From protocol to personalised care

Improving and tailoring
diabetes management in general practice

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Table of contents

1

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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2

Association between GP participation in a primary care group and monitoring of biomedical and lifestyle target indicators in people with type 2 diabetes: a cohort study (ELZHA cohort-1)

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Abstract

Objective Whether care group participation by general practitioners (GPs) improves delivery of diabetes care is unknown. Using 'monitoring of biomedical and lifestyle target indicators as recommended by professional guidelines' as an operationalisation for quality of care, we explored whether 1) in new practices monitoring as recommended improved a year after initial care group participation aim 1); 2) new practices and experienced practices differed regarding monitoring (aim 2).

Design Observational, real-life cohort study.

Setting Primary care registry data from Eerstelijns Zorggroep Haaglanden (ELZHA) care group.

Participants

Aim 1: from 6 new practices (n=538 people with diabetes) that joined care group ELZHA in January 2014, 2 practices (n=211 people) were excluded because of missing baseline data; 4 practices (n=182 people) were included.

Aim 2: from all 6 new practices (n=538 people), 295 individuals were included. From 145 experienced practices (n= 21,465 people), 13,744 individuals were included.

Exposure Care group participation includes support by staff nurses on protocolised diabetes care implementation and availability of a system providing individual monitoring information. 'Monitoring as recommended' represented minimally one annual registration of each biomedical (HbA1c, systolic blood pressure, LDL) and lifestyle-related target indicator (BMI, smoking behaviour, physical exercise).

Primary outcome measures

Aim 1. In new practices, odds of people being monitored as recommended in 2014 were compared with baseline (2013).

Aim 2: Odds of monitoring as recommended in new and experienced practices in 2014 were compared.

Results

Aim 1 After one year care group participation, odds of being monitored as recommended increased threefold (OR 3.00(95%CI 1.84–4.88,p<0.001)).

Aim 2 Compared to new practices, no significant differences in the odds of monitoring as recommended were found in experienced practices (OR 1.21(95%CI 0.18–8.37, p=0.844)).

Conclusions We observed a sharp increase concerning biomedical and lifestyle monitoring as recommended after one year care group participation, and subsequently no significant difference between new and experienced practices - indicating that providing diabetes care within a collective approach rapidly improves registration of care.

Strengths and limitations of this study

- Due to the observational real-life design of this study, interference with daily routines of GP practices was avoided, thus contributing to reliability and representativeness of our findings
- Because the outcome measure 'monitoring as recommended' is rooted in current professional GP guidelines and is associated with significant better HbA1c outcomes, our results are valuable for clinical practice
- Considering that for the first analysis, two practices missing baseline data had to be excluded - which might reflect at most limited registration of target indicators - the associations we found in the first analysis might be underestimated
- Although the diabetes protocol is targeted to structural and enduring care for adult people of any age, monitoring recommendations are determined for people younger than 80 years - in accordance with these recommendations, people younger than 80 years were included in our study
- Since people participating less than a year and people older than 80 years or without registration of age were excluded, the generalisability of our findings is limited to people registered within this age range and being exposed minimally one year to the care protocol

Introduction

In the last decades, the worldwide prevalence of type 2 diabetes has increased rapidly (1). This trend is also reported in the Netherlands where, in 2016, approximately 1.1 million people (constituting 6.4% of the entire population) had a diagnosis of type 2 diabetes (2). Although health systems may vary on a local level, organisational challenges regarding the implementation of effective diabetes care are internationally frequently reported. A recent review identified several barriers to the delivery of diabetes primary care in general practice, including a heavy workload, time pressure, and lack of information technology (IT) (3). In addition, general practitioners (GPs) and nurse practitioners have difficulty in keeping up to date with diabetes-related knowledge and skills.

To strengthen primary diabetes care, internationally, several programs have been initiated, in which GP practices, generally supported by payment structures, restructure the delivery of diabetes care. For example, in the UK, the Diabetes Integrated Care Initiative has been launched (4), aiming to integrate primary, secondary and community diabetes care. In the US, the Comprehensive Primary Care (CPC) and, successively, the CPC+ program have been introduced. The CPC and CPC+ provide practices with a robust learning system, including actionable data feedback to guide their decision making (5), Since it is widely known that adequate monitoring of diabetes-related health outcomes is tremendously important to reduce the risk of diabetes complications (6-8) both CPC and CPC+ support monitoring of people with type 2 diabetes through health technology data.

In the Netherlands, a national primary care diabetes program was introduced in 2007. To facilitate implementation of this program in terms of logistic support and quality control, various Dutch GPs joined together in local 'care group' collectives. These care groups provide a multidisciplinary care approach in which GP practices collaborate with allied health disciplines such as dieticians, podotherapists and optometrists (9).

Because the use of a computerised clinical decision support system (CCDSS) is associated with improvements in the monitoring of diabetes-related health outcomes (10), many care groups provide a CCDSS. In addition to a CCDSS, care groups offer continuing professional development training and other IT facilities. Moreover, care groups negotiate with local healthcare insurance companies about integrated reimbursements and annual care targets regarding the proportion of individuals with type 2 diabetes having at least one measure of biomedical indicators, such as haemoglobin A1c (HbA1c), systolic blood pressure, and low-density lipoprotein (LDL) profile. At the end of each year, the GP practices get feedback on the adequacy of monitoring, which may

result in tariff adjustment. In addition, during the individual practice coaching and professional development trainings, GP practices are systematically encouraged to pay sufficient attention to lifestyle-related factors.

According to professional GP guidelines in the Netherlands (11), HbA1c, systolic blood pressure, LDL cholesterol profile and lifestyle factors such as body mass index (BMI), smoking behaviour and physical exercise, can be considered 'diabetes target indicators'. These guidelines recommend to frequently monitor people with type 2 diabetes on these indicators, that is, at least once each year.

Previous studies showed that structured primary diabetes care and systematic monitoring of diabetes target indicators are associated with improved diabetes-related health outcomes, including Hba1c levels (12, 13), which in turn affects the risk of fatal and non-fatal myocardial infarction (14). Thus, monitoring of diabetes target indicators might be perceived as a measure of quality of diabetes care. However, little is known about the effects of providing protocolised primary diabetes care within a care group setting on the monitoring of individuals. Therefore, we aimed to explore whether providing protocolised primary diabetes care within a care group is associated with an increase in recommended monitoring of biomedical and lifestyle-related target indicators in individuals after one year (aim 1). In addition, we aimed to evaluate the impact of GP practices' experience with providing protocolised primary diabetes care (aim 2) by comparing recommended monitoring of people with type 2 diabetes in GP practices participating in the care group since one year with GP practices that participated in a care group for at least three years.

Methods

Study design and population

In this observational Eerstelijns Zorggroep Haaglanden (ELZHA) real-life Dutch cohort study, based on primary care registry data from 2013 to 2015, the monitoring of diabetes target indicators in individuals with type 2 diabetes was analysed. Data were obtained from Hadoks, formerly known as ELZHA, a care group collective in the western part of the Netherlands. In 2015, the care group numbered 168 practices, of whom six had been participating since 2014, and 146 had been participating for at least three years (since 2012). In February 2017, after pseudonymisation of the individual data, all GP practices were invited to participate in the present study based on an opt-out procedure.

Inclusion and exclusion of participating practices and people

For the first aim, all six GP practices that joined the collective in 2014 ('new' practices) were selected. GP practices were excluded if baseline data were missing, i.e., data of people related to calendar year 2013. People who were registered with type 2 diabetes in January 2014 and who had received within the care group approach continuously primary diabetes care during the previous 12 months were included in this study. Because Dutch national GP guidelines concerning the monitoring of systolic blood pressure and LDL are specifically defined for people aged younger than 80 years, all individuals aged ≥ 80 years were - in accordance with these guidelines - excluded. In addition, individuals missing data on essential characteristics for any diabetes treatment - age, gender, and duration of time since the diagnosis of diabetes - were excluded.

For our second aim, new practices were compared with practices that had participated in the care group for at least three years ('experienced' practices). Practices which were taken over or left the care group between 2013 and 2015 were excluded. In both groups of practices, individuals were included in January 2015 if they were aged younger than 80 years and if they had received care group supported diabetes care for at least 12 months.

Intervention

The care group approach is characterised by three cornerstones with regard to implementation of structured care in clinical practice: 1) Intensive support to GPs and nurse practitioners by specialised staff nurses with regard to implementation and delivery of structured diabetes care. All GP practices are frequently visited and coached by specialised staff nurses. These visits aim to give GP practices tailored feedback on the monitoring and health outcomes of individuals with diabetes, and to support GPs with the implementation and organisation of the primary diabetes care program. 2) Availability of a computerised clinical decision support system (CCDSS) to improve oversight of the diabetes population and recent monitoring outcomes. Since January 2013, a CCDSS has been used to monitor and improve the care process and outcomes. Based on the diabetes-related electronic GP information system, this system presents an overview of all individuals with diabetes, including the history of their diabetes registrations each quarter. As a result, the CCDSS provides GPs with up-to-date insight into the monitoring of people with diabetes, which makes it easier to manage this monitoring. 3) A programme of vocational courses for GPs and nurse practitioners to keep diabetes-related skills and knowledge up-to-date. The care group offers GPs and nurse practitioners each year mandatory courses on diabetes to keep their knowledge and skills up to date. Thus, from care group perspective, the aim is to realise tailored counselling and education for staff people,

fitting their needs and preferences. Furthermore, to join the care group, presence of a nurse practitioner in the practice team is necessary. For individuals with diabetes, the approach consists of a quarterly invitation to consult their GP practice, in which diabetes-related blood indicators are checked and lifestyle education is provided, combined with allied health care such as an annual foot examination, fundus screening and dietician´s counselling.

Outcomes

Registration of the six diabetes target indicators (HbA1c, systolic blood pressure, LDL profile, BMI, smoking behaviour and physical exercise) was measured at the end of each quarter. In correspondence with the GP guidelines (11), monitoring targets were based on proportions of people with minimally one registration of each indicator during the calendar year. For the present study, people were regarded 'being monitored as recommended' when there was at least one registration for each of the six target indicators in the previous calendar year on January 1st of the subsequent year. If one or more target indicators were not registered in this time frame, people were defined as 'not being monitored as recommended'.

Analysis

For the baseline characteristics, categorical variables were reported as numbers and percentages. Continuous variables which were non-normally distributed were reported as medians with interquartile ranges (IQR). In addition, for all measurement moments, the sum of the registered indicators was determined.

For the first aim, the recommended monitoring of people in the calendar year 2013 (baseline measure) was compared with the calendar year 2014 (follow-up measure). To investigate the second aim, the recommended monitoring in new practices was compared with experienced practices in the calendar year 2014. For both aims, multilevel logistic analyses were conducted, which allowed to adjust the individual observations (level 1) for variation at the level of GP practice (level 2). In addition, both analyses were adjusted for age, duration of diabetes and gender, which are relevant confounders regarding diabetes monitoring (15-19).

Descriptive statistics were analysed using SPSS version 24.0. Multilevel analyses were performed using ML WiN (Version 2.28; Centre for Multilevel Modelling, University of Bristol, UK).

Patient and public involvement

Since this study was targeted on a GP supporting approach of structured primary diabetes care, patients were not actively involved.

Ethical considerations

Based on an opt-out procedure, informed consent was obtained from the GP practices. Since the pseudonymised individual data only contained age and gender, the data could easily be aggregated without enabling investigators to reduce them to individual persons. Also, taking into account the large number of people, individual informed consent was not required. The study protocol was approved by the Medical Ethical Committee of the Leiden University Medical Center (code G16.102).

Results

Regarding our first aim, since none of the six new practices objected to participation in this study, all practices were included. Because baseline data from 2013 were missing in two practices, data of four practices were used (n = 327 individuals). In these latter practices, 182 individuals met the inclusion criteria (Figure 1).

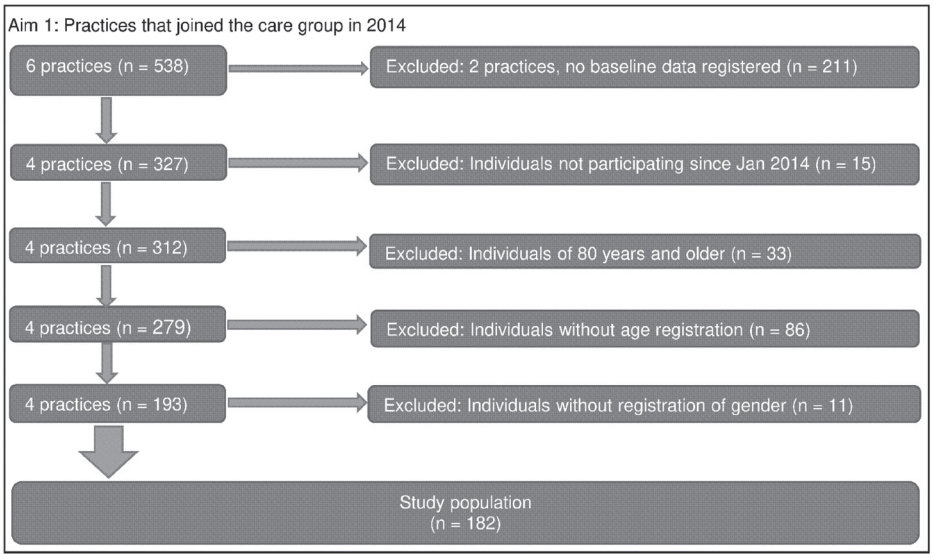


Figure 1. Flowchart of the practices (individuals) in the first analysis

Regarding our second aim, out of the 146 experienced practices, 145 did not object to participate in this study (n = 21,465 individuals) and were thus included. Concerning the study population, respectively 295 individuals in the six new practices and 13,744 individuals in the experienced practices fulfilled the study criteria (Figure 2).

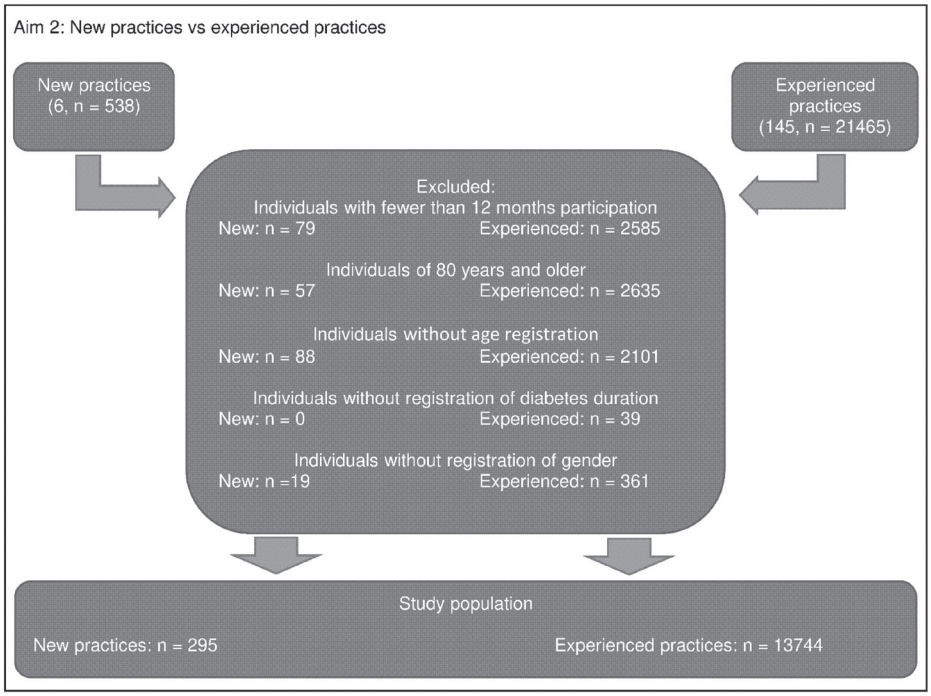


Figure 2. Flowchart of the practices (individuals) in the second analysis

Aim 1: Association between care group participation and recommended monitoring of people

Baseline characteristics are presented in Table 1. In the new practices that joined the care group collective in January 2014, at baseline the percentage of people being monitored as recommended was 25% (n = 45).

Table 1: Characteristics of individuals in the first and second analysis

	Aim 1[a]	**Aim 2[b]**	
Variable	**4 practices n = 182**	**Experienced 145 practices n = 13,744**	**New 6 practices n = 295**
Diabetes duration (years) median [IQR]	5.5 [2 – 7]	6 [3-10]	6 [3-9]
Age (years) median [IQR]	62.5 [55 – 70]	64 [56-71]	64 [56-72]
Gender: female n (%)	83 (46 %)	6,193 (45 %)	127 (43 %)
Monitored as recommended, n (%)	45 (25 %)	8,563 (62 %)	180 (61 %)

a) Baseline measure (calendar year 2013)

b) Measure calendar year 2014

The total number of registered indicators at baseline and at follow-up is presented in Figure 3. The unadjusted analysis showed that after one year care group participation, the proportion of people being monitored as recommended (25%, n = 45) increased to 51 % (n = 93) with an unadjusted OR of 3.18 (95%CI 2.04-4.96) compared to baseline (Table 2). Adjustment for duration of diabetes, age and gender resulted in a similar association [OR 3.00(95%CI 1.84-4.88)]. A detailed overview of the adjusted model is presented in appendix 1.

