From protocol to personalised care: improving and tailoring diabetes management in general practice

Bruggen, S. van

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General introduction

Prevalence and impact of type 2 diabetes mellitus

The prevalence of type 2 diabetes has been rising sharply for decades, and according to WHO estimates, globally 422 million adults aged over 18 years were living with diabetes in 2014 (1). Approximately 85 percent of all diabetes cases are type 2 (2), with an estimated increase to 500 million adults by 2028 (3). In line with global trends, the number of type 2 diabetes cases in primary care registry in the Netherlands has risen dramatically in recent years. increasing from an estimated 3.0 percent in 2000, type 1 diabetes included (4), to 6.0 percent of type 2 alone in 2015 and 2019 (5).

Type 2 diabetes occurs when the body cannot effectively use the insulin it produces. This results in raised levels of glycated haemoglobin (HbA1c). Over time, persistently high HbA1c levels cause serious damage to many of the body's systems, especially the nerves and blood vessels (6), culminating in a considerably higher risk for heart attack and stroke (7). A substantial proportion of people with type 2 diabetes will die prematurely as a result of cardiovascular causes (8-10). Furthermore, reduced blood flow in combination with nerve damage causes additional microvascular complications such as nephropathy, retinopathy, neuropathy and small vessel vasculopathy (9, 11). These pathologies can lead to serious health problems such as foot ulcers, infections and possibly the need for limb amputation (12). Diabetic retinopathy, which is related to long-term accumulated damage to the small blood vessels in the retina, is an important cause of blindness (13). Furthermore, diabetes is one of the leading causes of kidney failure (14). In summary, type 2 diabetes is a serious chronic condition with potentially severe health complications.

Importance of lifestyle adjustment and self-management skills

In terms of risk of diabetes-related complications, individuals do have considerable influence on the course of their disease. Obtaining a healthy weight and physical exercise alone are already associated with a sharp improvement of glycaemic control, blood pressure and cholesterol levels (15-18), thus reducing the risk of diabetes-related complications (19-21). Smoking cessation is strongly recommended to further reduce vascular complications (22). In other words, for people with type 2 diabetes, the importance of a healthy lifestyle can hardly be overestimated (8, 23, 24).

Since type 2 diabetes is highly prevalent amongst people with overweight (25-27) and lack of physical exercise (28-30), many individuals need to adjust their lifestyle dramatically. Moreover, people need to achieve an adequate level of self-management: the ability to manage the symptoms, treatment, physical and psychosocial consequences and lifestyle changes inherent

in living with a chronic condition (31). As reported by numerous studies, developing the self-management skills needed to adopt a healthy lifestyle can be quite challenging (32-35). A systematic focus on the psychological factors affecting an individual's behaviour is essential to realise sustained self-management (35-39). A whole body of literature describes strategies to improve compliance with lifestyle advice (40-43), including follow-up care (44-47) in order to avoid relapse (36, 48). Therefore, besides biomedical monitoring, enduring coaching and lifestyle counselling - targeting weight control, smoking cessation and physical exercise - is increasingly often recommended to stimulate the development of self-management skills in individuals with type 2 diabetes (24).

Delivery of diabetes care in general practice: development of care groups

Which healthcare institutions provide diabetes monitoring depends on the severity of the disease. People in need of complex diabetes care, for example because of serious comorbidities, are commonly referred to secondary care. Low-complex diabetes care for people without insulin treatment is mostly delivered in general practice.

As type 2 diabetes is a chronic disease and patients are supposed to go through a couple of structured diabetes consultations each year, providing diabetes care is quite demanding for general practitioners (GPs). Due to the increasing prevalence of type 2 diabetes, the workload for practices is growing dramatically. It is therefore difficult for GP practices to stay up-to-date with people with type 2 diabetes and systematically trace whether they are adequately monitored. In addition, although a substantial share of standard diabetes care can be performed by skilled nurse practitioners (23, 49), in daily practice delegating tasks from a GP to a nurse practitioner can be challenging (50). Furthermore, low-accessible monitoring of the retina and lifestyle counselling requires collaboration with allied health providers such as optometrists and dieticians, but separate reimbursement structures for primary and allied healthcare hamper efficient collaboration (51).

