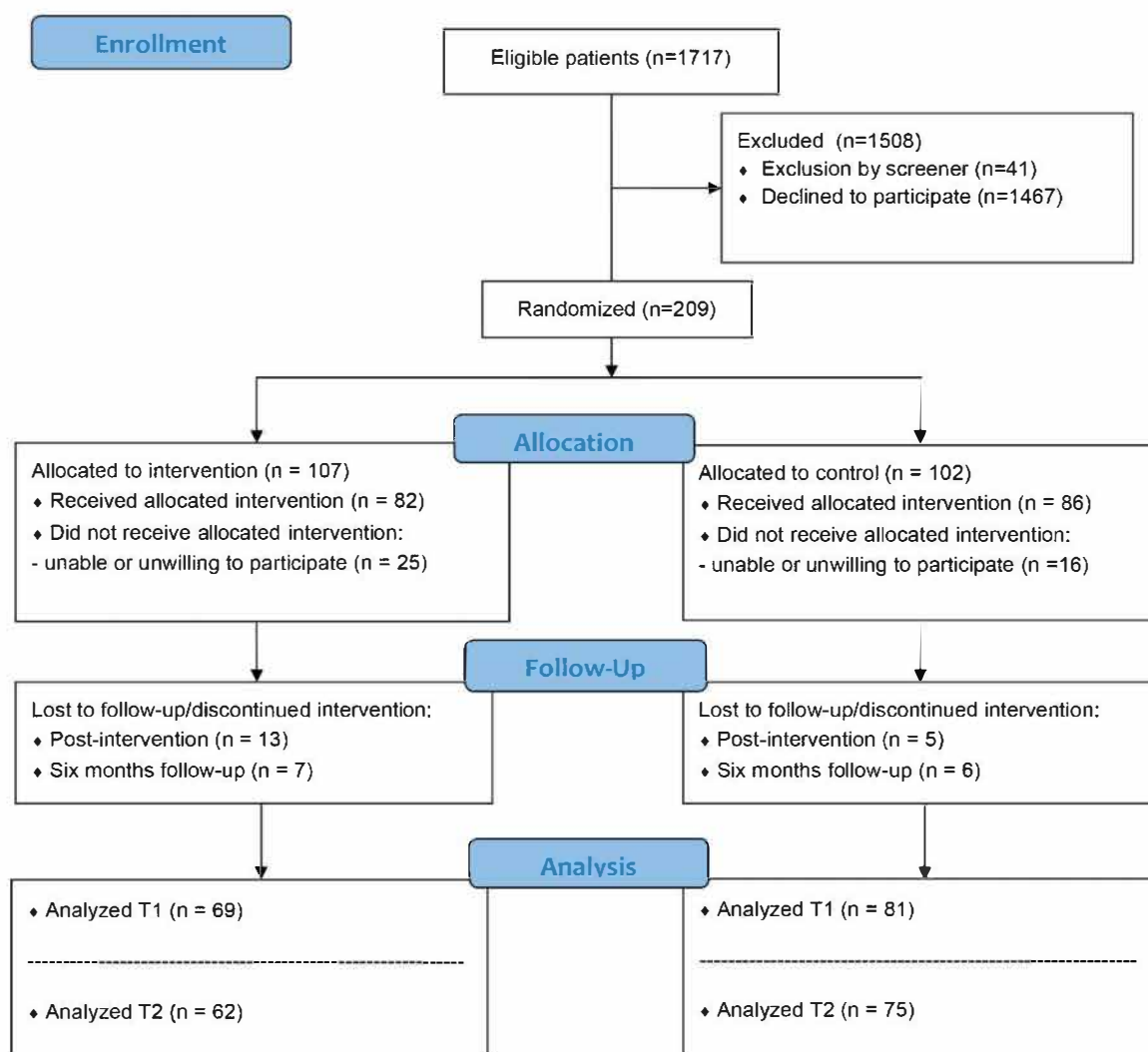
Figure 1 Flow-chart of participants.

Table 2 Baseline demographic and illness-related characteristics of the participants by study group; percentages or means (SD).

	Intervention (n = 82)	Control (n = 86)
Age (years), mean (SD)	63.5 (10.2)	63.7 (10.2)
Gender: male (%)	58.5 (n = 48)	52.3 (n = 45)
Education level (%)		
Low	27.9 (n = 22)	27.01 (n = 23)
Middle	43.0 (n = 34)	50.6 (n = 43)
High	29.1 (n = 23)	22.4 (n = 19)
Married or cohabiting (%)	79.8 (n = 63)	74.1 (n = 63)
Working population (%)	34.2 (n = 27)	24.7 (n = 21)
Diabetes duration (years), mean (SD)	2.4 (0.8)	2.4 (0.8)
Treatment (%)		
Lifestyle advice only	27.9 (n = 22)	37.7 (n = 32)
Oral hypoglycemics	68.4 (n = 54)	61.2 (n = 52)
Insulin	3.8 (n = 3)	1.2 (n = 1)
Complications: present (%)	19.5 (n = 15)	28.6 (n = 24)
Eye problems	6.5 (n = 5)	11.9 (n = 10)
Kidney problems	1.3 (n = 1)	2.4 (n = 2)
Nerve problems	1.3 (n = 1)	7.1 (n = 6)
Foot problems	10.4 (n = 8)	13.1 (n = 11)
Comorbid conditions: present (%)	61.5 (n = 48)	69.1 (n = 58)
Heart- and vessel condition	15.4 (n = 12)	23.8 (n = 20)
Cancer	1.3 (n = 1)	1.2 (n = 1)
Lung conditions	12.8 (n = 10)	17.9 (n = 15)
Joint conditions	33.3 (n = 26)	35.7 (n = 30)
Other conditions	15.4 (n = 12)	27.4 (n = 23)

Effects on diabetes self-care and distress

Multilevel analyses (Table 3) showed that, immediately after the program, the intervention group showed a significantly higher increase in physical activity (mean estimated difference 0.76, $p = .009$) and fruit and vegetable intake (mean estimated difference 0.68, $p = .014$) than the control group. At the follow-up six months after the intervention, these effects had disappeared. Regarding diabetes-related distress, neither immediate nor six-month effects were found. Baseline levels of self-care appeared to be somewhat higher in the intervention group, but not significantly.

Table 3 Effects of a group-based intervention for people with type 2 diabetes on self-care behaviors and diabetes distress immediately post-intervention and six months after the intervention, adjusted for age and sex.

	Baseline		Immediately post-intervention			Six months post-intervention		
	Unadjusted		*Unadjusted*		*Adjusted*	*Unadjusted*		*Adjusted*
	Mean (SD)		Mean (SD)		Mean estimated difference (95% CI)	Mean (SD)		Mean estimated difference (95% CI)
	Intervention (n=82)	Control (n=86)	Intervention (n=69)	Control (n=81)		Intervention (n=62)	Control (n=75)	
Self- care (0 – 7)								
Exercise	4.5 (1.8)	4.3 (2.0)	4.9 (1.6)	4.0 (1.9)	0.76 (0.19 – 1.34)**	4.4 (1.7)	4.3 (2.0)	-0.04 (-0.64 – 0.55)
Glucose testing	0.5 (1.3)	0.3 (0.8)	0.7 (1.6)	0.4 (1.1)	0.14 (-0.28 – 0.56)	0.4 (1.3)	0.7 (1.6) †	-0.35 (-0.79 – 0.08)
Foot care	1.3 (2.0)	1.3 (1.8)	1.7 (2.1)	1.2 (1.8)	0.42 (-0.18 – 1.02)	1.5 (1.8)	1.4 (2.0)	0.06 (-0.56 – 0.68)
Diet: general	5.3 (1.4)	5.1 (1.8)	5.4 (1.3)	4.9 (1.7)	0.29 (-0.18 – 0.76)	5.3 (1.2)	4.8 (1.8)	0.25 (-0.24 – 0.74)
Diet: fruit/vegetables	5.2 (1.9)	5.4 (1.9)	5.7 (1.5) †	5.3 (1.7)	0.68 (0.14 – 1.22)*	5.3 (1.6)	5.6 (1.6)	-0.16 (-0.72 – 0.39)
Diet: low fat	5.0 (1.9)	4.6 (2.1)	4.7 (2.0)	4.8 (1.9)	-0.48 (-1.14 – 0.18)	4.5 (2.2) †	4.2 (2.1)	-0.09 (-0.77 – 0.59)
Non-smoking (%)	87.2	77.1	87.0	74.4	0.85 (-3.36 – 5.06)	88.7	81.4	-3.74 (-8.09 – 0.61)
Diabetes distress (0 – 100)	12.6 (14.3)	13.9 (16.0)	15.4 (14.7)	14.9 (15.7)	1.80 (-.157 – 5.17)	13.5 (13.3)	12.7 (15.1)	1.57 (-1.92 – 5.06)

† Significant difference from baseline at the 0.05 level

* Significant intervention effect at the 0.05 level.

** Significant intervention effect at the 0.01 level

Table 4 Effects of a group-based intervention for people with type 2 diabetes on cognitions, empowerment and partner support, immediately post-intervention and six months after the intervention, adjusted for age and sex.