Table 2. Overview of difference in monitoring as recommended (aim 1 and aim 2)

Analysis	**Aim 1** [a]		**Aim 2** [b]	
	OR (95 % CI)	**p**	**OR (95 % CI)**	**p**
Model 1[c]	3.18 (2.04 - 4.96)	<0.001	1.06 (0.83 – 1.34)	0.65
Model 2[d]	3.00 (1.84 - 4.88)	<0.001	1.21 (0.18 – 8.37)	0.844

a) Difference in recommended monitoring of people after one year diabetes primary care in a care group (2014), compared to baseline (2013)

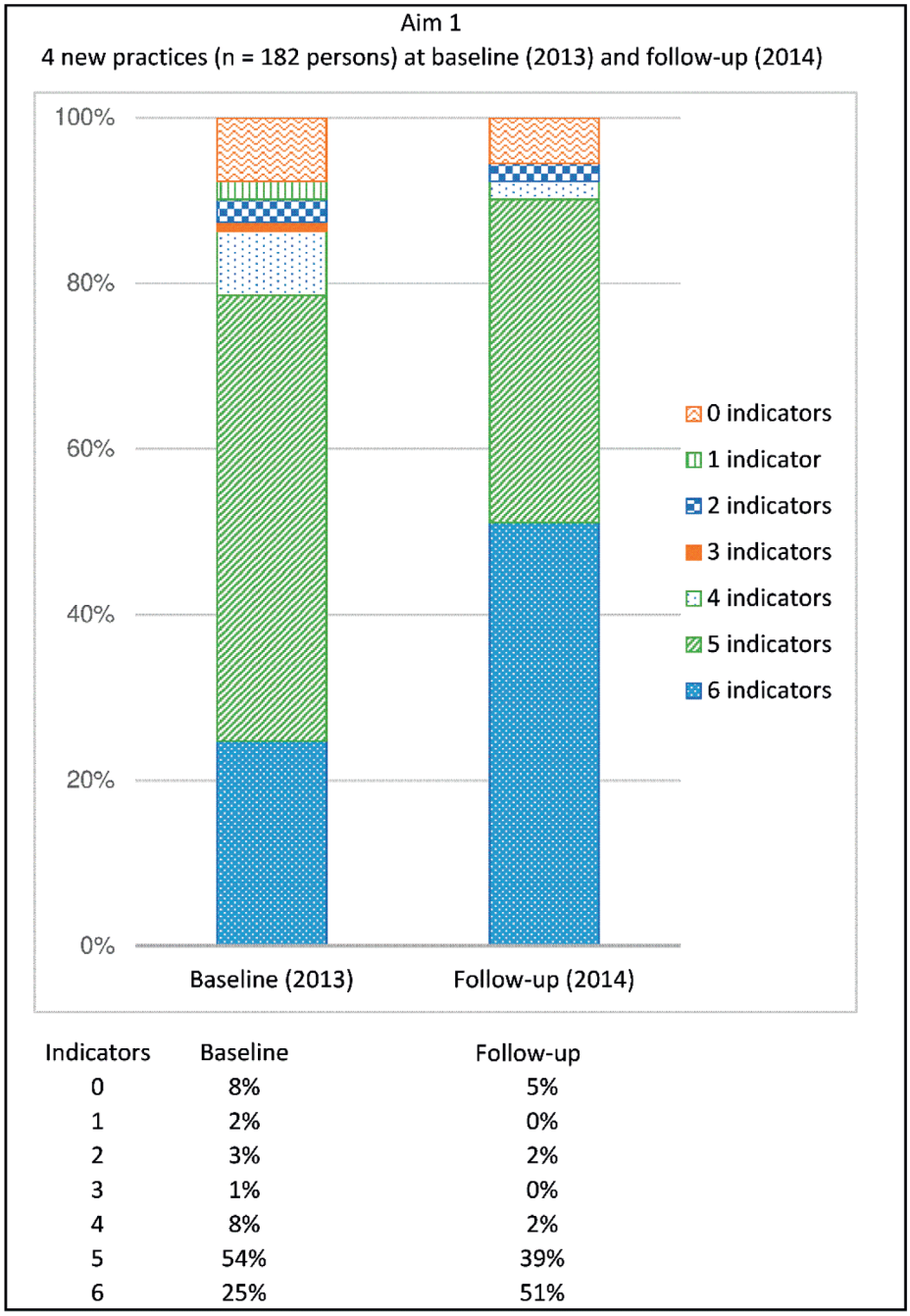
b) Difference in recommended monitoring of people in 2014: 145 experienced practices (n=13,744 individuals) compared to 6 new practices (n=295 individuals)

c) Unadjusted analysis

d) Multilevel analysis adjusted for age, duration of diabetes, and gender

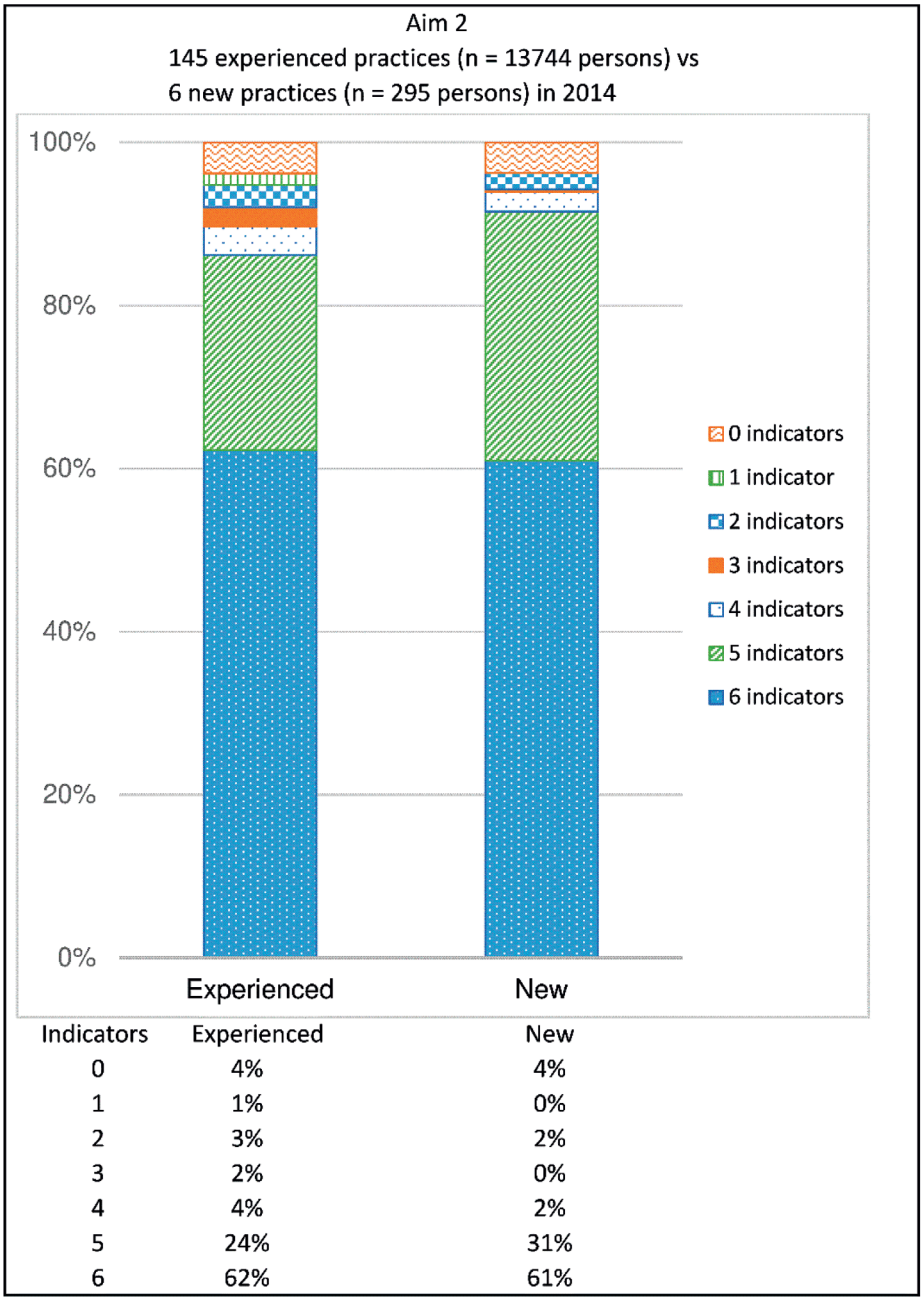
Aim 2: Association between care group experience and recommended monitoring of people

Table 1 presents the characteristics of individuals in the new and experienced practices; the two groups were comparable regarding duration of diabetes, age and gender. The proportion of people being monitored as recommended was 62% (n = 8,563) in the experienced group vs. 61% (n = 180) in the new group. In the unadjusted analysis (Table 2), experienced practices showed no significant difference from new practices in people being monitored as recommended [OR 1.06(95%CI 0.83-1.34), p = 0.65]. Multilevel analysis adjusting for practice level and additionally for age, duration of diabetes and gender revealed similar findings [OR 1.21(95%CI 0.18 – 8.37), p = 0.844]. A detailed overview of the adjusted model is presented in appendix 2. For both groups, the sum of registered indicators is presented in Figure 4.



Indicators	Baseline	Follow-up
0	8%	5%
1	2%	0%
2	3%	2%
3	1%	0%
4	8%	2%
5	54%	39%
6	25%	51%

Figure 3. Overview of registered type 2 diabetes mellitus indicators for aim 1



Indicators	Experienced	New
0	4%	4%
1	1%	0%
2	3%	2%
3	2%	0%
4	4%	2%
5	24%	31%
6	62%	61%

Figure 4. Overview of registered type 2 diabetes mellitus indicators for aim 2

Discussion

This study explored whether offering protocolised primary diabetes care in a care group is related to improvement of people with type 2 diabetes being monitored as recommended. We found that after one year of collectively organised and facilitated primary diabetes care, monitoring of people in line with GP recommendations increased substantially. In addition, we found in experienced practices, participating at least three years in the care group, no significant differences in recommended monitoring as compared to new practices, participating for one year. These findings indicate that participating in a care group has a rapid and enduring effect on the quality of monitoring of people with type 2 diabetes.

To our knowledge, this is the first study in Europe to explore the relationship between care group participation and registration concerning monitoring of essential biomedical and lifestyle diabetes indicators. As demonstrated by previous work (12), appropriate registration of diabetes monitoring is associated with significantly better HbA1c levels. Similarly, a meta-analysis established that appropriate self-monitoring of blood glucose was associated with better HbA1c levels (20). Thus, in our view, adequate monitoring is clinically relevant. Our findings underpin the outcomes of a longitudinal evaluation regarding the first Dutch initiative on collectively supported implementation and delivery of structured primary diabetes care. This study revealed a trend reflecting improved measure of indicators such as systolic blood pressure and LDL (21). In addition, our results support the conclusions of previous annual national benchmarks which were based on aggregated data of care groups between 2011 and 2013 (22) and which suggested that monitoring of people in line with professional GP guidelines has improved. Furthermore, our findings are confirmed by a British evaluation of GP support by diabetologists and nurse specialist concerning diabetes care, which showed that the number of appropriate referrals to secondary care increased significantly (23). In the USA, the CPC initiative has key characteristics in common with the Dutch care group approach. Our findings show a greater increase in monitoring than found in the evaluation of the first years CPC (24-26) which detected only small improvements in monitoring. This difference might be explained by the recent introduction of the CPC program, since an in-depth evaluation of US practices participating in the CPC program revealed that practice staff appreciated advice adjusted to their job roles and practice organisation, and the electronic health record system and other digital systems used in their practice (27) – indicating that a quality transition had been initiated. In addition, an evaluation of the first year of the Dutch care group approach reported much room for improvement of individual monitoring, hardly any significant improvement of diabetes-related health outcomes, and missing data due to registration problems (28); also, in an evaluation of the second and third year, only modest improvements in monitoring were

found (29). In other words, the better outcomes of our study might be explained by a broader experience with the care group approach.

In our view, one important strength of this study is the design. In general, a randomised clinical trial (RCT) might be useful to eliminate bias. However, in RCT's achieving adequate powering is a common problem. In contrast, observational studies generally allow inclusion of large-scale study populations. To illustrate, in the case of our study, meeting the powered study population within an RCT design would have been severely hindered by logistical barriers. That is, finding sufficient practices that were willing to be assigned to a randomisation procedure concerning care group participation or a control condition would virtually have been impossible. This problem can be avoided with an observational design. Thus, when using an observational design in this field, barriers with regard to the external generalisibility of the findings might be alleviated (30). In addition, since our design typically does not interfere with the daily organisation of GP practices, adequate reliability of our findings can be assumed. Moreover, in our study, the observational real-life setting reflects the reality of diabetes monitoring in this specific study population. The design we used is in line with other studies that also used a pragmatic design to conduct diabetes-related studies in primary care (31-35).

Nevertheless, some limitations warrant discussion. First of all, our findings are only generalisable to people younger than 80 years participating minimally one year in the care protocol. Second, the number of new practices was relatively low, which might have influenced our findings on the effect of care group participation. For example, two new practices lacked baseline data, indicating weak registration of diabetes monitoring, and were thus excluded for our first research analysis; in addition, in the new practices, a considerable number of people was excluded because of missing information on essential personal data (age, gender and diabetes duration). Missing data are a common challenge when using routine registry data (36). This implies that our results on the effect of care group participation are primarily applicable to people with registration of elementary diabetes-related information. Second, since no control group could be included, we cannot proof a causal relation between the observed increase in the monitoring of people and participation in a care group. In addition, it should be noted that given the observational design, our findings might be affected by residual confounding. Third, concerning the second analysis, different groups that varied in size were compared. Therefore, our findings might have been influenced by other factors (e.g. size and organisation of the GP practice, or characteristics of the practice population) even though we did correct our analyses for the level of GP practice and additionally for age, duration of diabetes, and gender of the individuals.

Our study shows that providing protocolised primary diabetes care in a care group context is associated with a rapid increase in monitoring of individuals with type 2 diabetes. This might be explained by the three cornerstones of the care group support. First, in the context of a high workload and competing priorities in daily GP practice (3), the support provided to GPs and nurse practitioners with regard to implementation and delivery of a diabetes care protocol might encourage essential organisational changes in individual practices. This is supported by a Canadian study showing that in the view of GPs, supporting access of GPs to other health professionals in primary care such as nurse practitioners facilitates interprofessional collaboration and improves diabetes care (37). To illustrate, although the collaboration process between GPs and nurse practitioners in daily practice is sometimes perceived as challenging (29), within care groups, different stakeholder groups report clarity about one another's expertise, roles and tasks (38). Accordingly, process coaching by an experienced staff nurse might ameliorate the functioning of the GP team and subsequently care delivery. More effective functioning of the GP team and improved care delivery might result in development of a team-based approach to realise timely invitation of people for diabetes consultations at ward or a team-based approach to reduce no-shows.

Second, effective use of a CCDSS enables systematic and appropriate monitoring of diabetes-related health outcomes. Because the accessibility of information technology systems is known to be a barrier in primary diabetes care (3, 39), appropriate coaching concerning the use of these systems is required (40). Care group-related support with regard to the use of a CCDSS stimulates up-to-date oversight of individual monitoring, thus contributing to a higher number of people being monitored as recommended. Third, the mandatory educational diabetes courses enable GPs and nurse practitioners to keep their knowledge and skills up to date. As a result, optimal benefits from the collective approach might be derived.

In other words, the care group approach tackles several internationally reported barriers on the delivery of diabetes care and thus contributed to improvement of care quality. Therefore, the benefits of collectively organised logistic and quality support might also be relevant for other protocolised diabetes care settings, such as the CPC+ program in the USA.

From the perspective of individuals with type 2 diabetes, quarterly consultation in a care group setting, which is characterised by systematic and ongoing attention for diabetes-related self-management and lifestyle support, is associated with an increase in being monitored as recommended, although for certain subgroups of people, a more flexible 'care protocol' might be sufficient (41).

For future research, further examination of factors that might affect relations between care group participation and outcomes within participating practices – such as local geographical and socioeconomic characteristics or practice organisation – is needed to gain a better understanding of the association between care group participation and monitoring of people. To add, previous studies have shown that structured primary diabetes care and structured monitoring of diabetes target indicators are associated with improved diabetes-related health outcomes, including Hba1c (12, 13), which in turn affects the risk of fatal and non-fatal myocardial infarction (14, 42). However, more detailed exploration of the relationship between monitoring of individual diabetes indicators in line with professional recommendations, diabetes-related changes in treatment and health outcomes (e.g. meeting treatment targets, cardiovascular complications, hospital admissions) might enhance our understanding of adequate, collectively supported primary diabetes care. Next, evaluating the financial costs and benefits of this diabetes care approach might be interesting for policy makers. Finally, although we found that protocolised primary diabetes care with collective support is associated with better monitoring, little is known about the personal perspective of the individuals themselves with regard to participation in a structured care protocol.

To summarise, in practices that started with protocolised primary diabetes care within a care group setting, the monitoring of people as recommended increased considerably after one year. In experienced practices, the odds of being monitored in line with professional guidelines did not significantly differ from new practices participating one year in the care group. Thus, collectively organised logistic and quality support of GP practices is associated with improvement of primary diabetes care monitoring. The association between care group participation and diabetes health outcomes needs further research. More insight into the personal perspective of the stakeholders (GPs, nurse practitioners and individuals with diabetes) is recommended.

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Supplementary file

Appendix 1. Overview of difference in monitoring as recommended (aim 1): people (n = 182 individuals) after one year diabetes primary care in a care group (2014), compared to baseline (2013)

Analysis	OR (95 % CI)	p
Model 1a Level of care group experience (one year vs. baseline)	3.18 (2.04 - 4.96)	<0.001
Model 2b		
Level of care group experience (one year vs. baseline)	3.00 (1.84 – 4.88)	<0.001
Age: 2nd quartile vs. 1st quartile	1.25 (0.52 – 3.06)	0.617
Age: 3rd quartile vs. 1st quartile	1.73 (0.74 – 4.03)	0.205
Age: 4th quartile vs. 1st quartile	1.88 (0.75 – 4.73)	0.178
Duration of diabetes: 2nd quartile vs. 1st quartile	1.89 (0.80 – 4.42)	0.145
Duration of diabetes: 3rd quartile vs. 1st quartile	2.62 (1.12 – 6.14)	0.027
Duration of diabetes: 4th quartile vs. 1st quartile	10.10 (3.81 – 26.77)	<0.001
Gender (female vs male)	0.94 (0.52 - 1.70)	0.839

a) Unadjusted analysis

b) Multilevel analysis adjusted for age, duration of diabetes, and gender

Appendix 2. Overview of difference in monitoring as recommended (aim 2): 145 experienced practices (n = 13,744 individuals) compared to 6 new practices (n=295 individuals)

Analysis	OR (95 % CI)	p
Model 1a Level of care group experience (experienced vs. new)	1.06 (0.83 – 1.34)	0.655
Model 2b		
Level of experience (experienced vs. new)	1.21 (0.18 – 8.37)	0.844
Age: 2nd quartile vs. 1st quartile	1.37 (1.21 – 1.55)	< 0.001
Age: 3rd quartile vs. 1st quartile	1.71 (1.49 – 1.96)	< 0.001
Age: 4th quartile vs. 1st quartile	1.59 (1.39 – 1.82)	< 0.001
Duration of diabetes: 2nd quartile vs. 1st quartile	1.31 (1.13 – 1.51)	< 0.001
Duration of diabetes: 3rd quartile vs. 1st quartile	1.20 (1.05 – 1.37)	0.006
Duration of diabetes: 4th quartile vs. 1st quartile	1.31 (1.13 – 1.50)	< 0.001
Gender (female vs male)	1.14 (1.04 – 1.25)	0.004

a) Unadjusted analysis

b) Multilevel analysis adjusted for age, duration of diabetes, and gender

3

Association between full monitoring of biomedical and lifestyle target indicators and HbA1c level in primary type 2 diabetes care: an observational cohort study (ELZHA-cohort 1)

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Abstract

Objective Management of type 2 diabetes mellitus (T2DM) requires frequent patient monitoring. Within a collective care group setting, doubts on the clinical effects of registration are a barrier for full adoption of T2DM registration in general practice. We explored whether full monitoring of biomedical and lifestyle-related target indicators within a care group approach is associated with lower HbA_{1c} levels.

Design Observational, real-life cohort study

Setting Primary care data registry from the Eerstelijns Zorggroep Haaglanden care group.

Exposure The care group provides general practitioners collectively with organisational support to facilitate structured T2DM primary care. Patients are offered quarterly medical and lifestyle-related consultation.