In 2004, the government of the Netherlands reported that only one-third of all Dutch people with diabetes received adequate diabetes care (52). To improve Dutch diabetes primary care, the government invited a taskforce of experts (53), which included stakeholders from national diabetes foundations, healthcare disciplines including primary care, diabetology, allied health and health insurance companies, to formulate a collective vision on key conditions for adequate diabetes care. Based on the taskforce's recommendations, the government initiated a national diabetes program which tackled financial barriers regarding collaboration between GP practices and allied health providers. More specifically, health insurance companies were

encouraged to contract diabetes care services from so-called 'care groups'. Care groups are legal entities formed by multiple healthcare providers, usually exclusively GPs. The price for the bundle of diabetes services is freely negotiated by insurers and care groups, and the fees for the subcontracted care providers are similarly freely negotiated by the care group and providers (54). In other words, concerning negotiations on type 2 diabetes care services, care groups are important representatives of individual GPs and their interests.

Care groups: structured care protocols with collective support

The bundle of diabetes health services that are contracted corresponds with the concept of the chronic care model (55, 56), a model that defines interrelated components to produce system reform in which informed, motivated patients interact with prepared and proactive practice teams. The services include a structured care protocol, which comprises four annual consultations for people with type 2 diabetes, dietetic counselling adjusted to individual needs, and an annual retina screening and foot examination (57, 58). Agreements on collaboration with external disciplines such as medical psychologists are also recommended (59). As previously mentioned, continuous support with regard to lifestyle adjustment is important to maintain long-term behavioural change. Therefore, within the care group approach, the structured diabetes care protocol explicitly offers room for self-management support. To illustrate, although healthcare insurance companies reimburse GP practices for four consultations each year, only a single yearly assessment of a defined set of diabetes health indicators such as HbA1c and systolic blood pressure is mandatory. All other consultations, which are usually delivered by nurse practitioners, are optional and include monitoring of biomedical diabetes indicators, additional lifestyle coaching related to weight loss, smoking cessation and physical exercise, or more general support regarding development of self-management skills.

Care groups provide support to individual practices regarding implementation of the protocol, such as a computerised clinical decision support system, and a general support team that offers help with task delegation from GP to nurse practitioner (60, 61). Although care groups vary regarding the exact support, in many cases a specialised diabetes nurse is employed to coach and educate nurse practitioners in the participating practices (60). In addition, within several care groups participating GP practices are visited by other care group representatives, such as a general nurse, who provide tailored support regarding care delivery (49). In all care groups, aggregated feedback information on patient monitoring in participating practices is compared with practices in affluent areas to stimulate practice awareness of patient health outcomes and quality of care. As a result, practices are encouraged to reflect on their care processes and to identify potential topics for improvement (49). Based on these comparisons,

care groups can formulate actions or programs for quality improvement in participating practices. If necessary, care groups also offer specific professional support to these practices. For example, with the involvement of a diabetes nurse, additional training of the nurse practitioner can be facilitated via a coaching-on-the-job construction. To summarise, care group support of individual practices may include a wide range of services and can be adjusted to the specific preferences of a practice.

Quality control targets

To improve the quality of care, care groups negotiate on behalf of participating practices with health insurance companies regarding process targets for patient monitoring. In the first years, negotiations on quality control focused on a few parameters of the implementation process itself. Subsequently, the number of target indicators, including the proportion of monitored people, gradually increased in many care groups. Although the exact selection of target indicators might vary locally, agreements generally include measurement of HbA1c, systolic blood pressure and LDL. The consequences of target achievement for care groups and participating practices also depend on these local agreements. The Eerstelijns Zorggroep Haaglanden (ELZHA) – a care group in the western part of the Netherlands which united with other local primary care organisations to Haaglandse Dokters (Hadoks) in 2019 - agreed targets with the local health insurance company concerning calendar year 2014 that covered the proportion of people with at least one measure of HbA1c and systolic blood pressure (92 %) and the registration of low-density lipoprotein (LDL, 86 %). Regarding the quality of care on a national level, since 2015 a modest set of nationwide target indicators has been decided by a national council of care groups in collaboration with the national GP council and other stakeholders (62). The first part of this dissertation evaluates the care group approach to delivery of protocolised diabetes primary care.