	Baseline		Immediately post-intervention			Six months post-intervention		
	Unadjusted		*Unadjusted*		*Adjusted*	*Unadjusted*		*Adjusted*
	Mean (SD)		Mean (SD)		Mean estimated difference (95% CI)	Mean (SD)		Mean estimated difference (95% CI)
	Intervention (n=82)	Control (n=86)	Intervention (n=69)	Control (n=81)		Intervention (n=62)	Control (n=75)	
Illness perceptions (1 – 5)								
Identity (0 – 14)	0.69 (1.41)	0.69 (1.41)	0.65 (1.50)	0.69 (1.27)	0.02 (-0.38 – 0.42)	0.53 (1.24)	0.50 (1.20)	0.06 (-0.35 – 0.47)
Timeline: chronic	3.92 (0.68)	3.92 (0.68)	4.08 (0.72) †	3.99 (0.67)	0.02 (-0.17 – 0.21)	3.87 (0.69)	4.02 (0.74) †	-0.22 (-0.41 – -0.02)*
Timeline: cyclical	2.35 (0.85)	2.35 (0.85)	2.43 (0.79)	2.45 (0.74)	0.03 (-0.22 – 0.28)	2.48 (0.90)	2.43 (0.80)	0.12 (-0.14 – 0.37)
Consequences	2.53 (0.66)	2.53 (0.66)	2.81 (0.60) †	2.65 (0.61)	0.17 (-0.01 – 0.35)	2.76 (0.57) †	2.60 (0.57)	0.18 (0.00 – 0.36)
Control: personal	3.88 (0.58)	3.88 (0.58)	4.02 (0.51)	3.66 (0.56)	0.10 (-0.08 – 0.28)	3.94 (0.44)	3.78 (0.56)	-0.08 (-0.27 – 0.10)
Control: treatment	3.81 (0.46)	3.81 (0.46)	3.90 (0.50)	3.70 (0.47)	0.08 (-0.08 – 0.24)	3.79 (0.45)	3.73 (0.55)	-0.04 (-0.20 – 0.13)
Illness coherence	3.50 (0.68)	3.50 (0.68)	3.71 (0.76) †	3.43 (0.77)	0.07 (-0.13 – 0.28)	3.64 (0.70)	3.45 (0.65)	0.02 (-0.19 – 0.24)
Emotional representations	2.21 (0.63)	2.21 (0.63)	2.20 (0.63)	2.26 (0.67)	-0.05 (-0.24 – 0.14)	2.18 (0.66)	2.28 (0.62)	-0.10 (-0.30 – 0.09)
Cause: psychological	2.19 (0.81)	2.19 (0.81)	2.32 (0.79)	2.40 (0.84) †	-0.04 (-0.23 – 0.15)	2.31 (0.81)	2.27 (0.74)	0.03 (-0.17 – 0.22)
Cause: risk behavior	2.51 (0.77)	2.51 (0.77)	2.56 (0.80)	2.52 (0.66)	-0.10 (-0.29 – 0.10)	2.50 (0.82)	2.50 (0.73)	-0.16 (-0.36 – 0.04)
Cause: bad luck	2.53 (1.22)	2.53 (1.22)	2.91 (1.14) †	2.67 (1.15)	0.45 (0.03 – 0.87)*	2.75 (1.09)	2.90 (1.07)	0.06 (-0.37 – 0.50)
Attitude (1 – 5)								
Need for special training	4.04 (0.54)	4.04 (0.54)	4.10 (0.57)	4.07 (0.60)	0.00 (-0.18 – 0.19)	4.09 (0.49)	4.06 (0.57)	0.01 (-0.18 – 0.20)
Seriousness	3.36 (0.61)	3.36 (0.61)	3.64 (0.58) †	3.45 (0.51)	0.15 (0.00 – 0.29)	3.57 (0.56) †	3.46 (0.52)	0.06 (-0.09 – 0.22)
Value of tight control	3.75 (0.40)	3.75 (0.40)	3.85 (0.48)	3.62 (0.47)	0.06 (-0.09 – 0.20)	3.73 (0.46)	3.57 (0.44)	0.00 (-0.15 – 0.14)
Psychological impact	3.03 (0.55)	3.03 (0.55)	3.15 (0.49)	3.05 (0.63)	0.15 (0.00 – 0.31)	3.15 (0.50)	3.12 (0.54)	0.09 (-0.07 – 0.25)
Autonomy	3.24 (0.42)	3.24 (0.42)	3.29 (0.46)	3.21 (0.46)	0.02 (-0.13 – 0.17)	3.32 (0.49)	3.22 (0.54)	0.04 (-0.11 – 0.20)
Empowerment (1 – 5)	3.65 (0.50)	3.65 (0.50)	3.89 (0.51) †	3.64 (0.50)	0.21 (0.06 – 0.37)**	3.86 (0.44) †	3.67 (0.46)	0.16 (0.00 – 0.32)*
Partner support (1 – 5)								
Active engagement	3.38 (0.83)	3.38 (0.83)	3.48 (0.76)	3.04 (0.84)	0.16 (-0.05 – 0.37)	3.42 (0.80)	3.01 (0.84)	0.00 (-0.21 – 0.21)
Protective buffering	2.22 (0.71)	2.22 (0.71)	2.22 (0.64)	2.31 (0.66)	-0.03 (-0.23 – 0.18)	2.20 (0.63)	2.29 (0.72)	-0.02 (-0.23 – 0.19)
Overprotection	1.91 (0.63)	1.91 (0.63)	1.99 (0.60)	1.71 (0.55)	0.07 (-0.11 – 0.25)	2.02 (0.73)	1.73 (0.59)	0.05 (-0.14 – 0.23)

† Significant difference from baseline at the 0.05 level

* Significant intervention effect at the 0.05 level.

** Significant intervention effect at the 0.01 level

Effects on illness perceptions, attitude, empowerment and partner support

Multilevel analyses (Table 4) showed that, immediately after the program, the intervention group showed a significantly higher belief in diabetes being caused by chance/bad luck (mean estimated difference 0.45, p = .039 and higher feelings of empowerment (mean estimated difference 0.21, p = .006) than the control group. Six months after the intervention, the differences in empowerment were still present (mean estimated difference 0.16, p = .044). The control group, on the other hand, showed a significantly higher increase in perceiving type 2 diabetes as having a chronic timeline (mean estimated difference 0.22, p = .029) at the six-month follow-up than the intervention group. No significant effects were found on partner support; neither immediately after the intervention nor six months after the intervention.

DISCUSSION

This study examined the immediate and six-month effectiveness of a group-based self-management support program for people with type 2 diabetes one to three years after diagnosis, and their partners. The intervention group showed more positive results regarding diabetes self-care, and empowerment than the control group. At six-months follow-up, the behavioral differences between the two groups had disappeared, while the differences in empowerment had persisted. Neither immediate nor six-month effects of the program were found on patients' levels of diabetes-related distress. Apparently, sustainable changes in patients' empowerment do not necessarily lead to sustainable changes in their behavior.

These results contribute to the still relatively sparse knowledge on the effectiveness of support programs that aim to improve diabetes self-care by targeting diabetes-related perceptions. We based our program on the assumption that more adaptive illness perceptions - in particular those concerning the seriousness of type 2 diabetes and its controllability by medical treatment and own behavior - would positively influence participants' diabetes self-care and distress. These theoretical assumptions seem to be only partly supported by the short-term intervention effects found in this study. Immediately after completion of the intervention program, participants reported higher levels of physical activity and fruit and vegetable intake than participants in the control group. In addition, participants in the intervention group felt more empowered to make treatment decisions. No (significant) changes, however, were found in the participants' cognitions regarding the seriousness and controllability of their condition, even though these were hypothesized to be important preconditions for behavioral change; particularly in this patient group. Furthermore, six months after the intervention program, the increased physical activity and fruit and vegetable intake of the participants in the intervention program had diminished, whereas the differences in empowerment between the intervention and control group had remained. Results from the two previous CSM-based studies in diabe-

tes [9,26] showed comparable modest or short-term intervention effects on self-care, although they did find sustained changes in illness- and treatment-related perceptions in their studies. Hence, these findings suggest that even if CSM-based self-management support effectively alters patients' cognitions, and as such establishes the necessary psychological conditions for behavioral change, this still appears to be insufficient to maintain healthy behaviors on the longer term. Achieving sustainable improvements in physical activity and diet are, however, considered to be among the most challenging health behaviors [6,42,43] and therefore require more intensive and prolonged support. Also, diabetes-related distress remained unaffected by the intervention over time. Levels of distress among participants were, however, already very low at baseline, which left little room for improvement by the program. Absence of diabetes-related distress during the first years after diagnosis might rather reflect the presence of misconceptions about the seriousness of type 2 diabetes and not being fully engaged in self-care than being an indication of successful adaptation to living with the condition [6]. The changes in lifestyle did not result in heightened distress levels, which might suggest that the intervention provided reassurance and helped participants to identify successful and acceptable methods to perform diabetes self-care. Hence, the mere finding that distress levels remained stable over time, might be an indication of the effectiveness of the intervention in itself. Nonetheless, we cannot rule out that the intervention did not work as intended.

There are some study limitations that need to be addressed. First, participants in our study may not have been fully representative for the target population, which could have implications for the generalizability of the study results. The low eventual participation rate of 10%, and rather high and non-random drop-out rate of 18% during the study seem to indicate that the study results especially apply to people with type 2 diabetes who are motivated to self-manage their condition. Also, participants appeared to be higher educated than patients who declined the invitation to participate, which could indicate that our study was less able to reach those patient populations that are generally more prone to unfavorable (health) outcomes [44–47]. Furthermore, it should be noted that half of the participating patients did not bring a partner to the course sessions which, considering the known important role of partners in diabetes management [19–21], could have had its implications on the effectiveness of the intervention. Unfortunately, our study sample does not allow for subgroup analyses to test for differences in results between patients with and patient without a partner. Furthermore, the control condition was not equivalent to the intervention condition regarding the frequency and duration of the sessions. Nevertheless, participants in the control group did receive an educational lecture, and as such received at least some kind of intervention (attention) as well. Another potential limitation is that all study outcomes were self-reported, and no clinical outcomes were included as more objective determinants of diabetes self-management. And even though this study was primarily focused on diabetes outcomes as perceived by the participants, the assessed self-care behaviors–one of the primary outcome measures–may have been subjected to social desirability bias [48]. Finally, many variables were tested in

this study, for we wanted to capture the broad sense of self-care and gain more insight into the changes in its underlying factors. As a consequence of this multiple testing strategy, it should be kept in mind that some of the statistically significant effects could have occurred by chance.