Main outcome measure Full monitoring of each target indicator in patients with T2DM. which includes minimally one measure of HbA_{1c} level, systolic blood pressure, LDL, BMI, smoking behaviour and physical exercise between January and December 2014; otherwise, patients were defined as ´incompletely monitored´. HbA_{1c} levels of 8,137 fully monitored and 3,958 incompletely monitored patients were compared, adjusted for the confounders diabetes duration, age and gender. Since recommended HbA_{1c} values depend on age, medication use and diabetes duration, analyses were stratified into three HbA_{1c} profile groups. Linear multilevel analyses enabled adjustment for general practice.

Results Compared to incompletely monitored patients, fully monitored patients had significantly lower HbA_{1c} levels [95%CI] in the first (-2.03 [-2.53;-1.52]mmol/mol) (-0.19% [-0.23%;-0.14%]), second (-3.36 [-5.28;-1.43]mmol/mol) (-0.31% [-0.48%;-0.13%]) and third HbA1c profile group (-1.89 [-3.76;-0.01]mmol/mol) (-0.17% [-0.34%;0.00%]).

Conclusions/interpretation This study shows that in a care group setting, fully monitored patients had significantly lower HbA_{1c} levels compared with incompletely monitored patients. Since this difference might have considerable clinical impact in terms of T2DM-related risks, this might help general practices in care group settings to overcome barriers on adequate registration and thus improve structured T2DM primary care. From population health management perspective, we recommend a systematic approach to adjust the structured care protocol for incompletely monitored subgroups.

Strengths and limitations of this study

- The observational real-life design of this study prevented any interference with daily routines of GP practices, thus contributing to good reliability and representativeness of our findings
- Because the availability of patient data on age, medication use and diabetes duration allowed to conduct our analyses - in correspondence with professional GP guidelines - for specific HbA1c threshold groups, the findings are relevant and useful for clinical practice
- Taking into consideration that a missing registration does not necessarily reflect a lack of care, but might be caused by technical or practical problems instead, the associations found in this study might be underestimated.

Introduction

Type 2 diabetes is a typical lifestyle-related disease (1). The course of type 2 diabetes and potential complications are influenced by smoking behaviour (2, 3), BMI (4) and physical exercise (5). Adopting a healthier lifestyle, e.g. by smoking cessation or weight loss, is known to be very demanding for individual patients (6, 7). It has been established that attention for non-conscious motivational factors affecting an individual's behaviour is important to realise sustained behavioural change (8). In addition, to avoid relapse (9, 10) and maintain long-term behavioural change, follow-up support for lifestyle-related themes is recommended (11, 12). Accordingly, in the Netherlands, a nationally acknowledged scientific council of general practitioners (GPs) has determined professional guidelines for diabetes primary care (13). In correspondence with the NICE guidelines (14), it is recommended to monitor at least once a year not only HbA_{1c} levels, but also the biomedical target indicators systolic blood pressure and LDL, as well as lifestyle-related indicators.

However, for an average GP, providing structured primary diabetes care with sufficient attention for both biomedical monitoring and lifestyle adaptation (15) is reported to be challenging (16). Therefore, in many Western countries, varying from the US and Europe (17, 18) to New-Zealand (19), an increasing number of GPs has delegated the regular structured primary diabetes care to nurse practitioners.

It is known that implementing structured primary diabetes care and delegation of tasks to a nurse practitioner has considerable impact on the organization of the GP practice (20, 21). For example, in the USA, an evaluation of the recent Comprehensive Primary Care (CPC) program revealed a need to refine practice workflows, to incorporate new staff roles, and to overcome incompatibility of health technology systems (22). To improve the delivery of structured primary diabetes care in the Netherlands, most GPs have joined together in local 'care groups' (23). Care groups negotiate collective structured diabetes care protocols with the funding institutions of Dutch primary care, namely, local health insurance companies. For GPs, participation in a care group is voluntary. However, the logistic and quality support to individual GP practices which is part of the care group approach, might be seen as an incentive for care group participation. That is, the agreements between care groups and health insurance companies on structured diabetes care protocols enable GPs to offer high-quality intensive primary diabetes care. To illustrate, on an annual basis, four consultations at the GP practice with an explicit focus on lifestyle support are facilitated, as well as complementary allied health (e.g. annual screening of fundus and feet). All patients who receive diabetes care in GP practice are eligible for participation in the structured care protocol. It is known that providing a structured diabetes

care protocol is associated with better monitoring of patients (24). In addition, adequate registration of the diabetes-related patient health indicators is associated with improvement of the care process (25). The costs of this protocol are fully covered by health insurance companies. For patients, participation is free of charge.

According to a recent study, care group participation is associated with improvement of the proportion patients with full monitoring of biomedical and life style related target indicators (26). However, a review on chronic care programs in primary care reported that doubts among care providers on the clinical effects of an intervention are a barrier for adoption (27). To our knowledge little is known about the relationship between full monitoring of biomedical as well as lifestyle related target diabetes indicators in a care group setting and clinical health outcomes. The Hba_{1c} level is established as a key diabetes health indicator (28). Therefore, this study aims to investigate the association between full monitoring of biomedical and lifestyle-related diabetes target indicators and HbA_{1c} level, in patients with type 2 diabetes who receive a structured diabetes care protocol, facilitated by a care group.

Research design and methods

Study design and population

Data were used of type 2 diabetes patients from the observational Eerstelijns Zorggroep Haaglanden (ELZHA) cohort, which is based on primary care registry data from a care group in the western part of the Netherlands. In January 2015, the care group numbered 168 GP practices (n=24,459 patients with type 2 diabetes). On a periodic basis, GP members share an overview of their patient monitoring data with the care group. In February 2017, all GP practices were informed in writing and, based on an opt-out procedure, were invited to participate in this cohort. For the present study, pseudonymized data on monitoring of diabetes target indicators and HbA_{1c} levels from patients were used from the calendar year 2014. Patients receiving continuously structured primary diabetes care from January 2014 through December 2014 at the same GP practice were included. At least one registration of HbA_{1c} in 2014 was necessary for inclusion. Since systolic blood pressure and LDL guidelines are specified for patients aged ≤80 years, patients aged ≥80 years were excluded. Patients were also excluded in case of missing data on age, gender or disease duration. Finally, because missing data on medication use were partly caused by technical problems, patients without registration of medication prescription were also excluded.

Exposure

Details of the ELZHA cohort study have been described previously (Van Bruggen et al., submitted). In short, within a care group setting, GPs are able to invite all their T2DM patients with primary care treatment for this structured care protocol. During a standard diabetes consultation or at time of diagnosis, patients are informed about this care protocol. Patients who provide consent to be enrolled, can join the structured primary care protocol. The protocol includes a quarterly diabetes consultation, in which diabetes-related target indicators are checked and lifestyle education is provided, combined with complementary allied health such as an annual foot check, fundus screening and dietician´s counselling. To facilitate the organization and quality control of this protocol, GP practices receive practical and logistic support, including a computerised system to improve the care process and outcomes. Measurement of the diabetes target indicators (HbA_{1c} level, systolic blood pressure, LDL level, BMI, smoking behaviour and physical exercise) took place in 2014 at the end of each quarter. In the present study, patients were regarded as 'fully monitored' when each target indicator was registered at least once between January and December 2014. If one or more target indicators were not registered minimally one time in calendar year 2014, patients were defined as ´incompletely monitored´.

Outcomes

The outcome of this study was HbA_{1c} level; this was computed in two steps. First, for each quarter, a mean HbA_{1c} value was calculated based on all available HbA_{1c} measures in that quarter. Based on the mean HbA_{1c} levels of all quarters, a mean was computed for the whole calendar year. HbA_{1c} level is presented in % and mmol/mol.

Analysis

For patient characteristics, categorical variables were reported as numbers and percentages. Continuous variables were reported as means with standard deviation (SD) or, when non-normally distributed, as medians with interquartile ranges (IQR). Baseline characteristics of excluded patients were, if available, compared to the study population. Linear multilevel analyses were conducted to compare HbA_{1c} levels of fully monitored and incompletely monitored patients. Multilevel analyses allowed to adjust the individual observations (level 1) for GP practice (level 2). In addition, the analyses were adjusted for patient age, duration of diabetes and gender, which are relevant possible confounders with regard to HbA_{1c} outcomes.

Tailored on specific key patient characteristics (age, intensity of medication treatment, and disease duration) professional Dutch GP guidelines recommend differentiated HbA1c targets

for three different patient profile groups based on age and prescribed medication. Details on the scientific determination of these target values are presented in the guidelines (13). To summarise, 1) for patients aged <70 years, and for older patients with a mild treatment regime (only metformin monotherapy prescription or lifestyle coaching), a target HbA1c value of 7.0% (53 mmol/mol) is recommended. 2) for patients aged ≥70 years who need more intensive treatment and were diagnosed with diabetes <10 years previously, a target HbA1c value of 7.5% (58 mmol/mol) is recommended; 3) for patients aged ≥70 years who need more intensive treatment and were diagnosed with diabetes ≥10 years previously, a target HbA1c value of 8.0% (64 mmol/mol) is recommended. In the present study, since missing data on medication might reflect administrative omissions rather than absence of medication treatment, patients without data on medication were excluded.

In view of the relevance for clinical practice, separate multi-level analyses were conducted and reported for each of these HbA_{1c} profile groups. In addition, in a non-stratified multi-level analysis, we tested whether the magnitude of the effect found in HbA1c profile 2 and 3 differed significantly from Hba1c profile 1. A p-value <0.05 was considered statistically significant; for interaction, a p-value <0.1 was considered statistically significant.

Descriptive statistics were analysed using SPSS, version 24.0. Multilevel analyses were performed using ML WiN (Version 2.28).

Patient and public involvement

Since this study was targeted on a GP supporting approach of structured primary diabetes care, patients were not actively involved.

Ethical considerations

Since the pseudonymized patient data contained only age and gender, the data could be aggregated without enabling investigators to identify individual patients. Due to the high number of patients, informed consent of individual patients was not required.

The study protocol was approved by the Medical Ethical Committee of the Leiden University Medical Center (code G16.102/SH/sh).

Results

This study included 167 GP practices (99%) with a total of 24,198 patients with type 2 diabetes; of these, 12,095 patients met the inclusion criteria (for a detailed flowchart of inclusion see Figure 1).

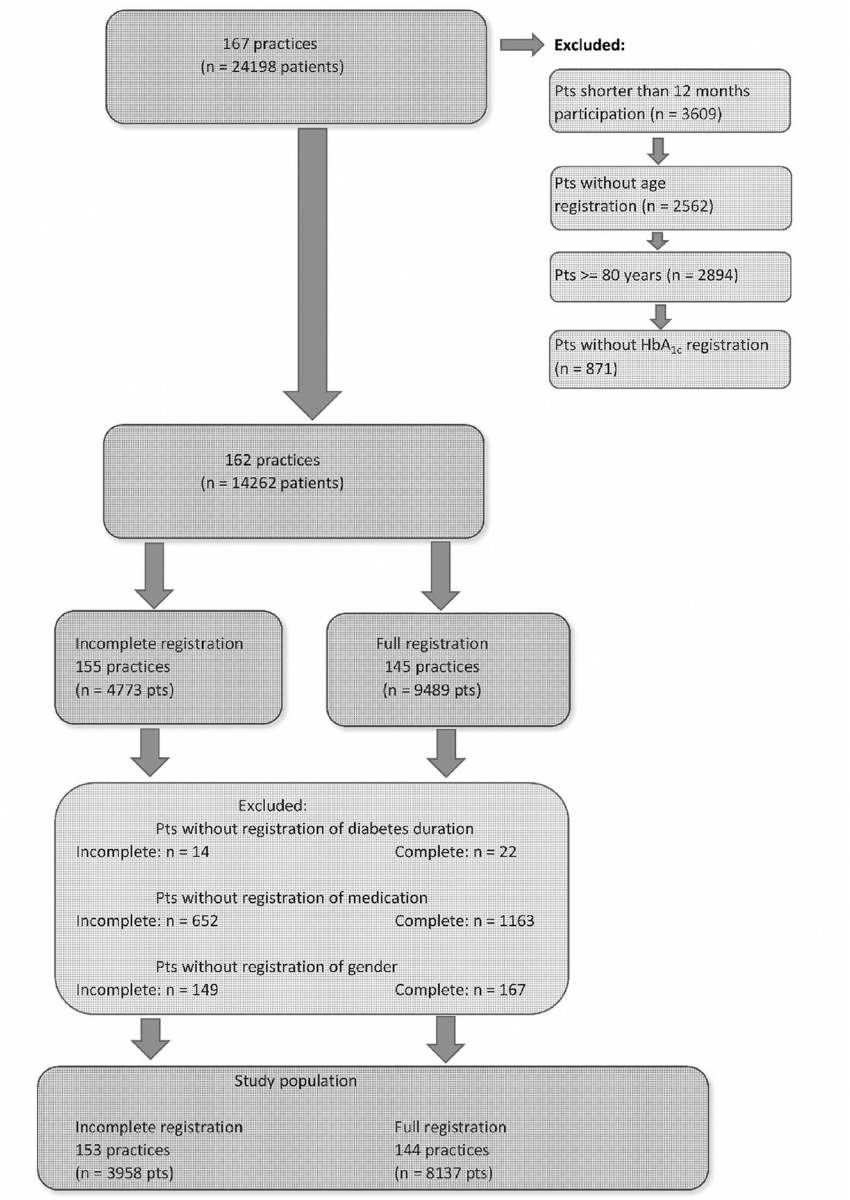

Figure 1. Flowchart of patient inclusion Pts = patients

By definition, in this population HbA1c was always monitored, as not having an HbA1c measure available was an exclusion criterion for the present study. Comparing characteristics of the excluded patients (n = 12,103 patients) with the study population (n = 12,095 patients, see supplementary file, table 1), in excluded patients mean HbA1c level (50.32 mmol/mol, SD = 12.8 mmol/mol; 6.76 % (SD = 3.32 %, 7.535 registrations missing) was slightly lower than in the study population (52.5 mmol/mol, SD=1.07 mmol/mol; 6.95 %, SD = 3.16%).

Table 1. Characteristics of the study population: classified by HbA_{1c} profile and monitoring completeness.

	HbA_{1c} profile 1[1] *Target HbA_{1c}: 53 mmol/mol (7.0%)*		**HbA_{1c} profile 2**[2] *Target HbA_{1c}: 58 mmol/mol (7.5%)*		**HbA_{1c} profile 3**[3] *HbA_{1c}: 64 mmol/mol (8.0%)*	
	Incomplete n =3,345	**Complete** n =6,794	**Incomplete** n = 396	**Complete** n = 656	**Incomplete** n = 217	**Complete** n = 687
HbA_{1c} level: mmol/ mol mean [SD][4] %	53.51 (12.31) 7.05 (1.13)	51.56 (10.51) 6.87 (0.96)	55.91 (11.66) 7.27 (1.07)	53.87 (10.60) 7.08 (0.97)	55.12 (10.57) 7.19 (0.97)	53.60 (8.98) 7.06 (0.82)
Diabetes duration, years: median [IQR][5]	3 [3 – 8]	7 [4 – 10]	3 [3 – 7]	7 [4 – 8]	13 [11 – 16]	13 [11 – 15]
Age (years): median [IQR]	61 [54 – 67]	62 [55 – 68]	74 [72 – 76]	74 [71 – 76]	74 [72 – 77]	74 [72 – 76]
Gender: % female (n)	44 (1,465)	46 (3,106)	46 (183)	45 (297)	51(110)	46 (316)

1. Profile 1: patients aged <70 years, and older patients with a mild treatment regime (only metformin monotherapy prescription)
2. Profile 2: patients aged ≥70 years who need more intensive treatment and diagnosed with diabetes <10 years ago
3. Profile 3: patients aged ≥70 years who need more intensive treatment and diagnosed with diabetes ≥10 years ago
4. SD = standard deviation
5. IQR = interquartile range

Comparing the median diabetes duration of excluded patients (5 years, IQR: 3 – 9, 63 registrations missing) to the study population (6 years, IQR: 3 – 10), no substantial differences were found. Regarding median age, excluded patients (71 years, IQR: 60 – 82, 2,917 registrations missing) were older than included patients (median: 64 years, IQR: 56 – 71 years) and slightly more often women (50 % (n = 4,251; 3,530 registrations missing) versus 45 % (n = 5,477). More detailed characteristics of our study population, classified by HbA_{1c} profile and monitoring completeness, are presented in Table 1. Of patients who were incompletely monitored, information on physical exercise was most often missing, followed by smoking, BMI, LDL, and systolic blood pressure (Figure 2).

Compared with incompletely monitored patients, fully monitored patients had lower mean HbA_{1c} levels in all three HbA1c profiles. In addition, fully monitored patients had a longer duration of diabetes than incompletely monitored patients.

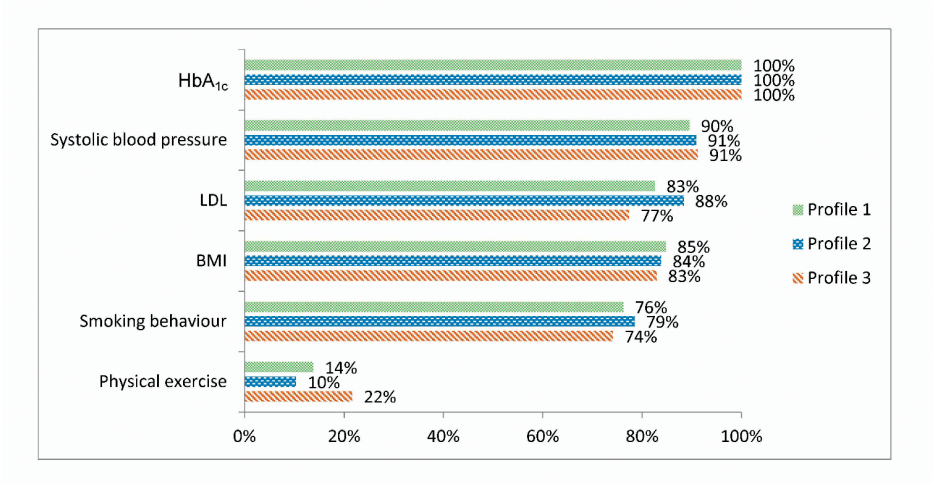

Figure 2. Overview of registered indicators in incompletely monitored patients within Hba_{1c} profile
HbA_{1c}: Hemoglobin A1c

The crude analysis showed that, compared with incompletely monitored patients, the mean HbA_{1c} of fully monitored patients was significantly lower in the first profile (-1.95 [95% CI -2.41; -1.49] mmol/mol) (-0.18% [-0.22%; -0.14%]), second profile (-2.03 [95 % CI -3.41;-0.66] mmol/mol) (-0.19% [-0.31%; -0.06%]) and third profile (-1.53 [95 % CI -2.96;-0.10] mmol/mol) (-0.14% [-0.27%; -0.01%]) (Table 2).

Table 2. Multilevel analyses evaluating the HbA_{1c} difference of fully-monitored patients compared to incompletely monitored patients, stratified for HbA_{1c} profile.

