1

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 recognize 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 indispensible roles in how the goals and recommendations of diabetes self-management are being pursued. While many programmes have focused 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 focusing on their illness and treatment perceptions. **Programme 2** focused 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.
REFERENCES


40. Broadbent E, Donkin L, Stroh JC. Illness and treatment perceptions are associated with adherence to medications, diet, and exercise in diabetic patients. Diabetes Care. 2011; doi:10.2337/dc10-1779