In conclusion, our group-based self-care support intervention for people with type 2 diabetes appeared to have had short-term favorable effects on patients' lifestyles and feelings of empowerment. However, in order to achieve sustainable behavioral changes, more prolonged support is necessary. For it does not appear feasible to motivate the often asymptomatic T2DM patient population to engage in more course sessions or educational training in addition to regular diabetes consultations during their first phases of illness, we believe that aspects from this intervention should rather be integrated within regular care and be monitored, for instance, in yearly comprehensive assessments and the resulting individual care plan. Regular and repeated discussion of patients' and partners' perceptions could help health care providers in identifying maladaptive beliefs that negatively affect behavioral and emotional management of diabetes, while the development of realistic action plans and regular discussion of its progress and the obstacles encountered may help patients stay focused on working towards their long-term goals.

Acknowledgments

APPENDIX: SUPPORTING INFORMATION

S1 Table Three-item screener.

1. How much uncertainty do you currently experience in your life as a result of being diabetic?				
None at all (0)	Slight amount (1)	Moderate amount (1)	Large amount (1)	Extremely large amount (1)
2. How effective are you in coping with your diabetes?				
Not at all (1)	Slightly effective (1)	Moderately effective (1)	Very effective (0)	Extremely effective (0)
3. My diabetes has major consequences on my life.				
Strongly disagree (0)	Disagree (1)	Neither agree not disagree (1)	Agree (1)	Strongly agree (1)

**S1 Box** Description of the scores on the subscales of the IPQ-r, DAS-3, and the partner support questionnaire.

IPQ-r

Subscale	Description
Identity	Higher scores indicate the presence of more symptoms, which are being attributed to diabetes by the individual.
Timeline acute/chronic	Higher scores indicate higher beliefs of diabetes being a long-term (or life-long) condition.
Timeline cyclical	Higher scores indicate higher beliefs of diabetes being a condition that changes over time.
Consequences	Higher scores indicate higher beliefs of diabetes being a (potentially) serious condition with a higher perceived impact on the individual's own life, and that of their close associates.
Personal control	Higher scores indicate higher beliefs in the individual's personal effectiveness and ability to control their diabetes.
Treatment control	Higher scores indicate higher beliefs regarding the effectiveness of (medical) treatment, and the effectiveness of health care providers in diabetes control.
Illness coherence	Higher scores indicate a greater perceived understanding of diabetes, with diabetes making 'more sense' to the individual.
Emotional representations	Higher scores indicate more emotional feelings towards living with diabetes, e.g. anger or fear.
Cause: own behavior	Higher scores indicate higher beliefs of own behaviors (e.g. diet) being a cause for diabetes.
Cause: psychological cause	Higher scores indicate higher beliefs of psychological factors (e.g. stress) being a cause for diabetes.
Cause: chance/bad luck	Higher scores indicate higher beliefs of chance or bad luck being a cause for diabetes.

DAS-3

Subscale	Subscale
Need for special training	Higher scores indicate a higher perceived need for health care professionals to have had special training in teaching, counselling and techniques for behaviour change.
Seriousness of T2DM	Higher scores indicate higher beliefs of diabetes being a serious condition.
Value of tight control	Higher scores indicate higher beliefs of the benefits of tight glucose control outweighing its 'costs' in patients.
Psychosocial impact	Higher scores indicate higher beliefs of diabetes having a psychosocial impact on patients' lives.
Patient autonomy	Higher scores indicate higher beliefs of patients being the primary decision-maker regarding their diabetes and its treatment.

Partner support questionnaire

Subscale	Description
Active engagement	Higher scores indicate more active engagement and support in helping partners use constructive problem-solving skills to manage their diabetes.
Protective buffering	Higher scores indicate more effort in hiding their own concerns and emotions regarding their partners' diabetes in order to protect them.
Overprotection	Higher scores indicate more (excessive) efforts in protecting their partners from the challenges of diabetes management.

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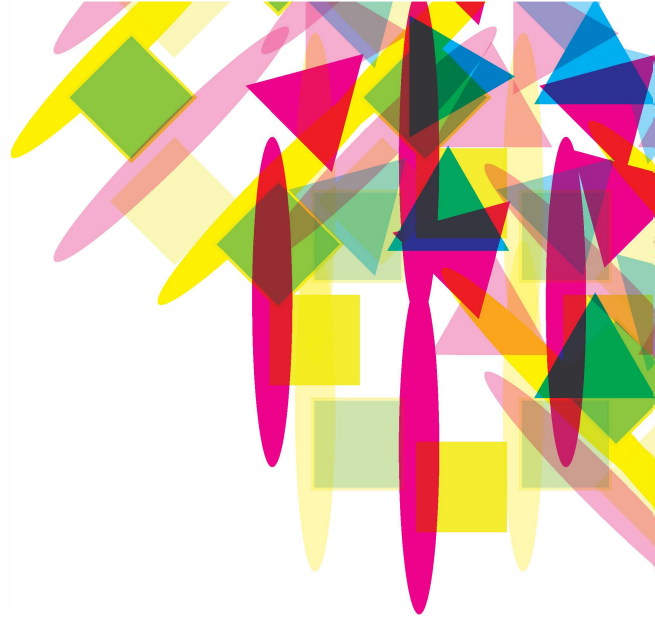
8

General discussion

GENERAL DISCUSSION

Type 2 diabetes (T2DM) confronts patients with the task of adapting to living with a chronic and progressive condition on a daily basis. The Diacourse study was developed to support patients in different phases of T2DM by examining the needs and challenges that (may) arise over the course of illness, and by developing and offering tailored self-management support. This thesis describes two parts of the Diacourse study in which we aimed to:

- Gain insight into the illness perceptions, self-management behaviours and quality of life of patients over the course of T2DM (part 1);
- Develop a group-based self-management support programme for recently diagnosed T2DM patients and their partners, and evaluate its effectiveness (part 2).

In this chapter, the results of the studies described in the previous chapters are summarised and discussed. Furthermore, a number of methodological aspects of the studies will be addressed, followed by a reflection on the implications of the findings for clinical practice and for further research.

Part 1: Illness perceptions, self-management and quality of life over the course of illness

The Diacourse study was based on the assumption that T2DM patients' self-management tasks change over time, for example, as a result of changes in treatment or the development of complications. When we focus on the first years after diagnosis, T2DM appears to be managed differently in the presence of complications, which is described in **chapter 2**. Where T2DM is generally perceived as a rather mild and controllable condition in this phase, patients who already experience complications perceive their condition as more unpredictable and less controllable by own behaviours and treatment, with a more serious impact on their daily life and emotional state. Patients with complications are also found to be more physically active and to check their feet more often than patients without complications. Weak, but logical correlations are found between illness perceptions and self-care; beliefs of personal control and T2DM being a chronic condition positively relates to healthier exercise and dietary behaviours and increased foot care respectively, while perceptions of own behaviours as a cause for T2DM negatively relates to fruit and vegetable intake and not smoking. Differences in self-care over the course of illness have been described in **chapter 3**, where the combined data of all three studies show that patients with a longer diabetes duration are less physically active, but monitor their glucose levels more frequently than patients who were more recently diagnosed. Less physical activity appears to be primarily related to the presence of macrovascular complications, whereas the frequency of glucose monitoring relates to the type of treatment, in particular whether patients are on insulin treatment or not. Furthermore, it appeared that patients who experience microvascular complications are less

likely to eat healthy, but more likely to perform foot care. **Chapter 4** indicates that T2DM patients with a longer illness duration experience more diabetes-related distress. This can be primarily explained by their higher chance of experiencing microvascular complications and of being on insulin treatment. Nonetheless, overall levels of diabetes distress appear to be low throughout the course of illness.

The variation in patients' illness perceptions, self-management and diabetes-related distress over the course of illness appears to relate to the presence of complications and the intensity of the treatment regimen (e.g., insulin) rather than diabetes duration itself. The findings among our recently diagnosed sample support previous studies indicating that T2DM patients generally underestimate the seriousness of their condition and overestimate their ability to control its course until complications arise[1–3]. The positive associations between perceived controllability and engagement in healthier lifestyles confirm that perceived personal control and treatment control are important determinants of self-management [4–7] or, in terms of Social Cognitive Theory (SCT), that self-efficacy beliefs and outcome expectancies are important determinants of health behaviour [8]. The negative association between physical activity and macrovascular complications is in accordance with the known increased risk of developing heart problems as a result of a lack of exercise [9,10], and – reversely - the fear and discomfort of patients who recently experienced an Acute Coronary Event (ACE) regarding physical activity [11,12]. Finally, our finding that microvascular complications and insulin treatment relate to higher levels of distress in T2DM patients is backed up by previous studies [13–16], although diabetes-related distress is shown to be more strongly associated with psychological factors, such as coping style and social support, than clinical factors [15,17].

Overall, our findings support the notion that complications could act as a cue to action by causing T2DM patients to take their condition more seriously and, consequently, creating a sense of urgency to engage in self-management to prevent further deterioration of their condition [1,3,18]. However, in order to improve diabetes self-management, patients need to understand that these complications relate to their diabetes. For example, the majority of participating patients in our study who had recently experienced an ACE did not attribute this event to their diabetes [19], which may explain the lack of association between the presence of macrovascular complications and increased levels of diabetes-related distress in our study. Likewise, self-management behaviours will most likely only be triggered when perceived as an effective strategy to reduce the risk of further progression or development of complications (i.e. positive outcome expectancies of these behaviours) [20]. Our finding that the presence of microvascular complications is positively associated with more frequent foot care - a diabetes-specific self-care behaviour - but not with more generic health behaviours such as exercising, healthy eating and non-smoking, seems to confirm this. Reversely, it should be noted that the presence of complications may also result in less self-management when these complications interfere with the performance of specific behaviours (e.g., foot problems may hamper physical activity) or cause patients to feel less able to successfully perform these

behaviours (i.e. negative self-efficacy beliefs) [20]. This seems to be reflected by the negative association between the presence of macrovascular complications and physical activity, and the lower levels of perceived personal control found among patients with complications.