		Profile 1			Profile 2			Profile 3	
	B	95% CI	p-value	B	95% CI	p-value	B	95% CI	p-value
Model 1[a] mmol/mol	-1.95	-2.41,-1.49	<0.001	-2.03	-3.41, -0.66	0.004	-1.53	-2,96, -0.10	0.037
%	-0.18	-0.22; -0.14		-0.19	-0.31; -0.06		-0.14	-0.27; -0.01	
Model 2[b] mmol/ mol	-2.03	-2.53, -1.52	<0.001	-3.36	-5.28, -1.43	0.001	-1.89	-3.76, -0.01	0.049
%	-0.19	-0.23; -0.14		-0.31	-0.48; -0.13		-0.17	-0.34; 0.00	

[a] Crude analysis

[b] Multilevel analysis adjusted for age, diabetes duration and gender

Multilevel analyses with adjustment for diabetes duration, age and gender revealed similar significant associations in the first (-2.03 [95 % CI -2.53; -1.52] mmol/mol) (-0.19% (-0.23%; -0.14%]), second (-3.36 [95 % CI -5.28; -1.43] mmol/mol) (-0.31% [-0.48%; -0.13%]) and third profile (-1.89 [95 % CI -3.76; -0.01] mmol/mol) (-0.17% [-0.34%; 0.00%]). The magnitude of these associations did not significantly differ between the HbA_{1c} profile groups (p=0.44 and p=0.35 for the second and third profile, respectively, compared with the first profile).

Discussion

This study explored whether monitoring completeness of biomedical and lifestyle-related diabetes target indicators in a care group setting is associated with HbA_{1c} level. In all HbA_{1c} profile groups – defined based on patient age, intensity of medication treatment and disease duration – we found that fully monitored patients had lower HbA_{1c} levels than incompletely monitored patients; the differences ranged from 1.89 mmol/mol (0.17%) to 3.36 mmol/mol (0.31%), indicating that adequate diabetes monitoring of biomedical and lifestyle indicators in primary care is associated with better HbA_{1c} levels. To our knowledge, this is the first study to analyse the association between systematic diabetes monitoring in primary care and HbA_{1c} levels. Apart from one longitudinal Dutch study on structured primary diabetes care in a care group setting which reported a sharp decrease in the proportion of patients with a HbA_{1c} level ≥53 mmol/mol (24), research on absolute HbA_{1c} differences is scarce and findings appear to be somewhat inconsistent (29-32). Therefore, caution is required when comparing our findings with any earlier studies. However, for each 1% (10.9 mmol/mol) reduction in mean HbA_{1c}, a significant decrease in health risk has been reported, ranging from 21% for any endpoint related to diabetes including deaths, to 14% for myocardial infarction, and 37% for microvascular complications (33). Further, our finding that registration of physical exercise was most often lacking, is in line with an earlier small-size study in which only 19% of patients with type 2 diabetes reported 'being guided properly' with regard to physical exercise (34).

Our finding that, compared with incomplete monitoring, full monitoring of patients is associated with a lower HbA_{1c} level might be explained by continuity of care in several ways. First, if patients are monitored at least once a year, an increasing HbA_{1c} level might be noticed at an early stage, resulting in fast and adequate treatment. Second, periodic monitoring and coaching of patients with regard to weight loss, smoking cessation and physical exercise contributes to enduring lifestyle adaptation (11, 12), which may lead to lower HbA_{1c} levels (35).

Since fully monitored patients with type 2 diabetes have significantly lower HbA_{1c} levels, their risk of any diabetes-related health complication is lower compared to incompletely monitored patients. Thus, in general, incomplete monitoring of a patient should be interpreted as an important sign of diabetes-related health risks – especially since incomplete records might not only be caused by no-show, but also by low patient motivation, missing of prescribed lab tests and limited overall adherence to diabetes treatment. As reported by others (36), a tailored approach based on data registry and adjusted to patient characteristics (e.g. monitoring completeness), is recommended. This might encourage awareness in GP practice regarding adequate diabetes management and might help GP's to overcome barriers on full adoption of the care group monitoring approach. In addition, the present findings might be relevant for other structured diabetes primary care settings which focus on frequent monitoring and adequate registration of diabetes-related health outcomes, such as the Comprehensive Primary Care Plus program in the USA (37).

The present study is characterised by several strengths. First, in our view, an important strength of this study is the design: although randomized clinical trials might help to eliminate bias, adequate powering and generalizability are familiar problems (38), whereas observational studies allow to include large study populations. For example, in this study, all patients participating in a structured primary diabetes care program were enrolled, thereby contributing to high representativeness of our study population. Second, generally, since our study design did not interfere with the daily routine of GP practices, we assume adequate reliability of our findings. Thus, the observational real-life setting in our study reflects the reality of diabetes monitoring and HbA_{1c} levels in primary care. Our design is in line with other studies that also used a pragmatic approach to conduct diabetes related studies in primary care (39-41). Third, since patients were included if they participated for at least one year at the same GP practice, bias caused by intermediate moving or referral to hospital diabetes care was avoided - which contributes to the stability and, thus, the validity of our findings. Finally, conducting separate analyses for each HbA_{1c} profile group allowed adjustment for the variety in the recommended HbA_{1c} target values.

Nevertheless, this study is also subject to some limitations that need to be mentioned. First, since no control group was included, no causal relation between monitoring completeness and HbA1c level can be proven. Second, a missing registration does not necessarily mean that the care has not been provided. For example, missings might be caused by technical problems, or lack of time for registration. Patients being considered erroneously as 'incompletely monitored'

might have underestimated the associations found, although we did correct our analyses for age, diabetes duration, gender and GP practice.

For future research, it might be useful to analyse the context of diabetes target monitoring and explore whether the association that we found reflects a causal relationship between monitoring completeness and HbA_{1c} level. In addition, from the GP perspective, examining potential barriers to complete monitoring, including potential benefits such as an increase of the proportion patients with HbA1c levels within recommended values, might provide keys to improvement of the monitoring process. To ameliorate the primary diabetes care of incompletely monitored patients, exploration of their preferences and needs is suggested. In addition, an evaluation of financial costs and benefits of this care approach is recommended.

To summarise, in patients with type 2 diabetes within a care group setting, full monitoring of biomedical and lifestyle target indicators is associated with lower HbA_{1c} levels compared with incomplete monitoring. These differences might be expected to have a considerable clinical impact in terms of diabetes-related risks. We recommend a systematic approach to analysing the needs of incompletely monitored patient groups, and to adjust the structured care protocol for these subgroups in terms of population health management.

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Supplementary file

Since missing data on medication prescription might reflect absence of medication treatment but also technical errors, all patients without medication registration were excluded. As a result, in the final analyses, T2DM patients with a lower HbA1c level and subsequently no medication prescription, were excluded.

Table 1. Characteristics of study population and excluded patients.

		Included patients n = 12,095	**Excluded patients (n = 12,103)**	
			Outcomes	**Missing registrations**
HbA1c: mean (SD)	Mmol / mol	52.55 (11.07)	50.32 (12.8)	7,535
	%	6.95 (3.16)	6.76 (3.32)	
Diabetes duration, years: median [IQR]1		6 [3 -10]	5 [3 – 9]	63
Age (years): median [IQR] 2		64 [56 – 71]	71 [60 – 82]	2,917
Gender: % female (n)		45 (5.477)	50 (4.251)	3,530

1) SD = standard deviation

2) IQR = interquartile range

4

Socioeconomic status is not associated with the delivery of care in people with diabetes but does modify HbA1c levels: An observational cohort study (ELZHA-cohort 1)

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Abstract

Background. Structured primary diabetes care within a collectively supported setting is associated with better monitoring of biomedical and lifestyle-related target indicators amongst people with type 2 diabetes and with better HbA1c levels. Whether socioeconomic status affects the delivery of care in terms of monitoring and its association with HbA1c levels within this approach, is unclear. This study aims to understand whether, within a structured care approach, 1) socioeconomic categories differ concerning diabetes monitoring as recommended; 2) socioeconomic status modifies the association between monitoring as recommended and HbA1c.

Methods. Observational real-life cohort study with primary care registry data from general practitioners within diverse socioeconomic areas, who are supported with the implementation of structured diabetes care. People with type 2 diabetes mellitus were offered quarterly diabetes consultations. 'Monitoring as recommended' by professional guidelines implied minimally one annual registration of HbA1c, systolic blood pressure, LDL, BMI, smoking behaviour and physical activity. Regarding socioeconomic status, deprived, advantageous urban and advantageous suburban categories were compared to the intermediate category concerning 1) recommended monitoring; 2) association between recommended monitoring and HbA1c.

Results. Aim 1 (n = 13,601 people): Compared to the intermediate socioeconomic category, no significant differences in odds of being monitored as recommended were found in the deprived (OR 0.45 (95% CI 0.19 - 1.08)), advantageous urban (OR 1.27 (95% CI 0.46 - 3.54)) and advantageous suburban (OR 2.32 (95% CI 0.88 - 6.08)) categories.

Aim 2 (n = 11,164 people): People with recommended monitoring had significantly lower HbA1c levels than incompletely monitored people (-2.4 (95 % CI -2.9; -1.8) mmol/mol). SES modified monitoring-related HbA1c differences, which were significantly higher in the deprived (-3.3 (95% CI -4.3; -2.4) mmol/mol) than the intermediate category (-1.3 (95% CI -2.2; -0.4) mmol/mol).

Conclusions. Within a structured diabetes care setting, socioeconomic status is not associated with recommended monitoring. Socioeconomic differences in the association between recommended monitoring and HbA1c levels advocate further exploration of practice and patient-related factors contributing to appropriate monitoring and for care adjustment to population needs.

What's known

- Structured primary diabetes care within a collectively supported setting is associated with better delivery of care, that is, better monitoring of biomedical and lifestyle-related target indicators amongst people with type 2 diabetes
- Appropriate monitoring of these target indicators is associated with better HbA1c levels
- Generally, socioeconomic deprivation is associated with worse diabetes monitoring and unfavourable disease-related health outcomes

What's new

- This study shows that socioeconomic differences with regard to the uptake of diabetes care might be overcome with a collectively supported structured care approach
- Considering that monitoring-related HbA1c differences were particularly high in deprived socioeconomic populations, our findings highlight the importance to adjust structured care to population needs

Introduction

Over the last decades, evidence suggests that people with type 2 diabetes mellitus can have considerable influence on the course of their disease, including the risk of complications. Since the course of type 2 diabetes is strongly affected by smoking behaviour, body weight and physical activity, people with type 2 diabetes need to adopt a healthy lifestyle and develop adequate diabetes-related self-management skills (1, 2). In addition, professional guidelines for general practitioners (GPs) recommend frequent monitoring of people – not only with regard to biomedical indicators such as HbA1c, systolic blood pressure and LDL cholesterol but also regarding lifestyle-related indicators including body mass index (BMI), smoking behaviour and physical activity. People are considered being monitored as recommended if these biomedical and lifestyle parameters are recorded at least once a year (1, 2).

Delivery of diabetes care within a structured setting

However, the increasing numbers of people with type 2 diabetes have led to pressure and limitations in the delivery of diabetes primary care (3). In an effort to improve diabetes primary care, Dutch GPs launched care groups (4). Using a collective approach, these care groups negotiate structured diabetes care protocols with health insurance companies and provide logistic and quality support to individual GP practices. The structured care protocol emphasises prevention and comprises four diabetes consultations a year, during which biomedical and lifestyle indicators are monitored. In addition, people are coached in lifestyle adaptation and the development of self-management skills.

Socioeconomic status and barriers in diabetes care

The prevalence and course of type 2 diabetes vary in relation to socioeconomic status (5). For example, prevalence of type 2 diabetes is higher in socially deprived areas (6-8). Although sufficient diabetes monitoring and self-management support are important for all people with type 2 diabetes, individuals in deprived areas are a particularly important target population. In socially deprived areas, smoking, obesity and a lack of physical exercise are common (9-12), and people in these neighbourhoods are more likely to have inadequate perceptions of lifestyle risks and barriers to physical activity. These can include the underestimation of the health risks related to smoking and obesity, as well as erroneous beliefs regarding the importance or added value of physical activity (13-15). Furthermore, higher rates of relapse in unhealthy behaviour (16-19) occur amongst people in socially deprived areas.

We recently found that care group participation by GPs is associated with an improvement of the monitoring of biomedical and lifestyle-related target indicators in people with type 2 diabetes

(20). Monitoring is considered an important measure for quality of care, since it is associated with better HbA1c levels (21). Studies on health inequalities in primary and secondary diabetes care have shown that a lower socioeconomic status is associated with worse monitoring and outcomes in people with diabetes, including early death (5, 22). In a British general practice setting, monitoring of diabetes indicators was shown to be lower in deprived areas or areas with a high number of non-western ethnicities compared to intermediate socioeconomic areas (23). However, it is not known whether this is also the case in a care group setting or if socioeconomic status affects the association between monitoring and HbA1c levels. Therefore, within a collective care group setting offering a structured care approach, the goals of the present study were (1) to compare the odds of people being monitored on biomedical and lifestyle target indicators as recommended in respective socioeconomic categories, and (2) to explore whether the association between recommended monitoring and HbA1c levels (aim 2) was modified by socioeconomic status.

Methods

Study design and population

This observational EerstelijnsZorggroepHaaglanden (ELZHA) real-life cohort study was based on primary care registry data collected in the Netherlands. Data were obtained from Hadoks, formerly known as ELZHA, a care group collective in The Hague. The Hague is one of the largest cities in the Netherlands and is specifically characterised by wide socioeconomic disparities. As of January 2015, ELZHA included 168 GP practices. On a periodic basis, GP members share an overview of their monitoring data of individual people with the care group. In February 2017, all GP practices were informed in writing and, based on an opt-out procedure, invited to participate in the present cohort study, with pseudonymisation of GP practices and data of individuals. For the current study, retrospective registration data from calendar year 2014 were used.

Aim 1: People who received structured diabetes primary care from January to December 2014 were included. Since systolic blood pressure and LDL guidelines are specified for people aged <80 years, people aged ≥80 years were excluded. In case of missing data on age, gender or disease duration, people were also excluded.

Aim 2: In addition to the above-mentioned eligibility criteria, not having an HbA1c measure available was an exclusion criterion for this analysis. Furthermore, professional Dutch GP

guidelines are tailored to certain key individual characteristics (age, intensity of medication treatment, and disease duration) and recommend specific HbA1c targets for each of three distinct patient profile groups, as defined by age, disease duration and prescribed medication (see text box 1). A detailed description of the scientific determination of these target values can be found in the guidelines (1). In the current analysis, people without data on medication were also excluded since missing data on medication might reflect administrative omissions rather than the absence of medication treatment.

Box 1: Overview and specifications of HbA1c profiles

Profile 1: 7.0% (53 mmol/mol)
People aged <70 years, and older people with a mild treatment regime (only metformin monotherapy prescription or lifestyle coaching)

Profile 2: 7.5 % (58 mmol/mol)
People aged ≥70 years in need of more intensive treatment and diagnosed with type 2 diabetes <10 years previously

Profile 3: 8.0% (64 mmol/mol)
People aged ≥70 years in need of more intensive treatment and diagnosed with type 2 diabetes ≥10 years previously

Measurements

Socioeconomic status

The ELZHA care group setting and the context of the Dutch healthcare system have been described in detail elsewhere (20, 21). For the present study, the socioeconomic status of all urban GP practice locations was determined using a combined deprivation score on the level of neighbourhoods (24), computed by the local municipality of The Hague (24). The following parameters are included in this score: a) percentage inhabitants unemployed for more than 3 years, b) average income, c) percentage non-western migrants, d) average official value of houses, and e) percentage inhabitants that moved in the last 3 years. Based on the deprivation score, all neighbourhoods were divided into three socioeconomic categories: advantageous, intermediate or deprived. Accordingly, practice locations in the city of The Hague were assigned to these categories. However, although official scores were not available for boroughs in the periphery of The Hague (Wassenaar, Leidschendam-Voorburg, Voorschoten and Rijswijk) we applied identical criteria to municipal registration data for these suburbs in order to obtain an approximate indicative deprivation score. The deprivation scores for all boroughs except for Rijswijk appeared homogeneous and were characterised by a high wealth. Rijswijk was, therefore excluded, and remaining peripheral boroughs were assigned to a separate suburban

advantageous socioeconomic category. Thus, four socioeconomic categories were compared: intermediate, deprived, advantageous urban, advantageous suburban.

Diabetes monitoring

The extent of registration of six diabetes target indicators (HbA1c, systolic blood pressure, LDL, BMI, smoking behaviour and physical activity) was measured at the end of each quarter of a year. People were regarded 'monitored as recommended' when, in line with professional GP guidelines (1), each target indicator was registered at least once between January and December 2014. If one or more target indicators were not registered in calendar year 2014, people were classified as 'not monitored as recommended'.

Hba1c levels

The Hba1c level was computed in two steps. First, for each quarter, a mean HbA1c value was calculated based on all available HbA1c measurements in that quarter. Based on the mean HbA1c levels for all quarters, a mean was then calculated for the whole calendar year. HbA1c level is presented as mmol/mol.

Analysis

Regarding the characteristics of individuals, categorical variables were reported as numbers and percentages. Continuous variables were reported as means with standard deviation (SD) or, when non-normally distributed, as medians with interquartile range (IQR). For aim 1, multilevel logistic regression analyses were conducted to compare the odds of people being monitored as recommended across neighbourhood deprivation categories with the intermediate category as reference. Multilevel analyses allowed adjustment for individual observations (level 1) per GP practice (level 2). To investigate aim 2, we first conducted multilevel analyses to evaluate whether HbA1c levels of people in deprived and advantageous socioeconomic categories differed from the intermediate category. Second, we explored the association between monitoring as recommended and HbA1c levels. Finally, we examined whether socioeconomic status modified the association between monitoring as recommended and HbA1c levels. For both aims, analyses were performed crude and adjusted for age, duration of type 2 diabetes and gender, which are relevant potential confounders with regard to diabetes monitoring and HbA1c levels (25-27). A p-value <0.05 was considered statistically significant; for effect modification, a p-value <0.1 was considered statistically significant. Descriptive statistics were analysed using SPSS, version 25. Multilevel analyses were performed using ML WiN (Version 2.28).

Patient and public involvement

Because this study was focussed on a GP supporting approach of structured primary diabetes care, people with type 2 diabetes were not actively involved.

Ethical considerations

Since the pseudonymised data of individuals contained no date of birth (calendar age only), data could be aggregated without enabling investigators to identify individual people. Due to the large number of people, informed consent of individual persons was not required. The study protocol was approved by the Medical Ethical Committee of the Leiden University Medical Center (code G16.102).