In the Netherlands, professional GP guidelines (24) provide recommendations for diabetes monitoring, such as periodic measurement of blood glucose and cardiovascular parameters. Recommendations also include periodical monitoring of kidney function and examination of the eyes and feet. Since the regulation of blood glucose and cardiovascular parameters relate directly to healthcare provision and reflect relatively short-term results of care, these biomedical indicators are considered as essential for effective primary diabetes care. Thus, three biomedical target indicators - HbA1c, systolic blood pressure and LDL – are determined, together with three lifestyle-related target indicators - body-mass index (BMI), smoking behaviour and physical exercise. In this dissertation, and in accordance with agreements between care groups and health insurance companies, people are subsequently categorised as ‘being monitored

as recommended' if all these indicators are measured at least once during a calendar year. Individuals missing registration of one or more indicators within this time frame are defined as 'not being monitored as recommended' or simply 'incompletely monitored'.

Care group participation in relation to delivery of structured diabetes primary care

Shortly after the care group approach was launched it became subject to controversy. Although annual aggregated data reports suggest that diabetes monitoring has improved substantially within the care group approach (63-66), a finding also confirmed by a health insurance company analysis (67), some GP practices felt that the registration duties required in this approach primarily generate an administrative burden (68).

In addition, sceptical articles in professional GP magazines reported that the care group approach is expensive (69, 70). Furthermore, one study found minimal evidence for a relation between quality policy in care groups and improved clinical patient outcomes – although it should be mentioned that care group participation rates in this study were relatively low and technical problems concerning the patient data registry probably affected clinical outcomes adversely (71). In contrast, earlier scientific evaluations of the implementation of care groups (49) or care group-like approaches (72, 73) reported positive findings, such as the delegation of a substantial portion of diabetes care from GPs to nurse practitioners (49, 72) - which is expected to result in alleviated time demands on GPs - and improved clinical outcomes (74). Another analysis reported reductions in the hospital treatment of diabetes-related complications and substitution of care (75), which was confirmed by a report emphasising that appropriate use of health services had increased (76). Specifically, the number of routine check-ups decreased for individuals with well-controlled blood-glucose levels but increased for individuals who needed more-intensive monitoring. However, the exact association between care group participation and individual monitoring as recommended by GP guidelines is still poorly understood.

Association between structural monitoring of target indicators and HbA1c

As previously discussed, HbA1c levels are known to strongly influence the risk of numerous diabetes-related health complications, and can even impact mortality. These findings have been confirmed in many studies, and it is now clear that diabetes-related health risks are at their lowest when deviation from recommended HbA1c values is minimalised (77, 78). Despite professional GP guidelines regarding type 2 diabetes monitoring (24), within GP practices there is some scepticism concerning whether the care group's approach to registration duties adds value to patient care (68). There is also substantial evidence concerning the relationship between HbA1c and health risks, including the association between lifestyle adjustment and

HbA1c control, but it is still unclear whether monitoring of biomedical and lifestyle-related diabetes indicators as recommended by GP guidelines is associated with better HbA1c levels.

The role of socioeconomic status in monitoring and its association with HbA1c levels

The prevalence of type 2 diabetes, including its course and risk of complications, vary together with socioeconomic status (79, 80). In most definitions of socioeconomic status, factors such as employment status, income level, quality of housing and cultural diversity are included (81-83). In deprived socioeconomic areas, characterised by relatively high rates of unemployment, low incomes, poor housing and a high cultural diversity, type 2 diabetes shows both a higher incidence (84) and prevalence (85, 86). In addition, people with type 2 diabetes living in deprived areas achieve glycaemic control targets less often, tend to have higher blood pressure and a worse lipid profile control (79). Moreover, specific cultural minorities have a higher risk for developing type 2 diabetes (87, 88), as well as worse glycaemic control (89) and a higher risk for diabetes-related complications such as myocardial infarctions (90, 91). These health differences might be affected by health literacy: communication and social skills that enable a person to understand health information and to apply this knowledge adequately in daily life (92).

Thus far, it is not known whether within a collectively supported care group approach - including the delivery of a diabetes care protocol – socioeconomic status is associated with monitoring in accordance with GP guidelines, and whether socioeconomic status affects the association between monitoring and HbA1c levels.