Part 2: Supporting self-management in the early phase of T2DM

The Living with diabetes course aimed to support patients and their partners in living with T2DM during their first years of illness, both behaviourally and emotionally. The protocol of the RCT on the effectiveness of the intervention was described in **chapter 5**. The brief interactive group-based course that focused on establishing adaptive illness perception models, supporting (proactive) goal and action plan setting and activating helpful ways of partner support appeared to be a suitable and acceptable manner to target self-management in this patient population, as indicated by the pilot study in **chapter 6**, but probably only for those who experience some degree of diabetes-related uncertainty or challenges. Results on the effectiveness of the course, as examined in **chapter 7**, indicate that participation has a short-term positive effect on patients' lifestyles, and a longer positive effect on their empowerment. Immediately after the course, the participants were more physically active and reported a higher intake of fruit and vegetables than the control group. These behavioural effects, however, did not sustain until six months after the course, despite the participants still feeling more empowered to manage their condition and its treatment. Levels of diabetes-related distress appear to be already low in this patient population, and remained unaffected by the intervention over time. Also, no significant intervention effects were found on patients' illness perceptions and perceived partner support.

The short-term improvements in lifestyle behaviours and the longer-term increased empowerment following the Living with diabetes course are largely in accordance with previous findings of self-management support in general [21–24] and CSM-based diabetes support specifically [25–30]. CSM-based intervention studies in T2DM have shown promising effects on health behaviours and outcomes, for instance, on glycaemic control in poorly controlled patients [25] and on lifestyle behaviours, weight loss, depression and medication adherence in ongoing and newly diagnosed patients [26-30]. However, similar to our intervention, behavioural effects usually diminished or disappeared in the long run. Contrary to our expectations and the results of the other CSM-based interventions [25–27], we did not find any significant intervention effects on participants' illness perceptions and attitudes.

Changing diet and increasing physical exercise are acknowledged to be among the most difficult aspects to tackle in diabetes management, particularly in the long-term [31–33]. Individuals are often required to change already (life)long existing behavioural patterns, as physical activity and diet are rather part of a person's overall lifestyle than diabetes-specific behaviours. Additional challenges are posed by the fact that the effects of (un)healthy behaviours often take a long time to become visible, and may not always be linked to diabetes outcomes, which – according to the principles of self-efficacy and outcome expectancies

in Bandura's SCT [8,20] – diminishes the chance of individuals initiating or maintaining these behaviours. The relatively recent diagnosis of T2DM of the participants in our study population may have contributed to the lack of intervention effects found in diabetes-specific self-care, as daily glucose monitoring [34] and daily foot checks are not generally recommended by the Dutch guidelines for all T2DM patients during the early phase of illness [35,36]. Finally, the already low baseline level of diabetes-related distress in our study sample left hardly any room for improvement by the intervention. On the other hand, as low levels of diabetes-related distress in recently diagnosed T2DM patients have previously been (partly) attributed to underestimation of the condition and not being sufficiently engaged in diabetes self-management [1], the unchanged low levels of distress in our study might indicate that illness perceptions and self-management behaviours have been targeted 'in the right manner', i.e. without causing additional distress. Finally, despite our focus on recently diagnosed T2DM patients' perceptions and beliefs as a starting point for behaviour change, no significant intervention effects were found on patients' illness perceptions and attitudes. Partly, this may have been due to our rather homogenous study population not showing a large variety in illness perceptions for the participants to mirror themselves to and change their beliefs as a result. The short-term changes in exercise and diet among the course participants may therefore be considered a direct result of the homework assignment of the third course session - in which participants were instructed to work on the goals and action plans they had developed - rather than resulting from changed illness beliefs; although it should be noted that trends were found in patients perceiving their condition to be more serious after participation in the course. Moreover, feelings of empowerment increased after participating in the course, which has been shown to be positively related to improved self-management [37–39].

Our experiences during the pilot and recruitment phase of the RCT confirmed that motivating patients for participation in a self-management support intervention in the early phase of T2DM might be particularly challenging [1]. This was reflected in the rather low participation rate, and the many patients indicating not to be interested in participating in the programme due to the (still) mild nature of their condition and/or the absence of complications or other diabetes-related problems. Furthermore, during the pilot of the intervention, it became apparent that this type of interactive group-based self-management support may require some degree of diabetes-related uncertainty in patients in order to meet their needs. As a result, a screener was developed to exclude patients who reported to manage their condition already very well and who did not experience any worries or uncertainty regarding their condition and its treatment. We are aware that application of the screener might have filtered out also those patients who underestimate their condition and overestimate how well they are dealing with it. However, our experiences during the pilot also taught us that this particular group is really difficult to motivate for active participation in the course, particularly in goal-setting and action-planning. Therefore, we preferred to exclude these patients from participation in the RCT, as they may have hindered the active participation of others in the course.

Methodological considerations

Study population

The Living with diabetes course was targeted at T2DM patients in the first years of illness, as we believe this is the phase where patients are still incorporating the condition and its treatment within the other goals and priorities that make up their daily lives, and where they have also already encountered challenges and barriers in doing so. An additional reason for focusing on this patient population was the assumption of self-management being extra challenging in the absence of diabetes-related symptoms or complications, for this often causes patients to underestimate the importance of engaging in this. A primary aim of our intervention was therefore to get patients to recognise that their condition could potentially have serious health consequences, and that self-management makes sense to diminish the changes of these complications, while the other two interventions of the Diacourse study focused more on how to deal with the physical and emotional consequences associated with diabetes-related complications. However, as was shown by the baseline data of the Diacourse study, the presence of complications was not as proportionally associated with illness duration as hypothesised beforehand. In our study population with a diabetes duration of one to three years, already one quarter of the participants indicated the presence of one or more diabetes-related complications, which was found to be related to different ways of perceiving and managing their condition. We therefore believe it might have been more suitable to distinguish the different phases in T2DM on the basis of the presence or absence of complications, or on the type of treatment, rather than on illness duration in itself.

Generalisability

For this study, we were able to reach a large and varied population of T2DM patients in their first years of illness. General practices in six different regions all across the Netherlands participated in this part of the Diacourse study. Also, since all patients in the Netherlands are registered with a general practice within the Netherlands, and all costs for participation in the course were covered for the participants, there were no patient groups excluded from participation beforehand. It should, however, be noted that only ten percent of the invited patients agreed to participate in the study. Furthermore, lower educated patient populations, who are known to be more prone to unfavourable health outcomes in diabetes [40–42], have been shown to be underrepresented in diabetes group-support [43], and it seems plausible to assume that this patient population may also not have been adequately reached by our study. As no single intervention is likely to be able to appeal to an entire patient population, targeting and tailoring self-management is of importance, as well as offering different types of support alongside each other.

Outcome measures

In this study, we decided to focus on so-called patient-reported outcomes, including self-management and quality of life, to determine effectiveness of the intervention rather than on clinical outcomes, such as glycaemic control. One drawback that should be mentioned in this regard, is the lack of available instruments to adequately capture the broad and multidimensional nature of diabetes self-management and diabetes-related quality of life at the time of the study. To assess (changes in) self-management behaviours, we used the Summary of Diabetes Self-Care Activity (SDSCA) [44] measure, which assesses lifestyle and self-care behaviours in diabetes (physical activity, diet, monitoring behaviours and smoking). Two important aspects of self-management, being communication with health care providers and coping with the social and emotional consequences of diabetes [45], are not covered by this instrument. Even though diabetes-related distress and empowerment – as assessed by the PAID and the Dutch DES-20 - somewhat cover (emotional) coping with diabetes and its treatment and consequences, a self-report questionnaire that properly covers all aspects of diabetes self-management and is sensitive to change over time was – and probably still is – not available.

We included the Problem Areas in Diabetes (PAID) scale, which assesses diabetes-related distress, as an indicator of patients' quality of life. Since distress is only one aspect of quality of life, we were unable to draw conclusions about the effects of the intervention on other aspects of quality of life. On the other hand, it should be noted that diabetes-related quality of life measures are supposed to be better able to pick up changes over time than more generic quality of life measures, and we had chosen the PAID because of its known responsiveness to interventions [46,47]. However, considering the limited focus of the PAID combined with the already low baseline levels that we found in many of the study participants, it might have had added value if we had included other, multi-dimensional measures of quality of life as well. This would have allowed us to study the effects of the intervention on participants' quality of life in more detail.

The Diacourse study consortium

We believe that the collaboration between Nivel, Amsterdam University Medical Centers, location VUmc, and Utrecht University medical center was a major strength of the study. The Diacourse study consortium consisted of researchers with various professional backgrounds, including general practitioners, epidemiologists, health scientists, and health psychologists, whom all sought to find effective strategies to support T2DM patients in the many challenges they encounter over the course of illness. This multidisciplinary team provided the valuable opportunity to combine the different perspectives and expertise that are needed to cover all the medical, behavioural, emotional and social aspects that make up the (daily) self-management regimen for type 2 diabetes. Furthermore, the mutual development of the studies on the three different support programmes allowed us to study a large and varied study

population, as datasets could be combined due to the alignment of the data collection and primary endpoints of the different studies. This provided us with the opportunity to examine diabetes self-management over the course of illness and check whether our underlying assumptions for the three separate interventions were correct.

Implications for clinical practice

Two important lessons that were learned during the study were that 1) a brief CMS-based intervention can effectively and positively change self-management behaviours, but only in the short-term, and 2) motivating patients to participate in these type of group-based self-management support intervention during the first years of illness seems to be challenging. These two findings suggest that interventions to alter illness perceptions and support diabetes self-management might be more successful when its elements are incorporated within regular diabetes care, rather than being offered in addition to this. In this manner, (almost) all T2DM patients can be reached and be offered long-term and regular self-management support. It is important that health care professionals are aware of the important role they have in this respect and that they have been sufficiently trained to explore and discuss patients' perceptions and behaviours. We believe that regularly exploring and discussing patients perceptions towards their illness and treatment is an essential part of good-quality diabetes care, all the more because new information, skills and behaviours are less likely to be adopted by individuals when these are not compatible with their already existing illness beliefs [48,49]. In doing so, health care professionals should, however, keep in mind that they ask about patients' perceptions of their own condition and treatment, as these perceptions may differ from patients' perceptions of T2DM in general. Also, health care professionals need to be aware that, when discussing the impact of T2DM, they often tend to focus on future well-being, while people with diabetes emphasise the impact of the demands of diabetes management in the present [50,51]. Therefore, diabetes-related goals ideally take both short- and long-term gains and demands into account, and are integrated within other goals and activities in patients' daily lives. Furthermore, more prolonged guidance may be needed in order to establish sustainable behavioural change in patients, which could be established by incorporating proactive goal-setting and action-planning within the three-monthly check-ups that T2DM patients in the Netherlands have with their diabetes or practice nurse.