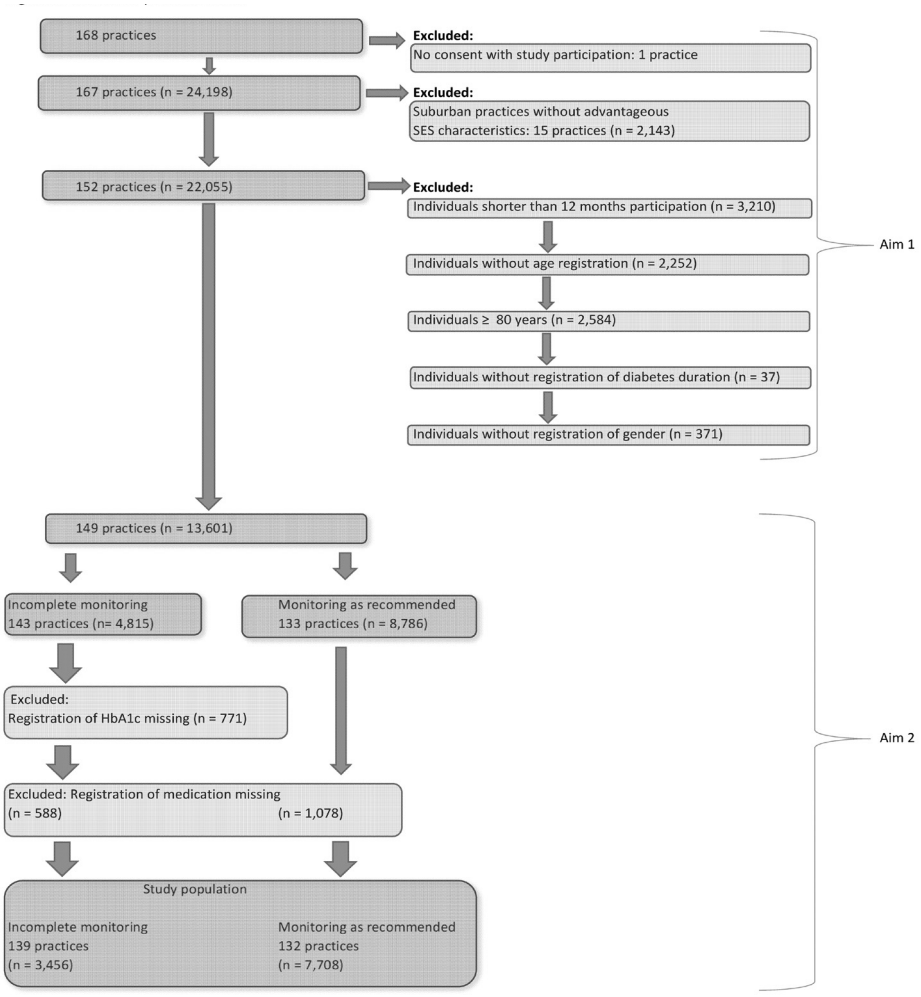

Figure 1. Inclusion of practices and people

Table 1. Characteristics of the study population for aim 1 and 2

	Aim 1				**Aim 2**							
	Socioeconomic status[a]				**Incompletely monitored**				**Completely monitored**			
	Socioeconomic status				**Socioeconomic status**				**Socioeconomic status**			
	o	--	++ urban	++ suburban	o	--	++	suburban	o	--	++ urban	++ suburban
Practices, n	42	47	26	34	40	46	26	27	39	37	24	32
people, n	3,508	5,968	1,971	2,154	923	1,890	371	272	1,923	3,115	1,208	1,462
Diabetes duration (years): median [IQR]	7 [3-10]	5 [3-9]	7 [4-10]	8 [4-10]	7 [3-11]	3 [3-6]	7 [4-10]	8 [4-10]	7 [4-10]	7 [4-11]	8 [5-11]	8 [5-10]
Age (years) median [IQR]	64 [56-70]	61 [53-69]	66 [59-72]	67 [60-73]	64 [56-71]	61 [53-68]	65 [58-71]	67 [60-73]	64 [56-70]	62 [53-69]	67 [59-73]	67 [60-73]
Gender: female, n (%)	1,535 (44)	2,802 (47)	866 (44)	942 (44)	411 (45)	869 (46)	157 (42)	114 (42)	848 (44)	1,498 (48)	531 (44)	655 (45)
HbA1c profile, n (%)												
1: 7.0 % (53 mmol/mol)[b]					767 (83)	1,650 (87)	303 (82)	219 (81)	1,637 (85)	2,661 (85)	972 (80)	1,175 (80)
2: 7.5 % (58 mmol/mol)[c]					80 (9)	189 (10)	35 (9)	30 (11)	164 (9)	211 (7)	100 (8)	145 (10)
3: 8.0 % (64 mmol/mol)[d]					76 (8)	51 (3)	33 (9)	23 (8)	122 (6)	243 (8)	136 (11)	142 (10)
People being monitored as recommended, n (%)	2,202 (63)	3,463 (58)	1,400 (71)	1,721 (80)								
HbA1c: mean (SD) in mmol/mol					52.8 (11.48)	55.1 (12.70)	52.4 (12.68)	52.1 (12.91)	51.3 (9.52)	53.3 (11.59)	50.9 (9.74)	50.3 (9.27)

[a] Socioeconomic status: o = intermediate, -- = deprived, ++ = advantageous

[b] Profile 1: people aged <70 years, and older people with a mild treatment regime (only metformin monotherapy prescription)

[c] Profile 2: people aged ≥70 years who need more intensive treatment and diagnosed with type 2 diabetes <10 years ago

[d] Profile 3: people aged ≥70 years who need more intensive treatment and diagnosed with type 2 diabetes ≥10 years ago

Results

In this study, 167 of the 168 practices (99 %) representing 24,198 people with type 2 diabetes were initially included. However, following exclusion criteria, all 15 practices situated in Rijswijk (n = 2,143 people) were excluded for being a suburban practice without advantageous SES characteristics (Figure 1). For aim 1, 13,601 people could be included in the analyses. For aim 2, 3,456 incompletely-monitored individuals and 7,708 individuals being monitored as recommended remained for further analysis. Characteristics of the study populations for aims 1 and 2 are presented in Table 1. Of all socioeconomic categories, the deprived category counted the highest number of practices and people.

Aim 1: Association between socioeconomic status and recommended monitoring

Compared to the intermediate category, crude analysis showed significant differences regarding the odds of people being monitored as recommended in all categories (Table 2): In the deprived category, the odds of people being monitored as recommended were significantly lower (OR 0.82 (95% CI 0.75 - 0.89)), whereas these odds were significantly higher in the advantageous urban (OR 1.45 (95% CI 1.29 - 1.64)) and suburban categories (OR 2.36 (95% CI 2.08 - 2.67)). After adjustment for practice level and additionally for age, duration of diabetes and gender, the associations were no longer statistically significant.

Table 2. Aim 1: Association between socioeconomic category and being monitored as recommended (n = 13,601)

	Model 1 [a]		Model 2 [b]	
Socioeconomic category	**OR (95% CI)**	**p**	**OR (95% CI)**	**p**
Deprived versus intermediate	0.82 (0.75 – 0.89)	<0.001	0.45 (0.19 – 1.08)	0.074
Advantageous urban versus intermediate	1.45 (1.29 – 1.64)	<0.001	1.27 (0.46 – 3.54)	0.648
Advantageous suburban versus intermediate	2.36 (2.08 - 2.67)	<0.001	2.32 (0.88 - 6.08)	0.087

[a)] Crude analysis

[b)] Model adjusted for age, diabetes duration, gender and GP practice

Aim 2: Comparison of socioeconomic categories on association between recommended monitoring and HbA1c levels

As presented in Table 3, compared to the intermediate category, HbA1c was significantly higher in the deprived category in the crude model (2.3 (95% CI 1.8 – 2.8) mmol/mol) as well as in the adjusted model (1.7 (95% CI (0.6-2.8) mmol/mol). HbA1c levels of the advantageous urban and intermediate categories did not significantly differ in the crude (-0.5 (95% CI -1.2; 0.2) mmol/mol) and adjusted analyses (-0.7 (95% CI -2.0; 0.7) mmol/mol). In the advantageous suburban

category, HbA1c was slightly lower than in the intermediate category (-1.1 (95% CI -1.8; -0.5) mmol/mol), but after adjustment, this association was no longer statistically significant (-1.1 (95% CI -2.4;0.2) mmol/mol).

Table 3. Aim 2: Association between socioeconomic category and HbA1c levels in mmol/mol (n = 11,164)

	Model 1 [a]		Model 2 [b]	
Socioeconomic category	**B (95% CI)**	**p**	**B (95% CI)**	**p**
Deprived versus intermediate	2.3 (1.8; 2.8)	<0.001	1.7 (0.6; 2.8)	0.003
Advantageous urban versus intermediate	-0.5 (-1.2; 0.2)	0.161	-0.7 (-2.0; 0.7)	0.316
Advantageous suburban versus intermediate	-1.1 (-1.8; -0.5)	<0.001	-1.1 (-2.4; 0.2)	0.105

[a)] Crude analysis

[b)] Model adjusted for age, diabetes duration, gender, HbA1c profile and GP practice

Table 4. Aim 2: Overview of association between monitoring as recommended and HbA1c levels (mmol/mol) for each socioeconomic category (n = 11,164)

Socioeconomic category	**Model 1** [a]	**Model 2** [b]
	B (95% CI)	**B (95% CI)**
Full population	-2.1 (-2.5; -1.7)	-2.4 (-2.9; -1.8)
Intermediate	-1.5 (-2.3;-0.7)	-1.3 (-2.2; -0.4)
Deprived	-1.8 (-2.5; -1.1) [c]	-3.3 (-4.3; -2.4) [d]
Advantageous urban	-1.5 (-2.7; -0.2) [c]	-1.9 (-3.3; -0.5) [c]
Advantageous suburban	-1.8 (-3.0; -0.5) [c]	-1.8 (-3.2; -0.5) [c]

[a)] Crude analysis.

[b)] Model adjusted for age, diabetes duration, gender, HbA1c profile and GP practice.

[c)] No significant difference found compared to intermediate category (p-interaction >0.10)

[d)] Significant difference found compared to intermediate category (p-interaction <0.10)

As reported in Table 4, in the full population, being monitored as recommended was associated with a significantly lower HbA1c level in the crude model (-2.1 (95% CI -2.5;-1.7) mmol/mol) and the adjusted model (-2.4 (95% CI –2.9;-1.8) mmol/mol). When assessing whether socioeconomic status modified the association between monitoring and HbA1c level, initially, no significant differences in the association between monitoring and HbA1c levels were found between the intermediate and the other categories (p >0.1). After adjustment, the HbA1c difference associated with monitoring completeness in the deprived category (-3.3 (95% CI -4.3;-2.4) mmol/mol) was, compared to the intermediate category (-1.3 (95% CI -2.2;-0.4) mmol/mol), significantly higher (p-interaction = 0.002). In the advantageous urban and suburban

categories, the adjusted analyses demonstrated no significant differences compared to the intermediate category (p-interaction > 0.1).

Discussion

Within a collectively supported structured primary diabetes care setting, this study examined whether socioeconomic status was associated with monitoring of biomedical and lifestyle-related target indicators as recommended by professional guidelines, and whether socioeconomic status modified the association between recommended monitoring and HbA1c levels. First, when comparing the deprived and advantageous categories to the intermediate category, we did not observe statistically significant monitoring differences after adjustment for confounders and practice level. Second, people in the deprived category had significantly higher HbA1c levels than people in the intermediate category. Monitoring as recommended was associated with significantly lower HbA1c levels. Socioeconomic status modified the association between monitoring and HbA1c levels: the HbA1c difference between people being monitored as recommended versus incompletely monitored people was significantly higher in the deprived category than in the intermediate category. In other words, in the deprived category, being monitored as recommended was an even more important indicator of lower HbA1c outcomes than it already was in the other categories.

The absence of significant differences in monitoring completeness between socioeconomic categories might be explained by the focus of collectively supported structured diabetes care. The aims of this approach include improving oversight of the diabetes population and up-to-date monitoring outcomes as well as tailored support for practices to achieve optimal delivery of care (20). Comparable approaches resulted in impressive amelioration of care delivery, regardless of socioeconomic deprivation (28, 29). Interestingly, the crude findings - suggesting significantly lower monitoring in deprived neighbourhoods and better monitoring in advantageous neighbourhoods - are in line with previous findings in other settings (5, 22). Nevertheless, our adjusted results indicate that monitoring is associated with non-modifiable individual characteristics – age, diabetes duration, gender– and practice factors rather than with socioeconomic status. Evidence for the association between these individual characteristics and diabetes compliance seems inconsistent (30, 31), but a range of modifiable practice-related factors affecting people's uptake of diabetes care is reported. Examples include contacting people before appointments or shortly after non-attendance, the extent to which practice staff focuses on practical reasons for non-attendance, and integration of diabetes care with other routine care (32) - although reasons for practice variation in patient uptake of diabetes

care sometimes might remain unknown (33). To summarise, consideration of individual characteristics and modifiable practice-related factors might be useful to improve monitoring of people with type 2 diabetes.

Our results concerning the association between socioeconomic deprivation and higher HbA1c levels, which resonate with previous studies (5, 34, 35), are relevant since every 1% reduction in HbA1c is associated with a lower risk on numerous diabetes-related health complications including death (36). In addition, our findings that monitoring as recommended is associated with lower HbA1c levels confirm other work (21). With regard to the modifying effect of SES, the HbA1c difference between people with recommended versus incomplete monitoring was higher in the deprived category than in the intermediate category. Being monitored as recommended was particularly in deprived people associated with better HbA1c levels. Literature about the modifying effect of socioeconomic status on the relationship between chronic conditions and health outcomes is scarce. One study amongst people with type 2 diabetes found effect modification in some subgroups; in high socioeconomic groups, absence of comorbidities was associated with substantially better health outcomes than in low socioeconomic groups (37). Furthermore, the ability to understand and apply disease-related knowledge and having sufficient financial resources contribute to (self-rated) adequate coping in terms of diabetes self-care and medication adherence (38, 39).

The high monitoring-related HbA1c difference in the deprived category might be explained by specific characteristics of deprived populations such as inadequate perceptions of lifestyle risks, erroneous health cognitions and beliefs (13-15) and limited disease-related knowledge (40). These factors might, in turn, be related to limited 'health literacy', which refers to skills that enable a person to understand health information and to apply this knowledge adequately in daily life (41). This is echoed by studies reporting lower health literacy in deprived areas (42), and associations between low health literacy and unhealthy behaviours (43, 44) or lower treatment compliance (45). In other words, diabetes outcomes in deprived populations are affected by essential person-related factors that are connected to lower health literacy.

To add, in deprived populations, lifestyle counselling is often limited or incompletely delivered (46, 47). This could be understood from frequently reported doubts among health professionals regarding the effectiveness of lifestyle counselling in these populations in general, fear to negatively affect the relationship with the individual patient and lack of confidence in own professional skills to coach these populations successfully (47, 48). Thus, the emphasis on sufficient

attention for lifestyle counselling (1, 2) in structured care approaches might be an additional factor explaining the high monitoring-related HbA1c difference in deprived populations.

Strengths and limitations

The current study has several strengths. First, an observational design is a commonly used pragmatic approach to diabetes-related studies in primary care due to several important merits, such as that it does not interfere with the daily routine in family practice. Consequently, our observational real-life setting mirrors actual practice with regard to monitoring and HbA1c levels in primary diabetes care. In addition, the stability and the validity of our findings were both improved by the fact that people were only included if they participated for a minimum of 12 months, and due to correction for age, diabetes duration, gender and GP practice. By contrast, while randomised clinical trials can reduce bias, they often suffer from inadequate power and generalisability (49).

Limitations of this study include the fact that socioeconomic characteristics were only available on neighbourhood level and that people from the district of Rijswijk were excluded due to heterogeneous socioeconomic characteristics. In addition, no conclusions can be drawn regarding causality, and the effect of care group participation on monitoring and HbA1c levels in different socioeconomic categories was unclear. Furthermore, as people older than 80 years old were not included, this might affect the generalisability; our findings is only applicable to a younger diabetes population. Moreover, a missing registration does not by definition imply that care has not been delivered. Therefore, it cannot be ruled out that missing data were due to a lack of time or technical problems rather than an absence of care itself. Finally, this study focused primarily on socioeconomic differences regarding recommended monitoring and associations with HbA1c levels. However, to achieve adequate monitoring might require far more effort in deprived compared to advantageous neighbourhoods, considering the previously described inadequate perceptions of health risks and the higher prevalence and relapse of unhealthy lifestyle-related behaviours. As our data endpoints did not take this possibility into account, our findings underline the need for greater understanding of the outcomes of structured primary diabetes care in a collectively supported approach. Our care group approach, characterised by a focus on prevention in primary diabetes care and systematic quality support for GPs and nurse practitioners, could be a first step in bringing the benefits of modern health facilities to high-risk populations (50). We therefore recommend that future research should aim to provide further insight into the effects of long-term structured primary diabetes care within a care group setting on monitoring completeness, HbA1c levels and their respective interactions. In addition, it could be interesting to explore more in detail how many and which indicators are

missing in incompletely monitored people and how this affects health outcomes. Moreover, given that practice and patient characteristics within SES categories might affect the delivery of diabetes care, further exploration of practice-related factors in the context of care provision is recommended.

Conclusions

To summarise, within a collectively supported structured primary diabetes care setting, socioeconomic status was not related to monitoring of biomedical and lifestyle target indicators as recommended by professional guidelines. Recommended monitoring was associated with lower HbA1c levels in all socioeconomic categories. Nevertheless, the observed HbA1c differences between people with recommended versus incomplete monitoring, which were significantly more pronounced in the deprived category, endorse further exploration of practice and patient-related factors contributing to appropriate monitoring. Moreover, these findings advocate care adjustment to population needs with specific attention for deprived populations.

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5

Towards tailoring of primary diabetes care: a mixed-methods study of key conditions for successful implementation of self-management interventions

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Abstract

Background Dutch standard diabetes care is generally protocol-driven. However, considering that general practices wish to tailor diabetes care to individual patients and encourage self-management, particularly in light of current COVID-19 related constraints, protocols and other barriers may hinder implementation. The impact of dispensing with protocol and implementation of self-management interventions on patient monitoring and experiences are not known. This study aims to evaluate tailoring of care by 1) Understanding experiences of practices when dispensing with protocol; 2) Determining the key conditions for successful implementation of self-management interventions; and 3) Exploring patients' experiences regarding dispensing with protocol and self-management interventions.

Methods in this mixed-methods prospective study, practices (n=49) were invited to participate if they met protocol-related quality targets, and their adult patients with well-controlled type 2 diabetes were invited if they had received protocol-based diabetes care for a minimum of one year. For practices, study participation consisted of the opportunity to deliver protocol-free diabetes care, with selection and implementation of self-management interventions. For patients, study participation provided exposure to protocol-free diabetes care and self-management interventions.

Qualitative outcomes (practices: 5 focus groups, 2 individual interviews) included experiences of dispensing with protocol and the implementation process of self-management interventions, operationalised as implementation fidelity. Quantitative outcomes (patients: routine registry data, surveys) consisted of diabetes monitoring completeness, satisfaction, wellbeing and health status at baseline and follow-up (24 months).

Results Qualitative: In participating practices (n=4), dispensing with protocol encouraged reflection on tailored care and selection of various self-management interventions. Furthermore, a focus on patient preferences, team collaboration and intervention feasibility was associated with high implementation fidelity.

Quantitative: In patients (n=126), likelihood of complete monitoring decreased significantly after two years (OR 0.2(95%CI 0.1-0.5), p<0.001), satisfaction decreased slightly (-1.6 (95%CI -2.6;-0.6), p=0.001), and non-significant declines were found in wellbeing (-1.3 (95%CI -5.4; 2.9), p=0.55) and health status (-3.0 (95%CI -7.1; 1.2), p=0.16).