Tailoring of diabetes care to individual needs

The content of structured diabetes care protocols is based on a central 'one size fits all' assumption. Even though the protocol does allow opportunities for tailoring care to individuals' needs, an increasing number of practices perceive the protocol and its registration duties as restrictive and reported an urgent need for more room to modify care to individual needs (68, 93). In addition, as noted earlier in this introduction, professional Dutch GP guidelines emphasise devoting attention to improvement of people's self-management skills (24). The second part of this dissertation focuses on the process of tailoring care and improving the self-management skills of people with type 2 diabetes.

Despite numerous studies of the effects of self-management interventions in primary care settings, evidence concerning self-management interventions in primary diabetes care is limited (94-97). This might be related to the content of interventions as, for example, uptake may be hindered by lack of knowledge or language problems (98). However, it has been

reported that on the process level, the implementation of interventions in a GP practice is often impeded by lack of time, competing priorities and insufficient room to deliver the intervention in line with its design (50). These factors have been incorporated in a model which examines the 'fidelity' concerning implementation of any intervention (99) – in other words, the extent to which an intervention is delivered in correspondence with its original design. According to this model, the outcomes of an intervention are affected by potential moderators - such as comprehensiveness of a policy description, quality of delivery and responsiveness of a targeted population – and by adherence, which includes details of content such as coverage and frequency. Hitherto, little was known regarding how abandonment of a fixed diabetes protocol is experienced in GP practices. In addition, insight is needed in facilitators of the successful implementation of self-management interventions in primary diabetes care.

Setting

The research questions described above were explored using primary care data from the Eerstelijns Zorggroep Haaglanden (ELZHA) registry. ELZHA, in 2019 integrated with two other local primary care organisations into Hadoks, is a care group including both city and suburbs of The Hague. In January 2015, the ELZHA care group numbered approximately 170 GP practices, with circa 25,000 people receiving the diabetes care protocol. The city of The Hague counted approximately half a million inhabitants in January 2015, including 51.2 % non-Dutch nationalities and a substantial Hindustani community (100). The Hague is characterised by very high wealth inequalities (101) and was predicted to be the setting for an epidemic of type 2 diabetes, with prevalence expected to rise to 17% by 2020 (102). Illustratively, between 2004 and 2011 the prevalence of type 2 diabetes rose from 2.9% to 6.3% (103). In other words, the Hague area has a complex and rapidly expanding population of people with type 2 diabetes.

As a result of these demographic challenges, GP practices in The Hague area foresee increasing demands on the delivery of diabetes care in general practice. To suitably prepare GP practices for these demands, the importance of adequate support for GP practices can hardly be overestimated. Therefore, a good understanding of the merits of diabetes care delivery within a care group setting is needed.

Within ELZHA, GP members share an overview of their patient monitoring data with the care group on a periodic basis. The ELZHA cohort is based on primary care registry data collected between January 2012 and January 2015.

Aims and outline of this dissertation

The main aim of this dissertation is to understand whether the care group approach is related to improved delivery and tailoring of primary diabetes care. The following two themes will be explored.

1. *An evaluation of structured primary diabetes care within a care group approach*
   Several elements of the structured diabetes care protocol within a care group setting are examined. **Chapter 2** evaluates whether care group participation by GP practices is associated with improved uptake of recommended monitoring of biomedical and lifestyle-related target indicators. In **chapter 3**, we investigate whether being monitored as recommended is associated with HbA1c levels in people.

2. *Tailoring of care to the needs of specific populations*
   Chapter 4 explores whether being monitored as recommended is associated with socioeconomic status and if socioeconomic status modifies the association between monitoring as recommended and HbA1c levels. In **chapter 5,** GP practice experiences of tailoring care to the needs of individual patients are explored. First, we examine the effect of dispensing with protocol and determine key conditions for successful implementation of self-management interventions in primary diabetes care. We then analyse the impact of dispensing with protocol and the implementation of self-management interventions on outcomes of individuals with type 2 diabetes.

The general discussion (**chapter 6**), presents a reflection on the findings in a broader scientific, clinical and societal context.

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