Our findings indicate that supporting self-management should be tailored to the specific challenges that are encountered in living with T2DM. Differentiating between patients with and patients without complications might particularly be warranted, considering the differences found in the way they cognitively, behaviourally and emotionally manage T2DM. Several studies and psychological models – including the CSM [52,53] and Health Belief Model (HBM) [54,55] – stress the importance of both perceived seriousness and perceived (personal) controllability as important determinants for patients' (motivation for) self-management. The shift towards T2DM being perceived as more uncontrollable in the presence

of complications may therefore undo the potentially beneficial effect of perceiving T2DM a more serious condition, which also often happens when complications appear. In patients without complications, health care professionals may therefore need to specifically underline the serious consequences of T2DM and the necessity to engage in self-management to prevent these, while patients with complications should rather be supported in regaining (perceived) control over the T2DM.

Implications for future research

We have argued that tailoring interventions to different illness phases, or perhaps even life phases, is important to increase participation in and effectiveness of diabetes self-management support interventions. In order to be able to properly tailor interventions to T2DM patient populations with different needs for support, more insight is needed in the differences in effectiveness between patient subpopulations, which calls for subgroup analyses. As mentioned before, one could imagine that the intervention might have had different effects in patients with complications than in patients without complications, considering these subgroups already perceived and managed their condition differently prior to the intervention. The presence of diabetes-related complications being a wake-up call for many patients to take their condition seriously and invest time and effort in self-management brings us to the next challenge that should be further investigated. Since one of the primary objectives of diabetes management is to prevent complications as much as possible, one of the major objectives in diabetes self-management research remains to find successful ways to help patients understand the importance of self-management before diabetes-related complaints arise. A similar challenge in which more insight is still needed is how sustainable changes in lifestyle and health behaviours can be achieved by self-management support interventions, in particular in patients who need to change (life)long maladaptive behavioural patterns, and when effects of behavioural change take a long time to become visible to individuals. Finally, we believe that future research should focus on developing questionnaires that can both capture the multifaceted nature of diabetes self-management and quality of life, and be sensitive to change over time. Both qualities are required to be able to properly judge whether support interventions have an effect on the several dimensions that make up self-management and health-related quality of life, instead of just on self-care behaviours and distress.

Conclusion

Patients with T2DM need lifelong self-management support, which should be tailored to individual needs and preferences that may change over time. Self-management support should differ over the course of illness, as patients appear to perceive and manage their condition differently when they have complications or are on insulin treatment. In the absence of complications, T2DM and its consequences are generally underestimated and, consequently, motivating patients for self-management (support) in the early phase of T2DM is challeng-

ing. Self-management support that focusses on establishing adaptive illness perceptions, supporting goal-setting and action-planning and mobilising effective ways of social support in the first years after diagnosis can effectively improve T2DM patients' empowerment and lifestyle. However, as the behavioural changes are short-lived, continuous self-management support incorporated in regular diabetes care is needed.

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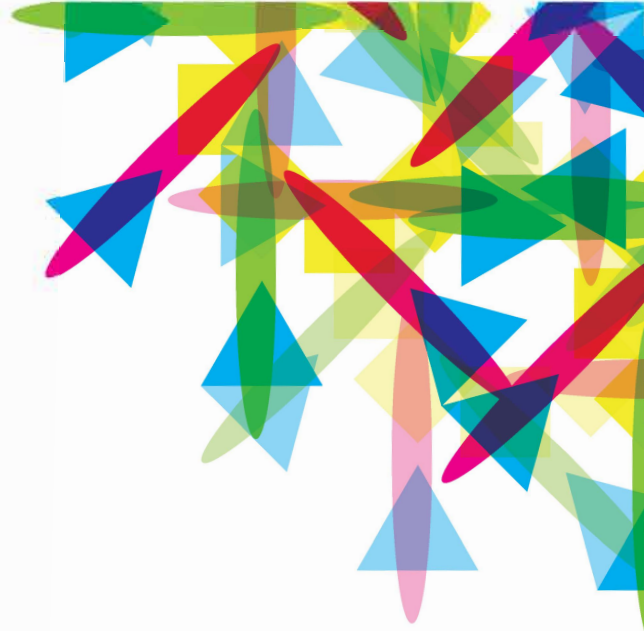
Summary

Being diagnosed with type 2 diabetes (T2DM) confronts patients with the challenging task of adapting to living with a chronic and progressive condition on a day-to-day basis. Despite the often asymptomatic manifestation of the condition, T2DM can result in serious complications which can have a major impact on the physical and mental health of patients. While active engagement in a multifaceted self-management regimen can diminish the risk of adverse diabetes-related health events, many patients perceive this to be a challenging task in which many barriers are encountered. Patients may also struggle emotionally with their condition and its treatment and (potential) consequences, which can – directly and indirectly - impact on their health. Finally, the progressive nature of the condition may require patients to adapt their self-management strategies over time, for instance, as a result of changes in treatment or complications. Considering that coping with a chronic disease and the lifestyle changes inherent to this are difficult for many, ongoing self-management support should be offered throughout the course of illness. We therefore developed the Diacourse study, which aimed to improve self-management and diabetes-specific health-related quality of life (i.e. diabetes distress) by 1) examining the self-management support needs of patients over the course of T2DM, and 2) developing and evaluating three self-management support programmes tailored to patients' needs in three different phases of the illness process. In this thesis, we focused on self-management (support) during the first few years after diagnosis, which is a phase in the illness process where patients are still figuring out ways to effectively incorporate the condition and its treatment within their daily lives. Particularly challenging in this mainly asymptomatic phase of illness is that many patients do not seem to take their condition seriously and postpone lifestyle changes and self-care behaviours until diabetes-related complications appear. By targeting patients' perceptions of their condition and its treatment and challenging the incorrect ones, and by enhancing their feelings of self-efficacy and support from close others, the Living with diabetes course aimed to improve self-management and diabetes-specific health-related quality of life in patients who had been diagnosed with T2DM for 1 – 3 years.

In the first part of this thesis, we examined the illness perceptions, self-management and diabetes-distress levels of patients over the course of T2DM. The Illness Perceptions Questionnaire Revised (IPQ-r) was used to assess the different illness perceptions dimensions that make up the personal models that individuals hold about their illness: identity, timeline acute/chronic, timeline cyclical, consequences, personal control, treatment control, illness coherence, emotional representations, and cause. Self-care, which is one of the aspects of self-management, was measured by the Summary of Diabetes Self-Care Activities (SDSCA) measure, which assessed how many days during the past week the following self-care activities were performed by patients: exercise, glucose monitoring, foot care, general diet, fruit and vegetable intake, fat intake and smoking. Diabetes-distress, which was used to assess diabetes-specific health-related quality of life, was measured by the Problem Areas in Diabetes (PAID) scale.

Chapter 2 describes the illness perceptions, self-care behaviours and their relationship in T2DM patients during the first years of illness, and examined whether these differed between patients with and patients without diabetes-related complications. Cross-sectional data from 192 T2DM patients with a known illness duration between 1 – 3 years were analysed. Findings showed that patients generally perceived T2DM as a chronic, yet controllable condition but with only minor consequences. Patients with complications, however, perceived their condition as more unpredictable and less controllable through self-care and medical treatment, and its consequences as more serious. Patients with complications were more physically active and performed foot care more often. Associations were found between perceptions of personal control and more exercise and healthier dietary behaviours, perceptions of T2DM being a chronic condition and more foot care, and between perceptions of past behaviours as a cause for diabetes and lower fruit- and vegetable intake and smoking. These study findings support previous studies indicating that, in the absence of complications, patients tend to underestimate the seriousness of T2DM and postpone lifestyle changes and self-care until complications appear. Hence, the challenge for health care professionals remains how to convince asymptomatic patients of the importance of self-management in order to prevent diabetes-related complications from occurring.

Chapter 3 discusses the relationship between the time that patients have been diagnosed with T2DM (diabetes duration) and their self-care behaviours, and the extent to which these relations are explained by the presence of complications, type of treatment regimen and levels of diabetes-related distress. Cross-sectional data from 590 participants of the three Diacourse studies were analysed. Patients with a longer diabetes duration reported to be physically active for fewer days, but to check their glucose level more frequently than patients with a shorter diabetes duration. The presence of macrovascular complications and the use of insulin partially explained these relationships with exercise and glucose monitoring respectively. The presence of microvascular complications was positively associated with foot care, but negatively with following general dietary recommendations. Finally, patients who reported higher levels of diabetes-related distress were more often smokers. Maximally 5% of the variance in self-care was explained by these models, except for smoking (11%) and glucose monitoring (37%). Even though other personal or illness-related factors than the ones assessed in this study seem to influence self-care, we do believe that tailoring support to the phase of illness - and to the presence or absence of complications in particular - might benefit patients' self-management.

In **chapter 4**, the relationship between diabetes duration and diabetes-related distress was examined among 590 T2DM patients, as well as the extent to which complications and type of treatment impacted this relation. Diabetes duration was linearly and quadratically related to higher levels of diabetes-related distress in patients. This association could be explained by the presence of microvascular complications and insulin treatment, which were more often found among patients with a longer diabetes duration, and which were positively related

to higher levels of diabetes-related distress. The model containing diabetes duration, age, gender, micro- and macrovascular complications and type of treatment explained 13% of the variance in diabetes-related distress. We suggest that health care professionals pay attention to diabetes-distress over the course of illness, and particularly when microvascular complications are present or when patient use insulin to control their diabetes. However, the explained variance of 13% indicates that diabetes-related distress is influenced by other factors as well.