Conclusions To tailor diabetes care to individual patients within well-organised practices, we recommend dispensing with protocol while maintaining one structural annual monitoring consultation, combined with the well-supported implementation of feasible self-management interventions. Interventions should be selected and delivered with the involvement of patients and should involve population preferences and solid team collaborations.

Introduction

Diabetes primary care is increasingly delivered based on structured care protocols (1-4). In the Netherlands, where 6.0 percent of all inhabitants had a diagnosis of type 2 diabetes in 2015 (5), more than 80 percent of them were treated in primary care (6). Professional guidelines for standard diabetes primary care - developed by a national scientific council for general practitioners (GPs) - include monitoring of HbA1c levels, systolic blood pressure and LDL together with lifestyle-related indicators, at least once a year (7). To improve adherence to these guidelines, most GPs have now unified into 'care groups', which facilitate delivery of structured diabetes care protocols and provide logistic and quality support to individual practices (8). For a description of the protocol and care group approach, see textbox 1 and figure 1.

Textbox 1. Care group approach and diabetes protocol

The care group approach supports stakeholders at several levels. People with type 2 diabetes are offered a protocol comprising 3-monthly consultations at the practice location by the GP or nurse practitioner. During these consultations, the GP or nurse practitioner monitors diabetes-related health indicators and provides lifestyle coaching (9). Generally, one annual consultation, specifically focused on monitoring of biomedical health indicators, is delivered by the GP. The additional three consultations, which are typically delivered by nurse practitioners, are primarily dedicated to lifestyle counselling and self-management support. Participation is free of charge for individuals and all consultations are reimbursed by health insurance companies.

For practices, care group support includes i) the availability of a team of specialised nurses who provide coaching with regard to the implementation of protocols, ii) task delegation from GPs to nurse practitioners, iii) an electronic system providing up-to-date monitoring information on the diabetes population; and iv) professional education.

In addition, care groups negotiate with health insurance companies on behalf of participating practices regarding the content of the structured care protocols, annual quality targets and reimbursements. Although quality targets and reimbursements vary depending on local agreements between care groups and insurance companies, annual quality registrations of all care groups are monitored on a national level. More specifically, all care groups are asked to provide data on the number of people with at least one registration of a predefined set of diabetes health indicators including HbA1c, systolic blood pressure, LDL and lifestyle-related variables. More details on care group support, roles and responsibilities in the practice team are presented in appendix 1, table 1.

Structured type 2 diabetes primary care is associated with improved monitoring of key biomedical and lifestyle-related health indicators (10, 11) and better monitoring of these indicators is associated with lower HbA1c levels (12), particularly in poorly-controlled people (13). However, given that guideline compliance is known to be affected by physician attitudes (14), protocol-based delivery of diabetes primary care is the subject of growing discussion. For example, many GPs find protocols too restrictive (15), or insufficiently flexible and thus of limited

value for individual patients (16). In addition, a systematic metareview revealed that GPs not only experience clinical professional guidelines as undermining their professional autonomy and limiting treatment options but also doubt the credibility of underlying scientific evidence (17). Furthermore, GPs who use care protocols report barriers such as additional registration duties and perceived bureaucracy (18), while at the same time, gaps have been reported concerning the adjustment of diabetes care to individual needs (19).

In line with the perspective of the so-called 'patient-centered medical homes' in the United States (20), GPs would reportedly prefer to adjust diabetes care to individual patient preferences (21), which might improve patient 'self-management', defined here as 'the ability to navigate optimally through a multitude of daily disease-related decisions and care activities' (22). Empowerment of patient self-management is considered a cornerstone of appropriate diabetes care (3, 22-24) - particularly considering recent developments around COVID-19 (25)that hinder delivery of in-person diabetes care. Many self-management interventions are available and a national Dutch toolkit of self-management interventions (26) includes, amongst others, group-based training to improve people's coping skills with regard to diabetes self-management, including goal-setting and problem-solving skills (27), an SMS service that healthcare professionals can use to periodically send patients messages encouraging lifestyle adjustment; and an online application in which health care providers can present 5-minute blocks of information on various disease-related topics. Unfortunately, evidence for the effectiveness of self-management interventions in primary care is fairly mixed (28-31), which might be partly related to the fidelity of the implementation process, since outcomes are strongly affected by process elements such as implementation strategies, quality of delivery and participant responsiveness (32). A refined model covering generic aspects of implementation (33) provides insight into implementation. These include A) Implementation strategies: specification of strategies used to support optimal and standardised implementation; B) Coverage: Proportion of intervention participants who received the implementation strategy; C) Participant responsiveness: The extent to which participants are engaged by and involved in the activities and content of the program; and D) Quality of delivery regarding intervention components: The extent to which the intervention is delivered in correspondence with its design. In this study, an implementation combined with sufficient attention for these process elements is classified as successful.

To our knowledge, however, little is currently known regarding the experiences of GP practices that dispense with care protocols or regarding facilitators of successful implementation of self-management interventions in primary diabetes care. Within a study setting, practices

may feel that interventions are 'time-consuming' and 'too disruptive', which may hinder implementation or delivery of interventions as originally intended (34, 35). In other words, successful implementation requires that factors related to providers and to the organisational context both receive sufficient attention (36). Furthermore, insight into effective strategies to select interventions (37) is needed in order to overcome practice-related barriers.

While more effort is needed regarding uptake of the implementation process, it is nevertheless important to respect professional autonomy and personalised care (38). Therefore, in the context of this study, we regard practices as experts in terms of possibilities to tailor care and in the selection of appropriate interventions in their specific population and organisational context. In our view, dispensing with protocol is relatively safe in well-organised practices that see the majority of their patients at least once a year. In view of the goal of tailored care, the primary aims of this study were explored with qualitative methods, in order to gain insight into a) practice experiences regarding dispensing with diabetes protocol including development of a vision concerning the tailoring of care for individual patients; and b) to determine the key conditions for successful implementation of self-management interventions as a 'proof of concept' within well-organised practices. Furthermore, to facilitate a better understanding of patient outcomes, we investigated - on an exploratory basis - the impact of tailored care on people with diabetes concerning monitoring, satisfaction, wellbeing and health status.

Methods

Setting

This study was conducted among practices participating in Hadoks, formerly known as care group ELZHA, which included 157 practices in January 2016. At that time, Hadoks offered structured primary care protocols for type 2 diabetes, chronic obstructive pulmonary disease and cardiovascular disease management to socioeconomically and culturally diverse populations. On behalf of practices, annual targets for the registration of patient monitoring were negotiated with insurance companies. Socioeconomic characteristics, categorised as deprived, intermediate or advantageous, were based on standardised calculations by the municipality of The Hague (39).

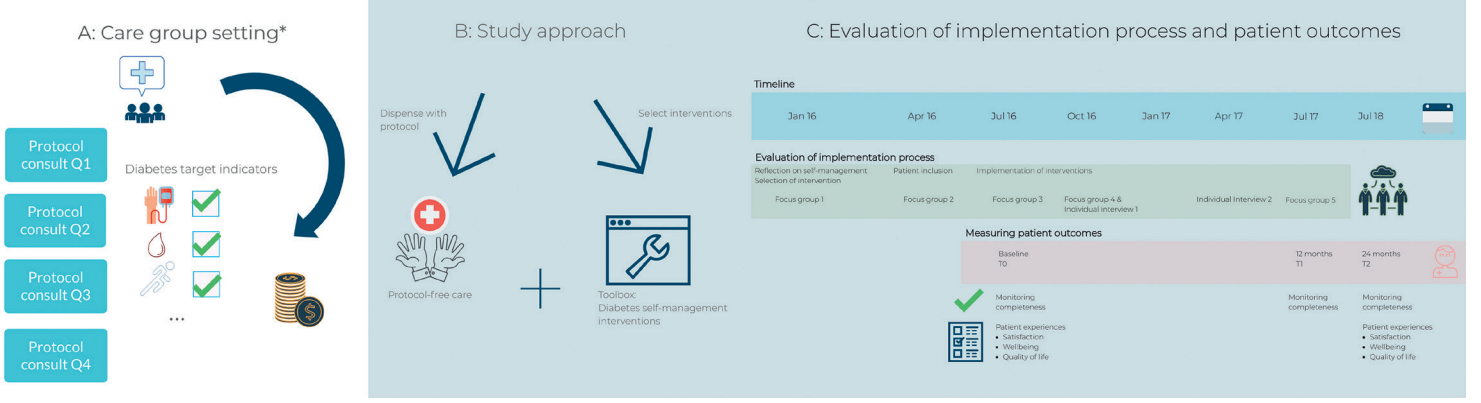

Figure 1. Overview of care group setting, study approach and study outcomes

Study design

In this mixed-methods prospective study, practices were allowed to dispense with diabetes protocol and to implement self-management intervention(s) as an alternative. A qualitative case study approach (40) was used to study experiences of practices regarding dispensing with protocol and the process of implementation of self-management interventions. Furthermore, to determine experiences of people with diabetes, quantitative methods were used to measure completeness of diabetes monitoring, satisfaction, wellbeing and health status.

Intervention

From January 2016 through July 2017, study practices were permitted to dispense with the diabetes protocol including registration duties, while maintaining reimbursements. Practices had the opportunity to choose and implement self-management interventions inspired by a nationally approved set of self-management tools (26), based on their view of the practice population and their preferences as a practice. Study participation included implementation support by KB, coordinator for the Hadoks staff nurse team, who was available for questions and general assistance. In addition, collective study meetings were organized, including development and presentation of an action plan for implementation, and the identification of barriers and facilitators affecting the implementation process etcetera, which enabled practice teams to reflect on their progress and to exchange tips and tricks. Moreover, these topics, including support needs, were discussed in more detail during the individual practice visits (see appendix 2, table 1). An overview of the study structure is presented in figure 1. From January to March 2016, practices were challenged to think about the tailoring of care to individual patients in their own practice and to subsequently choose at least one self-management intervention. From April to July 2016, practices invited patients to participate in the study. From August 2016 through July 2017, practices had the opportunity to implement the self-management interventions of their choice. From the perspective of the patients, the intervention included exposure to the self-management interventions as implemented by their practices.

Sampling of practices and patients

According to Hadoks quality standards, practices were classified as well-organised if 1) they offered the diabetes protocol and at least one other care protocol, and 2) monitoring targets were met in calendar year 2014. Details are provided in appendix 1, table 2. Between October and December 2015, all well-organised practices were invited to participate – both personally by Hadoks' staff nurses and in written form. Study practices selected adult individuals who at that point had received the diabetes protocol for at least one year, had a HbA1c≤64 mmol/mol and had no insulin treatment. All patients meeting these eligibility criteria were invited by their

practice, in writing, to participate in the study. If necessary, a written reminder was sent after a period of two weeks. Patients were only enrolled when written informed consent was received.

Data collection

Qualitative study

Five semi-structured focus group sessions, led by KB (health scientist and Hadoks' staff nurse team coordinator) and SvB (psychologist skilled in qualitative research methods) were held with GPs and nurse practitioners from all included practices. Furthermore, two semi-structured individual interviews, conducted by SvB and KB, were held at each practice location. All focus groups and individual interviews were attended by each practice team, and at least one GP and one nurse practitionerwas present from each practice. A topic guide (see appendix 2, table 1) was used for all focus groups and interviews, which also provided room for participants to raise their own issues. Focus groups and interviews were audiotaped with the consent of the participants and were transcribed verbatim.

Quantitative study

To determine monitoring completeness at baseline (T0), after 12 months (T1) and after 24 months (T2), we used pseudonymised data on patient monitoring that was obtained from the primary care data registry. To gain insight into various aspects of patient experiences, several questionnaires were used which participating patients received at home immediately after study registration (T0). They were asked to complete and return the questionnaires to the university's general support desk. If necessary, patients received a reminder after two weeks. Patients received follow-up questionnaires 24 months later (T2), which were also followed by a reminder after two weeks where necessary.

Outcomes

Qualitative study

Practice level: 1) GPs' and nurse practitioners' experiences regarding dispensing with diabetes protocol, which were measured during focus group 1, 2 and 5; 2) vision development concerning tailored care (focus group 1 and 2) and construction of action plan for the implementation of the selected intervention (focus group 2); 3) the implementation process regarding self-management interventions, operationalised by the assessment of implementation fidelity and identification of elements essential to successful implementation, which was investigated during focus groups 2, 3, 4 and 5 and the individual practice interviews.

Quantitative study

Patient level: 1) the odds of patients being monitored as recommended by professional GP guidelines (7). Accordingly, patients were defined as being 'monitored as recommended' if at least one measure had been registered in the previous 12 months for each of the biomedical (HbA1c, systolic blood pressure, LDL) and lifestyle-related (body mass index, smoking behaviour, physical exercise) target indicators (10, 12); 2) Patient experiences at baseline (T0) and after 24 months (T2) as determined by the following questionnaires: A) Treatment satisfaction: Diabetes Treatment Satisfaction Questionnaire (41) (DTSQ, 1,4,5,6,7,8, total score 0=very negative to 36=very positive); B) Wellbeing: World Health Organization Wellbeing Index-5 (42) (WHO-5, 5-item total score 0=very low, 100=very high); C)Health status: EuroQol Visual Analogue Scale (43) (EQ-VAS, 1 item), score 0=worst imaginable, 100=best imaginable).

Data analysis

Qualitative analysis

Pseudonymised transcripts of all group and individual sessions were studied independently by two researchers (SvB and JSM, master in clinical psychology). First, all transcripts were read and analysed separately based on content analysis (44). This included, after initial exploration of the transcriptions, deductive coding based on categories that were derived from our conceptual model. In each category, emerging themes were identified. Then, in an ongoing analysis, discrepancies and disagreements that emerged were discussed with co-authors until consensus was reached. Using the final coding, a codebook for dispensing with diabetes protocol and the implementation process was constructed.

A checklist (33) which was originally developed for the assessment of implementation fidelity within studies, was subsequently applied to the codebook to assess intervention implementation as reported by practices. Each intervention was assessed from zero to maximally two points on a) fidelity of implementation strategies, b) coverage and c) participant responsiveness (for the checklist including rating details, see appendix 2, table 2). In addition, the quality of delivery was rated as 'good' or 'limited'. The sum of all points resulting in a final rating of implementation fidelity. Components essential for successful implementation were derived from the facilitators within interventions with a high rating of implementation fidelity and from barriers within low-rated interventions.

Quantitative analysis

As regards patient baseline characteristics, categorical variables were reported as numbers and percentages. Continuous variables were reported as means with standard deviations (SD)

or, in case of non-normal distribution, as medians with interquartile ranges (IQR). To compare odds of patients being monitored as recommended at T0, T1, and T2, logistic multilevel analysis was carried out. To compare patient satisfaction, wellbeing and health status at T0 and T2 (not available at T1), linear multi-level analyses were performed. Multilevel analysis allowed us to adjust individual observations (level 1) for GP practice (level 2). In addition, analyses were adjusted for age and diabetes duration (in quartiles), and for gender. Descriptive statistics were analysed using SPSS version 24.0. Multilevel analyses were performed using ML WiN (Version 2.28).

Results

Qualitative study

Of the 49 practices approached, four practices varying in size, organisation and social-economic characteristics of practice location (table 1) agreed to participate in the study.

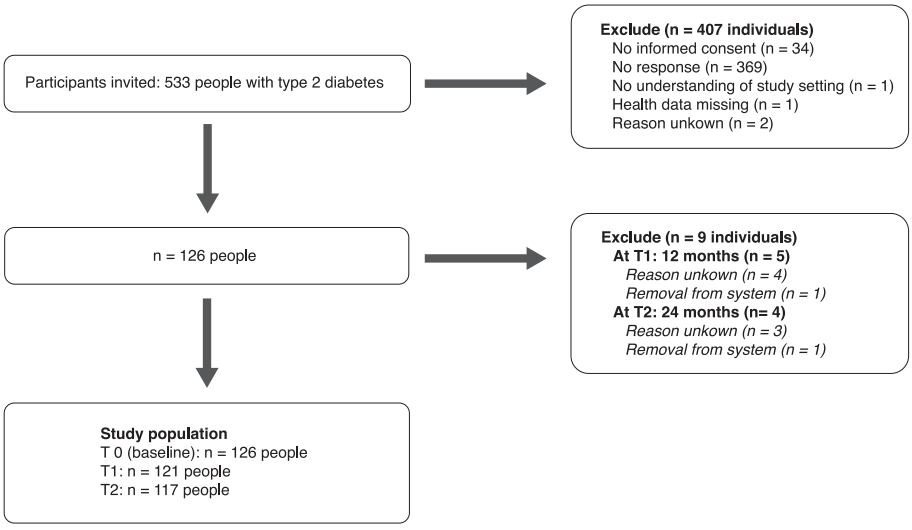

Figure 2. Flowchart of patient inclusion

No specific characteristics differentiated participating and non-participating practices. Participating GPs and nurse practitioners differed in age and years of experience and eExcept for one GP, all participants were female. Illustrative quotes of participants are presented in table 2.

Table 1. Baseline data of participating practices

	A	B	C	D	Total
Practice characteristics					
Volume of registered patients	2 * norm[1]	1.5 * norm	2* norm	> 2 * norm	
SES	Deprived	Mixed (deprived/ advantageous)	Advantageous	Deprived	
Primary intervention	SMS service	Exploration patient needs	Patient ePortal	Consultation reduction	
Patient characteristics					
Participants (n)	49	31	11	35	126
Age (years): median [IQR]	68 [61 – 72]	68 [64 – 76]	70 [59 – 80]	64 [62 – 70]	68 [62– 72]
Diabetes duration (years): median [IQR]	7 [3 – 9]	6 [2 – 8]	3 [2 – 8]	7 [3 – 10]	6 [3 – 9]
Gender: female n (%)	21 (43 %)	17 (55 %)	3 (27 %)	14 (40 %)	55 (44 %)
Monitoring as recommended, n (%)	48 (98%)	25 (81%)	11 (100%)	31 (89%)	115 (91 %)
DTSQ Status[2]: mean (SD)	30.8 (6.5)	32.3 (3.9)	31.3 (6.0)	29.6 (5.4)	30.9 (5.6)
WHO-5: mean (SD)	54.7 (25.0)	68.2 (15.5)	66.5 (26.4)	53.9 (22.9)	58.4 (23.3)
EQ-VAS: mean (SD)	65.3 (22.2)	77.8 (16.6)	82.8 (11.1)	65.8 (16.5)	69.5 (17.7)

Abbreviations:
DTSQ: Diabetes Treatment Satisfaction Scale; WHO-5 = World Health Organisation Wellbeing Index-5; EQ-VAS: EuroQol Visual Analogue Scale; SES: socioeconomic status

1 National norm for average practice volume: 2,095 patients, 2 DTSQ: Status = all items except no 2 and 3

Experiences concerning dispensing with diabetes protocol

Three practices had positive experiences concerning dispensing with diabetes protocol. In practice A, a sense of freedom was reported. "The liberating part . . . is that you think: 'This year, I don't get judged'. So that lowers the bar," (table 2, #A1.1). According to practice B, 'it provided the impetus to start conversations with people in a different way,' (table 2, #B1.1). Both experiences came together in practice C, "Because we could be independent of numbers . . . you get a different perspective . . ., can focus on self-management," (table 2, #C1.1). Practice D primarily experienced a lack of clarity about what to do: "We were not sure what it would entail and how it would continue, it was a bit of a wait," (table 2, #D1.1). Key themes can be characterised as *liberty facilitating a more person-centred approach* versus *confusion*.

Table 2. implementation fidelity: Interpretation and scoring of the implementation process in each practice

	Practice A	Practice B	Practice C	Practice D	Emerging themes
Experiences of dispensing protocol	**A1.1 FG 5, NP:** The liberating part of this project is that you can think: "this year I don't get judged." So that lowers the bar. Yes, I am in favour of dispensing with protocol, but not when I will be judged on it eventually.	**B1.1, FG 5, NP:** Well it provided the impetus to start conversations with people in a different way. (…) Yes, [we have] developed some more contact with other disciplines in the neighbourhood. And yes, indeed[when you] get started,. you get thrown in at the deep end.	**C1.1, FG 5, NP**: But because we could be independent of numbers (…) you get a different perspective, and a different focus. Now we can focus on self-management.	**D1.1, FG 5, NP:** I have often asked you what we would do with it. So we were not sure what it would entail and how it would continue. It was a bit of a wait.	-Liberty facilitating room for an approach more tailored to individual patients -Confusion concerning expected delivery of care
Vision on tailored care	**A2.1, PI 2, GP**: It might sound trivial, (…) but if they previously never showed up and now they do, then that is already a win.	**B2.1, FG 2, GP:** If the goal is to stimulate self-management and control in the patient, then the starting point is totally wrong if we decide what the patient has to work with. (…) Patients need to be able to make this choice themselves.	**C2.1, PI 1, GP:** Just that [personal aims related to diabetes] already, that people start to think about it at home, fill it in and write it down, then we have gained a lot already. **GP B:** Then you can provide much more targeted information.	**D2.1, FG 2, NP:** Actually, dispensing with protocol [is good] for people who have to come twice a year at most, who are doing fine and are taking responsibility (…). I am very happy with this project. [Besides that] I will not be pushing the unwilling anymore. If they don't want to, then don't. There's plenty of people who do want to and who are worth the energy investment.	- Improvement of protocol compliance - Shifting care to patient preferences -Encouraging patient involvement

Intervention	SMS reminder service		Layered exploration of patients' needs		Patient e-portal		Consultation reduction		
	Implementation fidelity element including rating (0=low, 2=high)								Emerging themes
Strategies[1]	**A.3.1 PI 1, NP:** The system is very easy. (…) We encountered some problems (…). Often, mobile phone numbers were not saved in the right place in the electronic patient record, and then the SMS service would not get linked to it. (…) [we worked on this with] the whole team: if someone shows up at the front desk, ask them whether they have a cellphone number and then check whether it is saved in the right place. (…). So it does have a sort of start-up phase (…). You really have to be dedicated (…) So we are already paying attention to it as much as possible. **A.3.2 PI 1, NP:** And I have to check: How much time does this cost? And thenI possibly [have to] cancel a consultation so that I have more time for that.	2	**B3.1, FG 2, GP**: We started thinking: how can we do this? (…) To approach a few project participants to attend an externally organised sort of meeting at the practice (…),that was our first step (…). The second step was that we wanted to invite the entire group of participants (…) to provide information about which self-management tools wewould offer as a practice (…) to these patients, and then see if people were keen (…). So we are still in the phase where we don't know what we will do at all. We will see. I'm curious. **B3.2, PI 1, GP:** Regarding our choice in favour of a patient portal, I think that we should give ourselves enough time (…) I think that it will be "yes", but I think that this needs to be a practice-wide decision.	2	**C3.1, PI 1, GP:** The primary aim is about putting the patient in control, with eVita as a means to make patients do their homework (…) That is the essence of eVita. So we expect a lot from this. **C3.2, FG 2, GP:** The user's manual for eVita has to be so simple that (…) you can explain everything on single sheet of paper. (…) There will be patients who do not know how to use a computer. They might get a notification: "Write it down [on paper]" and then you have already achieved something. That has to be possible too.	2	**D3.1 PI 2, NP:** We told a lot of people that they were doing fine and that visiting four times a year was unnecessary;. that once a year was also fine.	0	-Involvement of practice team -Consideration of patient preferences -Communication with patients

Table 2. Implementation fidelity: Interpretation and scoring of the implementation process in each practice (continued)

	Practice A		Practice B		Practice C		Practice D		Emerging themes
	SMS reminder service		**Layered exploration of patients' needs**		**Patient e-portal**		**Consultation reduction**		
Coverage[1]	**A4.1, FG 4, GP**: We can now invite people by SMS. And [having started with the study participants], we now want to extend this to all nurse practitioners and all of our diabetes patients.	2	**B4.1, FG 2, GP:** One is more articulate than the other in the practice (…) **FG 5, NP:** We invited four patients to join the patient panel. **B4.2, PI 1, GP:** A kind of patient meeting where we send a message to all diabetics. Kind of an open invitation (…). Maybe the physical therapist can give some more information. Maybe the dietician can join in. Just to give it some features, raise its profile a bit. **B4.3, FG 5, NP:** We sent by post. invitation letters fconcerning the health market to 230 patients	2	**C4.1, FG 5, NP:** Based on your inclusion criteria, 90 patients were eligible [in our entire T2DM-population] and 33 signed up. 15 people actually used it. **GP**: And 10 actually logged in.	1	**D4.1, FG 3, NP 2:** I feel like I should only let the motivated people take part , otherwise it is just a constant up hill struggle (…) Some say: "Maybe." Then I think: Well, this one is not motivated.	1	Not applicable

	A5.1, **FG 5, NP:** Patients always ask "Will I get a text message again next time? Because I really appreciate it." (…) Other people are like "well if you hadn't sent that text, I wouldn't have come." (…) You can see that patients do really appreciate it.	2	**Patient panel:** **B5.1, PI 1, NP:** Look, obviously it was a very small group, but I am very happy with what has come out of it. **FG 5, NP:** People have often told me: "We thought it was a really nice evening, because you could share experiences with each other." **Health market:** **B5.2, FG 5, NP:** It was in the late afternoon. But a Thursday or a Friday? (…) Also neighbourhood-wide (…). I think about seventy came. There were fifty who filled in the evaluation forms. Five or six patients signed up for eVita at the time, but now, I have got three additional registrations. (…) Nine people also registered for a course about 'Living with diabetes' (…) Three nights of two and a half hours, for a maximum of 12 people. **B5.3, FG 5, NP:** Yes, but afterwards we did hear from people "it was great fun, you should do this more often!" There were also people wo said: "Well... that wasn't really necessary." It gave a boost to do something like this again.	2	**C5.1, FG 5, NP:** Even if you say "This is eVita, you can enter your improvement goals here," people still need guidance. (…) That it is of no use to them if you say "Okay, we figured it out: you actually have four goals of improvement, now get to work to see which ones you want to work on and then figure out how you want to do that (…). It is really letting the patients decide for themselves: "Well we have four things that stand out, what would you like to work on? And shall we write that down as a goal for improvement? Then we get back to that the next time." That is really what works (…) People really have to be motivated and you have to lead them by the hand to maintain self-management. **C5.2, FG 5, NP:** No, and not everyone was equally enthusiastic about eVita. Many people felt it was patronising.	1	**D5.1, FG 5, NP:** Well yeah, you may not want them to visit, but still they want to come. [It must give a feeling] of safety, familiarity. [They are] scared too, that if they don't visit for a year, it gets a lot worse all of a sudden. What then? So for some patients, it was quite difficult not to have to come anymore.	1	-Variability in response of patients

Table 2. implementation fidelity: Interpretation and scoring of the implementation process in each practice (continued)

	Practice A		Practice B		Practice C		Practice D		Emerging themes
	SMS reminder service		**Layered exploration of patients' needs**		**Patient e-portal**		**Consultation reduction**		
Quality of delivery[2]	**A6.1, PI 2, NP:** First, I created a text message group, which was much faster. But then if someone cancels you can't remove that person from the group. I find that very patient unfriendly. You can't do that. (…) Then people get confused "I thought I cancelled?"	+	**B6.1, FG 5, NP:** Last year was one of the first steps (…) [creating] a patient panel (…). We wanted to keep it neutral, [so] we were not present ourselves. (…) Different things were brought up. (…) For example, the need to look up information and blood results (…), a diabetes course, advice about food (…) and exercise (…) As a result, we organised a health information market (…). A range of disciplines of the local area participated (…) Although everyone focused on diabetes care, some also covered care for the elderly.	+	**C6.1, PI 2, NP:** In my opinion, eVita is not yet where it has to be. (…) I don't think it is very clear, it is a bit abracadabra. That is also the feedback I get from people. (…) Well some [already encounter problems] upon signing up, but then you have problems really early on. I had a man in here twice saying: (…) "I really want it, but I just can't do it". (…) [In contrast to the desktop version], the [mobile] app only allows the input and display of certain predetermined values. And there you can't see the videos. That's a pity. **C6.2, PI 2, GP:** And those videos were pretty stupid.	-	**D6.1, PI 3, NP:** I feel like (…) we didn't keep going. (…) A person with diabetes attends your consultation hour and our system then states says "Participating in the project." But the program is not any different. At least, with the people I see, I do the same things I always do. **D6.2, PI 3, NP:** No, nothing has changed. **NP:** I think that some people may have visited less often, but I don't have an overview of that.	-	-Sensitivity to patients' needs - Involvement of practice team -Negative experiences concerning user-friendliness of the ePortal
General Implementation fidelity: fidelity: sum score	6		6		4		2		
			High		Low				

Abbreviations: FG = focus group; PI = practice interview; GP = general practitioner; NP = nurse practitioner

[1] For details on rating: see adjusted checklist (supplementary file 2)

[2] + represents good quality of delivery, - represents limited quality of delivery

Vision development on tailored care and selection of self-management interventions

The process of reflection on the tailoring care to individual patients resulted in a disparity of views across the participating practices. Practice A, where the no-show rate was high, aimed at supporting patients to improve consultation attendance: "It might sound trivial . . . but if they [previously] never showed up and now they do, then that is already a win," (#A2.1). This resulted in the selection of an SMS reminder service to help patients remember their diabetes consultation.

Practice B stated that patients should have an important voice in the development of care tailoring. "…The starting point is totally wrong if we decide what the patient has to work with . . . Patients need to be able to make this choice themselves," (#B2.1). Subsequently, they developed a layered approach to exploring patients' preferences.

In the view of practice C, tailoring of care meant adapting the consultation to a patient's information needs, "…That people start to think about it at home . . . then you can provide much more targeted information," (#C2.1) Therefore, a patient ePortal was selected for implementation.

Practice D perceived tailoring of care as investing in the people willing to receive diabetes care with a frequency adjusted to the patient's wishes, in preference to investing in people with little motivation. "Actually, dispensing with protocol [is good] for people . . . who are doing fine and taking responsibility. [Besides that] I will not be pushing the unwilling anymore . . . There's plenty of people . . . who are worth the energy investment (#D2.1).

Amongst the multiplicity of views on tailored care, several themes were observed that could be refined to *'improvement of protocol compliance', 'shifting care to patient preferences'* and *'encouraging patient involvement'*. These different themes were mirrored in the varied choices of self-management interventions, which were primarily patient-focused, such as the SMS reminder service, explicit exploration of patient needs with subsequent selection of instruments, and the ePortal, or, in the case of consultation reduction, practice-focused (appendix 2, table 3).

Implementation process: conceptual elements of implementation fidelity

Implementation strategies

The applied implementation strategies could be broadly differentiated. For example, although the implementation of the SMS service for patients in practice A appeared relatively straightforward,

it still required changes regarding registration procedures and information sharing within the entire practice team, including medical assistants. "We encountered some problems . . . [We worked on this] with the whole team . . . So it does have a sort of start-up phase. . . . You really have to be dedicated," (#A3.1). Practice B decided to consult a representative patient panel concerning their preferences regarding self-management interventions. Subsequently, this practice presented the panel's recommendations to all patients with diabetes registered at their practice during a large-scale health event known as a 'health market', with the aim of implementing popular interventions. "To approach a few project participants to attend an externally organised sort of meeting at the practice. . . , that was our first step. The second step was to invite the entire group of participants to provide information about which self-management tools we would offer as a practice . . . and then see if people were keen," (#B3.1). Furthermore, concerning the selection of concrete interventions, the commitment of the full practice team was important. "Regarding our choice . . . I think it will be a yes but I think that this needs to be a practice-wide decision," (#B3.2).

Practice C decided to implement the ePortal for patients while providing support with an easily-accessible instruction guide. "The user's manual has to be so simple that you can explain everything on a single sheet of paper," (#C3.2). Practice D did not report actually considering of patients' preferences, but simply offereda reduction of consultation frequency within a framework of standard diabetes consultations. "We told a lot of people that they were doing fine and that visiting four times a year was unnecessary; that once a year was also fine," (#D3.1). Key themes that emerged concerning implementation strategies included *involvement of the practice team*, *consideration of patients' preferences* and *communication with patients*.

Coverage

Practice A, B and C targeted their interventions to all the diabetes patients in the practice. Practice A: "We can now invite people by SMS. And [having started with the study participants] we now want to extend this to all nurse practitioners and all of our diabetes patients," (#A4.1). Practice B: "We invited four patients to join the patient panel,"(#B4.1). "We sent by post information letters concerning the health market to 230 patients (#B4.3). Practice C: "Based on your inclusion criteria, 90 patients were eligible and 33 signed up," (#C4.1). Practice D focused exclusively on motivated patients amongst the study participants. "I feel like: I should only let the motivated people take part, otherwise it is just a constant up hill struggle," (#D4.1).

Participant responsiveness

Participant responsiveness was high in practice A, where patients actively requested continuation of the SMS service. "Patients always ask, 'Will I get a text message again next time? . . . Other people are like 'Well if you hadn't sent that text, I wouldn't have come'," (#A5.1). The layered approach chosen by practice B was also very positively received, by patients as well as by the practice team itself. "Look, obviously it was a very small group, but I am very pleased with what has come out of it. People have often told me: 'We thought it was a really nice evening, because you could share experiences with each other," (#B5.1). Furthermore, the health market was well-attended. "It was in the late afternoon. I think about seventy came. . . . Five or six patients signed up for eVita at the time, but now I have three additional registrations. Nine people also registered for a course about 'Living with diabetes'," (#B5.2). There was an overall good response from patients– which in turn resulted in enthusiasm among the practice team. "It gave a boost to do something like this again," (#B5.3).

In practice C, patients apparently needed more than a user manual to be able to use the ePortal. "Even if you say: 'This is eVita, you can enter your improvement goals here', people still need guidance. . . . People really have to be motivated and you have to lead them by the hand to maintain self-management," (#C5.1). In addition, the enthusiasm of patients was limited. "Many people felt it was patronising," and participant responsiveness was consequently limited (#C5.2). In practice D, patients' willingness to reduce consultation frequency was low for reasons of safety and fear of worsening diabetes health, "Well yeah, you may not want them to visit, but they still want to come. [It must give a feeling] of safety, familiarity; [they are] scared too, that if they don't visit for a year, it gets a lot worse all of a sudden," (#D5.1). Thus, across the participating practices, the responsiveness of patients to the selected interventions varied considerably.

Quality of delivery

The SMS service in practice A was delivered with high sensitivity from the perspective of patients. "First, I created a text message group, which was much faster. But then if someone cancels you can't remove that person from the group. I find that very patient-unfriendly. You can't do that . . . . Then people get confused; "I thought I cancelled?'" (#A6.1). The layered exploration of patient needs by practice B was also characterised by thorough delivery in agreement with its initial goal, "Last year was one of the first steps . . .[creating] a patient panel . . . Different things were brought up. . . For example, the need to look up information and blood results (. . .), a diabetes course, advice about food . . and exercise . . . As a result, we organised a health information market . . . A range of disciplines from the local area participated . . . Although everyone focused on diabetes care, some also covered care for the elderly," (#B6.1).

In the other practices the quality of intervention delivery was limited. Implementation of the ePortal by practice C was not yet feasible since patients reported that the ePortal was complicated to use. "In my opinion, eVita is not yet where it has to be. . . . That is also the feedback I get from people. . . . Well some [already encounter problems] upon signing up, but then you have problems really early on. I had a man in here twice saying . . . "I really want it, but I just can't do it". . . . [In contrast to the desktop version], the [mobile] app only allows the input and display of certain predetermined values. And there you can't see the videos. That's a pity," (#C6.1). Furthermore, the tutorial clips were perceived as low-quality, "And those videos were pretty stupid," (#C6.2). In practice D, the plan to reduce consultations had simply not been implemented and no differences in daily care delivery were reported. "I feel like . . . we didn't keep going. . . . A person with diabetes attends your consultation hour and our system then states: "Participating in the project." But the program is not any different. At least, with the people I see, I do the same things I always do . . . I think that some people may have visited less often, but I don't have an overview of that," (#D6.1). In other words, there was no perceived delivery of consultation reduction . The themes that emerged regarding quality of delivery included *differing sensitivity to patients' needs and preferences*, *involvement of the practice team* and *negative experiences regarding user-friendliness of the ePortal*.

Rating of implementation fidelity and identification of essential components

Implementation fidelity in practice A and B (overall score: 6) was rated as high, but was limited in practice C (score: 4) and D (score: 2) (table 2). As three practices reported that dispensing with protocol encouraged new ideas regarding changes to care and stimulated out-of-the-box reflection on appropriate interventions. Thhis was identified as the first essential component for successful implementation of self-management interventions.

Practices A and B, both of which had with high implementation fidelity, were characterised by high sensitivity to patient needs and preferences (see #A6.1 and #B2.1) and a strongly collaborative team (see #A3.1 and #B3.2). As the implementation of the patient ePortal by practice C demonstrated, interventions should first be adjusted to users' needs before implementation. In practice D, a lack of focus on people's needs coincided with limited development of a vision on patient-centred care. To summarise, development of a consistent view on the tailoring of care that is rooted in awareness of people's needs and preferences, together with suitable implementation strategies, was of crucial importance for successful implementation.