In the second part of the thesis, we developed an intervention aimed to support T2DM patients in their self-management during the first years of illness, and evaluated its effects in a pilot study and randomised controlled trial (RCT). Illness and treatment beliefs, which are central components in Leventhal's Common-Sense Model of Self-Regulation (CSM), were primary targets in our intervention. Furthermore, Bandura's Social Cognitive Theory (SCT) and social support theories were incorporated in the theoretical framework of the intervention.

Chapter 5 describes the protocol of the RCT study to test the effectiveness of the group-based self-management support programme for relatively recently diagnosed T2DM patients and their partners. The aimed study population consisted of 160 T2DM patients from different regions in the Netherlands who had been diagnosed with T2DM between one and three years ago, and who indicated to experience some degree of diabetes-related uncertainty, as assessed by a three-item screener. The intervention group received a group-based course consisting of three monthly sessions and a booster session three months later, focusing on illness perceptions, goal and action plan setting for self-management, and social support. The control group was invited to a single educational lecture. Data were collected as baseline, (T0) immediately after the third course session (T1), and six months after the third course session (T2) and included self-care and diabetes-related distress as primary outcomes, and illness perceptions, attitudes, empowerment and social support as secondary outcomes. Multilevel analyses were used to determine the intervention's effect. The results of our study will contribute to the still relatively sparse knowledge on the effectiveness of CSM-based intervention in diabetes.

Chapter 6 reflects on the theoretical background of the group-based self-management programme and the first experiences obtained during a pilot of the intervention. A three-session group-based course was developed, based on principles of the CSM, SCT and social support theories. The course aimed to improve self-management and quality of life in patients by changing maladaptive illness perceptions, enhancing self-efficacy by practicing goal-setting and behavioural actions, and creating a supportive environment by discussing helpful ways of providing social support. The intervention was piloted in T2DM patients with a known illness duration between one and three years, who were selected from one general practice. Sixteen of the 74 inviting patients agreed to participate (participation rate: 22%), and were divided in two groups: one group of patients (n = 8) participating with their partner, and one group of patients (n = 8) attending the sessions alone. Data were retrieved by observation and audio-recordings of the sessions, discussion between the group leaders, and evaluation

forms filled in by the participants. Overall, the intervention was deemed feasible and suitable by the participants and course leaders. The group-based format and participation of partners was generally appreciated. The challenges encountered during the goal setting and action plan development, however, indicated that patients needed to experience some degree of diabetes-related challenges or uncertainty to be sufficiently motivated for active participation in the course, which called for the development of a screener for the RCT. The observed discrepancies between perceptions of one's own condition and T2DM in general should also be taken into account when discussing patients' perceptions.

In **chapter 7**, the immediate and six-month effectiveness of the group-based self-management support programme was evaluated in a RCT. T2DM patients (diagnosed one to three years ago) from six different regions in the Netherlands were invited for the study, of which 10% was willing to participate. Multilevel analyses were conducted on 82 patients in the intervention group and 86 patients in the control group, according to the intention-to-treat principle. The intervention group showed a significantly higher increase in physical activity and fruit and vegetable intake than the control group, although these effects did not sustain until six months after the intervention. Despite higher beliefs of diabetes being caused by chance/bad luck, the intervention group also felt more empowered to handle their condition and its treatment than the control group; a finding that was still retrieved six months after the intervention. As similar short-term behavioural effects were found in other CSM-based interventions, we believe that more prolonged support is needed to achieve more sustainable lifestyle changes, for instance, by incorporating elements of the intervention within regular diabetes care.

In **chapter 8**, our findings and its implications, and the methodological considerations are discussed. From our study findings, it can be concluded that self-management, and therefore self-management support needs, differ over the course of T2DM. Furthermore, it was shown that a brief CSM-based interactive course specifically aimed at T2DM patients and their partners in the early phase of illness had positive effects on participants' physical activity and dietary behaviours in the short-term, and longer-term positive effects on empowerment. The presence of complications and type of treatment regimen should specifically be taken into account when tailoring interventions to different phases in the illness process, rather than diabetes duration. In asymptomatic patients, the challenge of self-management support primarily lies in convincing patients of the importance of lifestyle changes and self-care behaviours, while in patients with complications support should rather focus on gaining (back) feelings of personal controllability over T2DM. Some degree of diabetes-related uncertainty appears to be necessary in order for patients to be motivated to actively engage in group-based self-management support programmes that include goal-setting and action-planning. Furthermore, the link between health behaviours and outcomes in T2DM should be clear for

patients in order to motivate them for self-management. Finally, it appears that long-term changes call for long-term support by health care professionals.

The small proportion of participating patients may have had its consequences for the generalizability of the study results. Another methodological aspect of the study that should be considered is that both the SDSCA measure and the PAID only assessed elements of self-management and health-related quality of life, rather than covering the entire multifaceted constructs. Adding other multidimensional measures of quality of life would have allowed us to study the intervention's effect more into detail, especially considering that diabetes-related distress - the aspect of quality of life we measured - was already low at baseline. One major strength of the study was the consortium between the three different research centers that allowed us combine data, as well as knowledge and experience to examine (effective strategies for) self-management.

Our study findings have resulted in some recommendations for clinical practice and future research. Considering the challenge of getting and keeping patients engaged in (long-term) behavioural changes, particularly in the early, often asymptomatic phase of T2DM, we suggest that elements of the intervention are incorporated within regular diabetes care, rather than offered additionally. Ideally, illness- and treatment perceptions, and their diabetes-related goals and their associated short- and long-term gains and pains are discussed during the three-monthly check-ups, in order to find successful and sustainable ways to incorporate the care for T2DM within the daily lives of patients, and to identify potential barriers in time. In order to properly tailor self-management support and increase its effectiveness, more insight should be gained into the effects of interventions among different patients populations, as well as into successful ways to yield long-term effects in exercise and diet. Finally, to properly assess the effects of future interventions, instruments for self-management and quality of life should be developed that are capable of capturing the broad nature of these concepts, but that are also sensitive enough to detect change over time.
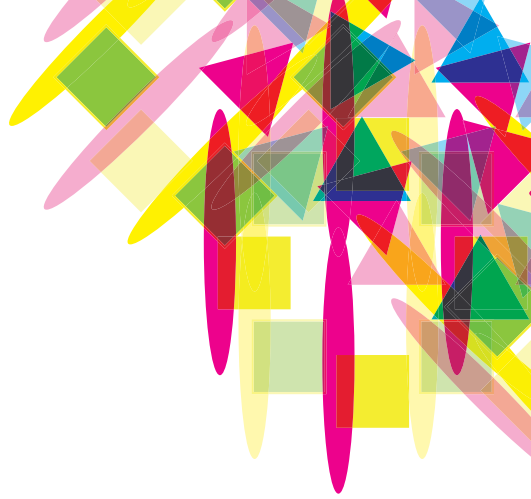
Samenvatting

Gediagnosticeerd worden met type 2 diabetes (T2DM) stelt patiënten voor de uitdaging om te leren om dagelijks te leven met een chronische en progressieve aandoening. Ondanks het feit dat T2DM zich meestal zonder symptomen aandient, kan de aandoening leiden tot ernstige complicaties die een grote invloed kunnen hebben op de lichamelijke en mentale gezondheid van patiënten. Actieve betrokkenheid bij zelfmanagement kan het risico op ongunstige diabetesgerelateerde gebeurtenissen verminderen, maar veel patiënten beschouwen dit als een moeilijke taak waarin zij veel obstakels tegenkomen. Patiënten kunnen ook in emotionele zin worstelen met hun aandoening, de behandeling en (potentiële) gevolgen hiervan, wat hun gezondheid direct en indirect kan beïnvloeden. Tot slot kan de progressieve aard van de aandoening erom vragen dat patiënten hun zelfmanagementstrategieën in de loop van de tijd aanpassen, bijvoorbeeld als gevolg van veranderingen in de behandeling of complicaties. Aangezien het omgaan met een chronische aandoening en de leefstijlveranderingen die hierbij horen voor veel mensen een lastige opgave is, zou zelfmanagementondersteuning gedurende het verloop van de ziekte eigenlijk doorlopend aangeboden moeten worden. We hebben daarom de Diacourse studie ontwikkelt, met als doel om zelfmanagement en diabetesspecifieke kwaliteit van leven (diabetesgerelateerde stress) te verbeteren door 1) te onderzoeken welke behoeften patiënten hebben aan zelfmanagementondersteuning gedurende het verloop van T2DM en 2) het ontwikkelen en evalueren van drie zelfmanagementondersteuningsprogramma's die zijn afgestemd op de behoeften van patiënten die zich in drie verschillende fases in het ziekteproces bevinden. In deze thesis focusten we op zelfmanagement(ondersteuning) gedurende de eerste jaren na diagnose; een fase in het ziekteproces waarin patiënten nog aan het uitzoeken zijn hoe zij hun aandoening en behandeling op een effectieve manier kunnen integreren in hun dagelijks leven. Een grote uitdaging is dat veel patiënten gedurende deze voornamelijk asymptomatische fase van de aandoening deze niet erg serieus lijken te nemen en leefstijlverandering en zelfzorg uitstellen totdat er complicaties verschijnen. Het Leven met diabetes programma beoogt zelfmanagement en kwaliteit van leven te verbeteren bij patiënten die één tot drie jaar geleden zijn gediagnosticeerd met T2DM en is gericht op hun ziekte- en behandelpercepties, het betwisten van onjuiste percepties, en door het verbeteren van hun vertrouwen in eigen kunnen en ondersteuning door naasten.

In het eerste deel van deze thesis onderzochten we ziektepercepties, zelfmanagement en diabetesgerelateerde stress bij patiënten gedurende het verloop van T2DM. De gereviseerde Illness Perceptions Questionnaire (IPQ-r) werd gebruikt om de verschillende ziekteperceptiedimensies te meten van het beeld dat individuen vormen over hun aandoening: identiteit, tijdlijn acuut/chronisch, tijdlijn cyclisch, consequenties, persoonlijke controle, controle door behandeling, coherentie/begrip van de aandoening, emotionele representaties, en oorzaak. Zelfzorg, één van de aspecten van zelfmanagement, werd gemeten met de Summary of Self-Care Activities (SDSCA) vragenlijst, die vaststelde op hoeveel dagen gedurende de afgelopen week patiënten de volgende zelfzorgactiviteiten hebben uitgevoerd: beweging,

glucose monitoring, voetzorg, dieet gevolgd, groente- en fruitinname, vetinname en roken. Diabetesgerelateerde stress, wat gebruikt als indicator voor kwaliteit van leven, werd gemeten met de Problem Areas in Diabetes (PAID) schaal.

Hoofdstuk 2 beschrijft de ziektepercepties, zelfzorg en hun onderlinge relatie in T2DM-patiënten gedurende de eerste jaren van de ziekte, en onderzocht of deze verschilden tussen patiënten met en zonder diabetesgerelateerde complicaties. Cross-sectionele data werden ge-analyseerd van 192 T2DM-patiënten met een ziekteduur tussen de één en drie jaar. Resultaten lieten zien dat patiënten, over het algemeen, T2DM beschouwden als een chronische, maar toch controleerbare aandoening met weinig gevolgen. Patiënten met complicaties, echter, ervoeren hun aandoening als minder voorspelbaar en minder controleerbaar door zelfzorg en medische behandeling, en met ernstigere gevolgen. Patiënten met complicaties waren vaker lichamelijk actief en deden meer aan voetzorg. Associaties werden gevonden tussen percepties van persoonlijke controle en beter beweeg- en dieetgedrag, tussen percepties van T2DM als chronische aandoening en meer voetzorg, en tussen percepties van eigen gedrag als oorzaak voor T2DM en roken en een lagere inname van groenten en fruit. Deze studiebevindingen ondersteunen eerdere studies die erop wijzen dat, in de afwezigheid van complicaties, pati-enten de neiging hebben om de ernst van T2DM te onderschatten en leefstijlveranderingen uit te stellen totdat complicaties optreden. De uitdaging voor zorgverleners blijft dan ook hoe zij asymptomatische patiënten kunnen overtuigen van het belang van zelfzorg om ervoor te zorgen dat complicaties niet op zullen treden.

Hoofdstuk 3 bespreekt de relatie tussen hoe lang geleden patiënten zijn gediagnosticeerd met T2DM (diabetesduur) en hun zelfzorggedrag, en de mate waarin deze relaties verklaard worden door de aanwezigheid van complicaties, type behandeling en het niveau van diabetes-gerelateerde stress. Cross-sectionele data van 590 deelnemers aan de Diacourse studie werden geanalyseerd. Patiënten met een langere diabetesduur gaven aan minder dagen lichamelijk actief te zijn, maar vaker hun bloedglucoseniveaus te checken dan patiënten met een kortere diabetesduur. Deze relaties met lichaamsbeweging en glucosemonitoring werden gedeelte-lijk verklaard door respectievelijk de aanwezigheid van macrovasculaire complicaties en het gebruik van insuline. De aanwezigheid van microvasculaire complicaties was positief geassocieerd met voetzorg, maar negatief geassocieerd met het opvolgen van algemene dieetadviezen. Tot slot waren patiënten die hogere niveaus van diabetesgerelateerde stress rapporteerden vaker rokers. Deze modellen verklaarden maximaal 5% van de variantie in zelfzorg, behalve bij roken (11%) en glucosemonitoring (37%). Alhoewel zelfzorg beïnvloed lijkt te worden door andere persoonlijke of ziektegerelateerde factoren dan in dit onderzoek zijn gemeten, zijn we toch van mening dat het afstemmen van ondersteuning op de fase van de ziekte, en dan in het bijzonder op de aanwezigheid of afwezigheid van complicaties, het zelfmanagement van patiënten ten goede kan komen.

In **hoofdstuk 4** werd onder 590 T2DM patiënten de relatie tussen diabetesduur en dia-betesgerelateerde stress onderzocht, evenals de mate van invloed van complicaties en het

type behandeling op deze relatie. Diabetesduur bleek lineair en kwadratisch gerelateerd aan hogere niveaus van diabetesgerelateerde stress. Deze associatie werd deels verklaard door de aanwezigheid van microvasculaire complicaties en behandeling met insuline, welke vaker voorkomen bij patiënten met een langere diabetesduur, en welke gerelateerd zijn aan hogere niveaus van diabetesgerelateerde stress. Het statistisch model dat diabetesduur, leeftijd, geslacht, micro- en macrovasculaire complicaties en type behandeling bevat, verklaarde 13% van de variantie in diabetesgerelateerde stress. Wij raden zorgverleners aan om gedurende het ziekteverloop aandacht te besteden aan diabetesgerelateerde stress, met name wanneer er microvasculaire complicaties zijn of wanneer patiënten insuline gebruiken om hun diabetes te behandelen. De verklaarde variantie van 13% laat echter zien dat diabetesgerelateerde stress ook door andere factoren wordt beïnvloed.

In het tweede deel van de thesis ontwikkelden wij een interventieprogramma dat gericht is op het ondersteunen van T2DM-patiënten bij hun zelfmanagement gedurende de eerste ziektejaren, en evalueerden de effectiviteit van het programma in een pilotstudie en een gerandomiseerde gecontroleerde trial (RCT). Ziekte- en behandelpercepties, welke centrale componenten zijn in Leventhal's Commen-Sense Model of Self-Regulation (CSM), waren primaire speerpunten in onze interventie. Verder maakten Badura's Social Cognitive Theory (SCT) en theorieën over sociale steun deel uit van het theoretische raamwerk van het programma.

Hoofdstuk 5 beschrijft het protocol van de RCT studie die de effectiviteit test van het groepsprogramma voor zelfmanagementondersteuning bij recentelijk gediagnosticeerde T2DM-patiënten en hun partners. De beoogde studiepopulatie bestond uit 160 T2DM-patiënten uit verschillende regio's in Nederland, die tussen de één en drie jaar geleden gediagnosticeerd zijn met T2DM en die enige mate van diabetesgerelateerde onzekerheid ervoeren, zoals werd aangegeven door een screeningsvragenlijst met drie vragen. De interventiegroep nam deel aan een groepscursus bestaande uit drie maandelijkse bijeenkomsten en één terugkombijeenkomst drie maanden later, welke zich richtten op ziektepercepties, het stellen van zelfmanagementdoelen en actieplannen en sociale steun. De controlegroep werd uitgenodigd voor een éénmalige informatiebijeenkomst. Data werd verzameld met vragenlijsten op baseline (T0), direct na de derde cursusbijeenkomst (T1) en zes maanden na de derde cursusbijeenkomst (T2). Zelfzorg en diabetesgerelateerde stress waren primaire uitkomsten, en ziektepercepties, attitudes, empowerment en sociale steun waren secondaire uitkomsten. Het interventie-effect werd bepaald d.m.v. multilevelanalyses. De resultaten van onze studie zullen bijdragen aan de nog schaarse kennis over de effectiviteit van interventies gebaseerd op het CSM in diabetes.

Hoofdstuk 6 reflecteert op de theoretische achtergrond van het groepsprogramma voor zelfmanagementondersteuning en de eerste ervaringen die zijn opgedaan tijdens een pilot van de interventie. Een groepscursus bestaande uit drie sessies werd ontwikkeld, gebaseerd op

principes uit het CSM, de SCT en theorieën over sociale steun. Het doel van de cursus was om zelfmanagement en kwaliteit van leven onder patiënten te verbeteren door middel van het veranderen van ongunstige ziektepercepties, het verbeteren van het vertrouwen in eigen kunnen en het creëren van een steunende omgeving door te bespreken op welke manieren nuttige ondersteuning geboden kan worden. De pilot van de interventie werd uitgevoerd onder T2DM-patiënten met een ziekteduur tussen de één en drie jaar en werden geselecteerd uit één huisartsenpraktijk. Zestien van de 74 uitgenodigde patiënten stemden toe om deel te nemen (participatiegraad: 22%) en werden onderverdeeld in twee groepen: één groep patiënten (n = 8) die deelneemt met hun partner, en één groep patiënten (n = 8) die in hun eentje deelneemt. Data werden verzameld door middel van observatie en audio-opnamen van de sessies, besprekingen tussen de groepsbegeleiders en evaluatieformulieren die ingevuld werden door de deelnemers. Over het algemeen werd de interventie haalbaar en geschikt bevonden door de deelnemers en de cursusbegeleiders. Het groepsformat en de deelname van partners werd over het algemeen gewaardeerd. De uitdagingen die tijdens het opstellen van de doelen en actieplannen naar voren kwamen, geven echter aan dat patiënten een bepaalde mate van diabetesgerelateerde moeilijkheden of onzekerheid moeten ervaren om voldoende gemotiveerd te zijn voor actieve deelname aan de cursus. Dit vroeg om de ontwikkeling van een screener voor de RCT studie. Ook moet tijdens het bespreken van de percepties van patiënten rekening gehouden worden met de verschillen die waargenomen werden tussen de percepties van de eigen aandoening en die van T2DM in het algemeen.

In **hoofdstuk 7** werd door middel van een RCT geëvalueerd wat de effectiviteit direct na afloop en na zes maanden was van het groepsprogramma voor zelfmanagementonder-steuning. T2DM-patiënten (één tot drie jaar geleden gediagnosticeerd) uit zes verschillende regio's in Nederland werden uitgenodigd voor de studie, waarvan 10% bereid was om deel te nemen. Multilevelanalyses werden volgens het intention-to-treat principe uitgevoerd bij 82 patiënten in de interventiegroep en 86 patiënten in de controlegroep. De interventiegroep liet significant meer verbetering zien op lichaamsbeweging en groente- en fruitinname dan de controlegroep, hoewel deze verschillen niet aanhielden tot zes maanden na de interventie. Ondanks dat de interventiegroep er meer in geloofde dat diabetes door pech veroorzaakt wordt dan de controlegroep, voelden zij zich ook meer empowered om om te kunnen gaan met hun aandoening en de behandeling dan de controlegroep: een resultaat dat zes maanden na de interventie nog steeds gevonden werd. Aangezien andere interventies gebaseerd op het CSM-model soortgelijke resultaten laten zien, denken we dat het teweeg brengen van langdu-rigere leefstijlveranderingen vraagt om langere ondersteuning, bijvoorbeeld door elementen van de interventie te integreren in de reguliere diabeteszorg.

In **hoofdstuk 8** worden (de implicaties van) onze bevindingen en de methodologische overwegingen besproken. Uit onze studiebevindingen kan worden geconcludeerd dat zelf-management, en daarom zelfmanagementbehoeften, verschillen gedurende het ziekteverloop

van T2DM. Daarnaast is er aangetoond dat een korte interactieve cursus die gebaseerd is op het CSM en zich specifiek richt op T2DM patiënten in de eerste fase in het ziekteproces en hun partners een positief kortetermijneffect had op lichaamsbeweging en dieet, en een langeretermijneffect op empowerment bij de deelnemers. Bij het aanpassen van interventies op de verschillende fases in het ziekteproces zou men eerder rekening moeten houden met de aanwezigheid van complicaties en het type behandeling dan met de ziekteduur. Bij asymptomatische patiënten ligt de uitdaging voor zelfmanagementondersteuning met name bij het overtuigen van deze patiënten van het belang van leefstijlveranderingen en zelfzorg, terwijl ondersteuning bij patiënten met complicaties zich juist zou moeten richten op het (terug)krijgen van het gevoel van persoonlijke controle over T2DM. Een bepaalde mate van diabetesgerelateerde onzekerheid lijkt noodzakelijk voor patiënten om gemotiveerd te zijn om actief deel te nemen aan zelfmanagementondersteuningsprogramma's waarin doelen en actieplannen moeten worden opgesteld. Daarnaast moet de link tussen gezondheidsgedragingen en uitkomsten duidelijk zijn om patiënten gemotiveerd te krijgen voor zelfmanagement. Tenslotte lijkt het erop dat langetermijnverandering vraagt om langetermijnondersteuning door zorgverleners.

De kleine groep deelnemende patiënten kan gevolgen hebben gehad voor de generaliseerbaarheid van de studieresultaten. Een ander methodologisch aspect van de studie waar rekening mee gehouden moet worden, is dat zowel de SDSCA vragenlijst als de PAID schaal slechts elementen van zelfmanagement en kwaliteit van leven maten, in plaats van dat zij de gehele veelzijdige constructen omvatten. Het toevoegen van andere multidimensionale meetinstrumenten voor kwaliteit van leven had ervoor kunnen zorgen dat wij het effect van de interventie gedetailleerder hadden kunnen onderzoeken, vooral wanneer je bedenkt dat diabetesgerelateerde stress – het aspect van kwaliteit van leven dat we hebben gemeten – op baseline al laag bleek te zijn. Een sterk punt van deze studie was het consortium tussen de drie verschillende onderzoekscentra dat ervoor zorgde dat zowel data, als kennis en ervaring gecombineerd kon worden in het onderzoek naar (effectieve strategieën voor) zelfmanagement.

Onze studieresultaten hebben geleid tot een aantal aanbevelingen voor de klinische praktijk en toekomstig onderzoek. Rekening houdend met het feit dat het een uitdaging is om patiënten betrokken te krijgen en te houden bij (langdurige) leefstijlverandering, met name in de vroege, vaak asymptomatische fase van T2DM, raden wij aan om elementen van de interventie aan te bieden in de reguliere diabeteszorg, in plaats van deze aanvullend aan te bieden. Idealiter worden ziekte- en behandelpercepties, en diabetesgerelateerde doelen en de investeringen en opbrengsten op de korte en lange termijn die hierbij horen besproken tijdens de driemaandelijkse controlemomenten om zo succesvolle en duurzame manieren te vinden om de zorg voor T2DM te integreren in het dagelijks leven van patiënten en eventuele barrières tijdig te signaleren. Om zelfmanagementondersteuning op de juiste manier op maat te kunnen maken en de effectiviteit ervan te vergroten, is er meer inzicht nodig in de effecten van interventies in verschillende patiëntpopulaties, evenals in succesvolle manieren

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Ondersteuning vanuit de omgeving was niet alleen een belangrijk thema ín mijn proefschrift, maar zeker ook tíjdens mijn proefschrift. Talloze mensen hebben mij de afgelopen jaren op verschillende manieren geholpen, waardoor ik nu - bijna tien jaar na de start - alsnog mijn dankwoord kan schrijven. Lieve (oud-)collega's, vrienden en familie: dit hoofdstuk is voor jullie.

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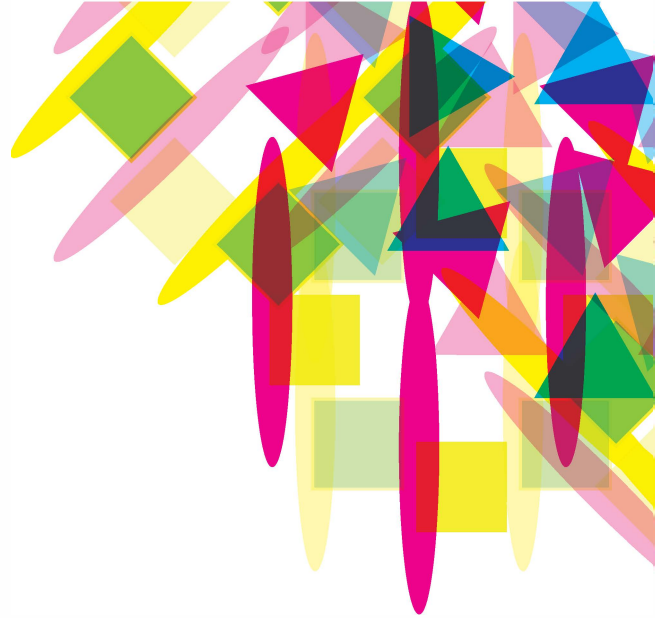
About the author

Anne Lieuwkje van Puffelen was born on the 1st of October in Delft, the Netherlands. In 2002, she finished her secondary education at the Christelijk Lyceum in Delft and started her study in Psychology at the University of Leiden in 2003. In 2009, she obtained a Master in Health Psychology with a thesis on the effects of implementation intentions on condom preparatory and condom use behaviours in Dutch and Belgian youngsters. During her Master's study, she also worked as an internship student at the Trimbos-instituut in Utrecht on the 'Collaborative Care: Depression Initiative in the Medical setting (CC:DIM)' project were she conducted an observational study on the relationship between diabetes-related complications and depression. The experiences gained during this internship paved the way to becoming a PhD student on one of the three self-management support programmes of the Diacourse study at the Nivel in Utrecht from 2010 until 2015.

After the Diacourse study, Anne has worked as a researcher on the HIV Transmission Elimination Amsterdam (H-TEAM) project at the AIGHD in Amsterdam until 2017. Currently, she works as an assistant for the Interstitial Lung Disease (ILD) and Pulmonary Hypertension (PH) team at the Erasmus MC in Rotterdam.

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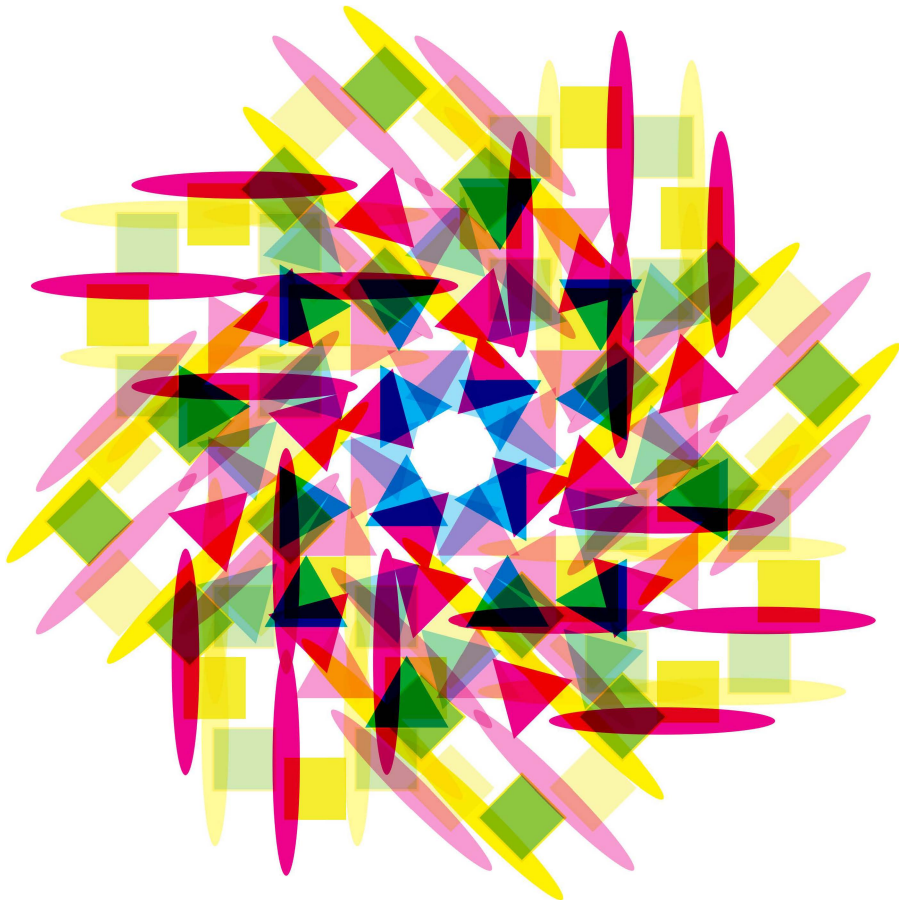
*"Life is like an ever-shifting kaleidoscope
- a slight change, and all patterns alter"* -

Sharon Salzberg

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