Table 3. Patient outcomes at baseline, 12 and 24 months

Measure	T0 (baseline) (n = 126)	T1 (n=121)	T2 (n=117)
Monitoring as recommended, n (%)	115 (91%)	106 (88%)	84 (72%)
DTSQ Status: mean (SD)	30.9 (5.6)	N/a[1]	29.2 (5.1)
WHO-5: mean (SD)	58.4 (23.3)	N/a[1]	56.2 (23.5)
EQ-VAS: mean (SD)	69.5 (19.7)	N/a[1]	66.6 (19.2)

Abbreviations:
DTSQ: Diabetes Treatment Satisfaction Scale; WHO-5: World Health Organisation Wellbeing Index-5; EQ-VAS: EuroQol Visual Analogue Scale
[1] N/a: not available

Quantitative study

Of the 533 eligible patients within the four participating practices, 24% (n=126 patients) provided informed consent (figure 2). Loss to follow-up was 4% at T1 (n=5 patients), and an additional 3% at T2 (n=4 patients). Patient outcomes (diabetes monitoring, satisfaction, wellbeing and health status) at T0, T1 and T2 are presented in table 3. With regard to monitoring, adjusted analyses showed that patients were less likely to remain monitored as recommended, with a non-significant difference at T1 (OR 0.7 (95%CI 0.3-1.5),p=0.34, see table 4) and a significant difference at T2 (OR 0.2(95%CI 0.1–0.5),p<0.001), compared to T0. Patient satisfaction with diabetes treatment at T2 was slightly lower compared to T0 (-1.6(95%CI -2.6;-0.6),p=0.001). For wellbeing (-1.3(95%CI -5.4;2.9),p=0.55) and health status (-3.0(95%CI -7.1;1.2),p=0.16), no significant differences were observed between T0 and T2.

Table 4. Multi-level analysis evaluating the difference at T1 and T2 compared to T0 (baseline)

	T1				T2			
	Crude		Adjusted[1]		Crude		Adjusted[1]	
	OR (95 % CI)	p	OR (95 % CI)	p	OR / B (95 % CI)	p	OR / B (95 % CI)	p
Monitoring as recommended (OR)	0.7 (0.3-1.5)	0.35	0.7 (0.3-1.5)	0.34	0.2 (0.1-0.5)	<0.001	0.2 (0.1-0.5)	<.001
DTSQ-Status[2] (B)	N/A[2]		N/A		-1.8 (-2.8;-0.8)	<0.001	-1.6 (-2.6;-0.6)	0.001
WHO-5[4] (B)	N/A		N/A		-1.3 (-5.5;2.8)	0.53	-1.3 (-5.4; 2.9)	0.55
EQ-VAS[5] (B)	N/A		N/A		-3.0 (-7.1;1.2)	0.16	-3.0 (-7.1; 1.2)	0.16

Abbreviations:
DTSQ Status: Diabetes Treatment Satisfaction Scale (all items except no. 2 and 3); WHO-5: World Health Organisation Wellbeing Index-5;
EQ-VAS: EuroQol Visual Analogue Scale
[1] Analysis adjusted for age, duration of diabetes, and gender
[2] N/A: not available

Discussion

This study had a number of goals, including the use of qualitative methods to explore the experiences of well-organised GP practices when dispensing with diabetes protocol, vision development concerning the tailoring of care to individual patients, identifying key conditions for the successful implementation of self-management interventions in primary diabetes care, and exploratory measurement of patient outcomes.

The freedom to dispense with the care protocol enabled practices to develop their own vision on self-management. As illustrated by our findings, the interventions chosen by practices to help patients in optimally navigate life with diabetes, varied substantially and were not only targeted at the patient population, but sometimes also to the practice itself. This demonstrates that interventions targeted at self-management support can take many different forms. Generally, we observed a high level of commitment regarding the implementation process. In addition, a clear focus on the individual needs and preferences among the practice's own patient population, solid team collaboration and intervention feasibility were identified as crucial factors underlying successful implementation. The importance of these factors was confirmed by their absence in one practice where a lack of focus on patients' needs and team collaboration resulted in early abandonment of attempts to tailor care.

To the best of our knowledge, clinicians' professional experiences when not limited to treatment protocols have not yet been systematically investigated. Nevertheless, considering previously reported barriers with regard to protocol compliance, a less rigid protocol can be recommended. A more flexible protocol should be tailored to specific groups, including individuals needing support in order to obtain appropriate diabetes outcomes (45). Considering that adherence to professional treatment protocols is associated with better diabetes knowledge among care providers (46) and with improved processes of care (47), we would advocate finding a balance between the benefits of these protocols and protocol-free care. Factors facilitating the application of protocols include a short and simple presentation, recommendations that require minimal resources before implementation and the involvement of end-users in the development, implementation and testing of guidelines (17).

Adjusting care in order to better match patients' preferences is recommended internationally (20, 48, 49) and accords with previously defined strategies to involve patients in the implementation effort (50). Although self-management interventions primarily aim to improve self-management among patients, factors to the practice itself also emerged as relevant to successful implementation. By dispensing with protocol and allowing a free choice of

interventions, recognised barriers to the delivery of self-management interventions might have been overcome (34). Together with a firm, team-based view on self-management that is rooted in the needs and preferences of the patient population, strong team collaboration confirms previously reported strategies designed to build a coalition of partners in the implementation effort (50). Sufficient intervention feasibility might also be obtained through co-creation with the involvement of users (51). Our findings may also contribute to a shift, from the perspective of the care provider, towards the more active involvement of patients in their own care (52), and thus represent an important step towards patient-centred care (53, 54).

In terms of the exploratory quantitative findings, we found significantly lower odds that people maintained recommended monitoring two years later. A decreased monitoring completeness following departure from protocol accords with data from recent, large-scale studies which found associations between financial incentives and quality-of-care measures in primary chronic care (55, 56). Patient satisfaction, wellbeing and health status showed little or no significant declines over a two-year period. Despite satisfaction with many of the implemented measures, the small decline in patient satisfaction is in line with previous studies which found that patients with diabetes were slightly more satisfied with a higher annual consultation frequency (57). In addition, appropriate monitoring is associated with better HbA1c levels (12). This suggests that when dispensing with diabetes protocol, surveillance should still include at least one annual 'monitoring consultation' but this should be adjusted to patients' needs. However, it should be noted that these analyses had an exploratory character and further studies are needed to achieve a deeper understanding of patient outcomes. This study had several strengths and limitations. A key strength of this study was the mixed-methods observational setting, which avoided any interference with the dynamics of daily GP practice and enabled inclusion of experiences from practice professionals and patients. Secondly, triangulation of researchers' background including social scientists, health scientists and practicing GPs, together with team validation (58), improved the understanding and interpretation of our findings. Thirdly, considering that little is known about the gains when care providers are guided by – rather than limited to – treatment protocols, within this study, we aimed to provide greater dclarity on the impact of a departure from protocol and the tailoring of care on care providers. Moreover, besides our findings concerning the tailoring of care in practices, this study also provided unique initial insights into actual patient experiences when exposed to tailored care.

Some limitations also deserve mention. With regard to our qualitative study, the actual number of participating practices was relatively low. In the midst of competing priorities in daily GP practice, this might be explained by a low sense of urgency regarding self-management (34). Nevertheless, the diversity of the participating practice contributed to the reliability of our qualitative findings.

Concerning our quantitative study, firstly, the design of our quantitative arm did not allow for causal inferences. Secondly, in terms of monitoring completeness of patients, a missing registration does not by definition imply that care was not provided. Thirdly, as clinical outcomes were not included, it is unclear how participant's diabetes-related health parameters have developed – although we know from existing work that recommended monitoring generally is associated with better HbA1c levels (12). Moreover, the generalisability of our quantitative analyses is limited due to the small number of patient participants, an obstacle that also precluded deeper quantitative analysis comparing individual practices or interventions.

As regards future research, we recommend exploring how practices can develop a team-based view on the needs of people with diabetes, how team collaboration can be improved, and how practices can implement self-management interventions without losing sight of patients' diabetes health indicators. Moreover, to deepen our understanding of patient experiences in the context of patient-centered medical homes, it might be interesting to further explore clinical outcomes such as HbA1c levels, treatment satisfaction and, for example, consultation frequency, preferably comparing individual practices, interventions and level of implementation fidelity.

To summarise, our study shows that well-organised GP practices experience shift away from diabetes protocol as liberating and encouraging reflection on tailored care. A focus on patient needs, solid team collaboration and intervention feasibility are all crucial for successful implementation of self-management interventions in diabetes primary care.

In the context of COVID-19, tailoring of care to individual patients is essential to reducingd the negative impact of protocol departure on structural monitoring of individual patients. Therefore, when dispensing with diabetes protocol, we recommend maintaining one structural annual monitoring consultation, together with the implementation of feasible self-management interventions - selected and delivered with a focus on patients' preferences and solid team collaboration. This approach can potentially lead to feasible tailored diabetes care, delivered by highly committed practice teams, with optimal empowerment of diabetes patients.

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Declarations

Ethics approval and consent to participate The study protocol was approved by the medical ethical committee of the Leiden University Medical Center (P16.032). Thus, all methods were carried out in accordance with relevant guidelines and regulations. Before study participation, informed consent was obtained from both GP practices and patients. To ensure confidentiality of participating practices and patients, all qualitative and quantitative data was pseudonymised before analysis.

Consent for publication The informed consent included permission to use the study data after pseudonymisation for publication.

Availability of data and materials The data sets generated and analysed for the current study are not publicly available due to administrative reasons, but are available from the corresponding author on reasonable request.

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Authors' contributions SvB and MJK analysed qualitative and quantitative data and wrote the manuscript. SPR analysed quantitative data and reviewed the manuscript. JSM analysed qualitative data and edited the manuscript. KB edited the manuscript. MEN reviewed the manuscript and contributed to the discussion. NHC is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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Supplementary files

Appendix 1. Details on Dutch diabetes care and well-organised practices

Table 1. Aims and components of the care group approach

Aim	Service	Details
Delivery of care		
	Care protocol	3-monthly patient consultations at the practice location, with options for monitoring of biomedical and lifestyle-related diabetes parameters. The physician bears responsibility for the quality of care and generally conducts one annual consultation personally. The other three consultations are typically performed by nurse practitioners. Participation is free of charge for individuals and all consultations are reimbursed by health insurance companies.
	Computerised clinical decision-making support system (CCDSS)	A system that provides a real-time overview of monitoring information for each patient. Monitoring information includes: a) most recent diabetes measures (such as HbA1c level, systolic blood pressure and body-mass index), and b) an alert when available information is no longer up-to-date.
	Quality support of patient monitoring	Based on the monitoring information registered in the CCDSS, barriers to delivery of care and other obstacles may be highlighted *(examples include internal obstacles related to the quarterly invitation of patients or a high 'no-show' rate due to socioeconomic vulnerability/ limited diabetes awareness).* Tailored support is delivered or coordinated by the Hadoks staff nurse to help practices overcome these barriers.
Stimulating maintenance of up-to-date diabetes-related knowledge and skills		
	Program of relevant vocational courses adjusted to the needs of physicians and nurse practitioners	Each year, an expert team of general practitioners and staff nurses - both specialised in type 2 diabetes - selects vocational diabetes courses that meet the needs of practices participating in the care group – generally, practices with an active focus on structured diabetes care. Based on the expert-based selection of courses, the care group develops a vocational course program for participating practices. Vocational courses can include 'medical' themes (such as new HbA1c medication) or lifestyle-related themes (such as smoking cessation). For physicians and nurse practitioners, attending part of the program is mandatory.

Table 1. Aims and components of the care group approach (continued)

Aim	Service	Details
Organisation of care		
	Coaching by staff nurse	- Delegation of care from physician to nurse practitioner - Team collaboration between physicians, nurse practitioners and medical assistants - On-the-job tailored teaching based on personal needs and preferences of practice team
	Collaboration with other local disciplines	Organisation of educational or prevention-related events for diabetes patients, tailored to local population needs, in cooperation with other disciplines in the neighbourhood such as dieticians, lifestyle coaches and community workers.
Negotiations with healthcare insurance companies on behalf of participating practices		
	Quality control	- Determination of indicators that are clinically relevant and that reflect delivery of diabetes care - Determination of targets with regard to the proportion of patients being monitored for these indicators
	Reimbursement of care	- Tariffs concerning primary care services - Reimbursement of costs related to additional care services supporting primary diabetes care, such as dietician counseling and smoking cessation coaching

Table 2. Requirements for well-organised practices

Delivery of care protocol [1)]	**Monitoring targets** *(at least one measure in calendar year 2014)*
Type 2 diabetes	
	MDRD: 90 %
	Foot examination: 80 %
	Fundus examination: 80 %
Chronic obstructive pulmonary disease	
	Registration of smoking status: 80 %
	Registration of functioning/health status (MRC or CCQ): 70 %
Cardiovascular risk management	
	Systolic blood pressure: 80 %
	LDL profile: 80 %
	Registration of smoking status: 70 %

Abbreviations: MDRD: Modification of diet in renal disease; LDL: Low-density lipids

[1)] Type 2 diabetes and at least one additional protocol

Appendix 2. Materials of the qualitative study

Table 1. Topic list for each focus group and each interview with participating GP practices

Date	Theme	Topics
Jan 16	Focus group 1: Reflection and vision regarding development of tailored care	- Views on the opportunity to leave the structured diabetes care protocol - Ideals regarding diabetes care - The meaning of diabetes-related self-management in participating practices - Room for additional discussion points
Apr 16	Focus group 2: 1) Dispensing with protocol 2) Aims regarding tailoring of care	- Experiences of dispensing with current protocol - Objective of participating practices - Selection of target population - Choice of self-management interventions for implementation - Action plan for implementation of selected interventions - Identification of potential facilitators or barriers regarding the implementation process, including incorporation of these factors into the action plan - Room for additional discussion points
July 16	Focus group 3: General monitoring of implementation process of self-management interventions	- Progress of implementation process in participating practices - Identification of intermediate facilitators or barriers - Needs for support (practical, logistic, general coaching) from the project team - Room for additional discussion points
Oct 16	Focus group 4: General monitoring of implementation process	See description focus group 3
Oct 16	Practice interviews, round 1: Monitoring of implementation process in individual practices	- Progress of implementation process in participating practices - Identification of new intermediate facilitators or barriers - Needs for support (practical, logistic, general coaching) from the project team - Room for additional discussion points
April 17	Practice interviews, round 2: Monitoring of implementation process in individual practices	See description practice interviews round 1

Table 1. Requirements for well-organised practices (continued)

Date	Theme	Topics
July 17	Focus group 5: Reflection on dispensing with protocol and tailoring of care:	- Experiences of dispensing with protocol in participating practices - Overview of selected interventions in each practice - Reflection on the implementation process and its outcomes - Observed barriers and facilitators of the implementation process - Evaluation of benefits resulting from practice participation in this project - Room for additional discussion points

Table 2. Checklist for assessment of implementation fidelity

Element	Description	Conditions	Scoring
Implementation strategy			
	Specifying **the implementation strategy**(s) *and* evidence of the extent to which this/these implementation strategy(s) took place	1: Does the practice describe all implementation strategies used? AND 2: Does the practice provide detail on how all implementation strategies were carried out?	2
		1: Does the practice describe some but not all implementation strategies used? AND 2: Does the practice provide detail on how some but not all implementation strategies were carried out?	1
		1: Does the practice describe all or some implementation strategies used? OR 2: Does the practice provide detail on how all or some of the implementation strategies were carried out?	0[a]
Coverage			
	Proportion of intervention **participants** who received the implementation strategy(s)	1: Does the practice provide a description of the number of people receiving all of the implementation strategies? AND 2: Does the practice provide a description of the strategy or strategies all of the groups received?	2
		1: Does the practice provide a description of the number of people receiving some but not all of the implementation strategies? AND 2: Does the practice provide a description of the strategy or strategies for some but not all of the groups?	1
		1: Does the practice provide a description of the number of people receiving some or all of the implementation strategies? OR 2: Does the practice provide a description of the strategy or strategies for some or all of the groups?	0[a]

Table 2. Checklist for assessment of implementation fidelity (continued)

Element	Description	Conditions	Scoring
Participant responsiveness			
	The extent to which participants are engaged by and involved in the activities and content of the program	1: Does the practice state participants' involvement in the development, evaluation, or receptivity to the implementation strategy? AND 2: Does the practice provide a description of the extent of participant involvement in the development, evaluation, or receptivity to the implementation strategy?	2
		1: Does the practice provide a description of the number of people receiving some but not all of the implementation strategies? OR 2: Does the practice provide a description of the strategy or strategies for some but not all of the groups?	1[b]
		1: Does the practice provide a description of the number of people receiving some or all of the implementation strategies? OR 2: Does the practice provide a description of the strategy or strategies for some or all of the groups?	0[c]

[a]: One condition present or no conditions present

[b] One condition present

[c]: No conditions present

Table 3. Overview of selected interventions in each GP practice

	Primary intervention	Description	Reported actions regarding implementation	Reported stakeholders in practice
A	SMS service	**Reminder**, which patients receive by SMS, two or three days before a diabetes consultation. The message includes the exact date and time of the consultation and the request to cancel the consultation if the patient is unable to attend	Regarding the accuracy of telephone numbers: - Check availability of current telephone numbers - Check correctness of current telephone numbers - Registration in the appropriate field in the electronic medical record system Regarding the delivery of SMS messages: - Preparation of list for distribution - Programming of individual messages for each separate patient, including scheduled date and time of consultation	 Full practice team (medical assistants, nurse practitioners and general practitioners (GPs)) Medical assistants and nurse practitioners Nurse practitioner Nurse practitioner
B	Exploration of patient needs	This intervention consisted of several elements **A. Small-scale patient panel:** focus group for in-depth exploration of patient needs regarding diabetes care	- Selection and invitation of patients - Reflection on generated output within GP team, decision-making regarding approval of potential interventions	 GP GP and colleague GPs within team

Table 3. Overview of selected interventions in each GP practice (continued)

		B. Diabetes health market Large-scale patient meeting, based on input from patient focus group and approved by FP team: presentation of potential interventions, during which patients can express preferences for specific interventions C. Implementation of interventions most preferred by patients: -Diabetes educational training for patients, offered by diabetes federation -Digital portal for patients (for further details see practice C)	- Selection and reservation of location - Development of a meeting program - Written invitation of all patients with type 2 diabetes and their primary caregivers - Development of collaboration with local allied health, which includes several meetings -Registration and referral of patients - Personal training at practice location regarding use of digital portal - Registration of patients in system - Instruction of patients regarding use of system	GP GP GP GP Nurse practitioner Nurse practitioner Nurse practitioner Nurse practitioner
C	Type 2 diabetes e-portal	Digital portal for patients Functionalities include: Registration of health measures such as systolic blood pressure; Registration of personal health targets; Availability of educational videos	- Personal training at practice location regarding use of digital portal - Registration of patients in system - Instruction of patients regarding use of system	Nurse practitioner Nurse practitioner Nurse practitioner
D	Consultation reduction	**Option** offered to patients during diabetes consultation, which includes reduction of consultation frequency from 4 to 1 or 2 annual consultations	- Identification and selection of patients who are eligible for intervention: stabilized T2DM and appropriate self-management skills - Oral invitation during consultation	Nurse practitioners Nurse practitioners

6

General discussion

Background

The main aim of this dissertation was to explore whether the care group approach as implemented by the Eerstelijns Zorggroep Haaglanden (ELZHA) has improved the delivery and tailoring of primary type 2 diabetes care. In the general discussion, the findings of this dissertation are considered, with a focus on the improvement of the delivery of diabetes care in general practice. In the final sections of this chapter, implications for the tailoring of type 2 diabetes care are considered and recommendations for future research are proposed.

Structured diabetes care with collective support for GP practices: promising outcomes

As described in previous chapters of this dissertation, the care group approach was developed to improve the delivery of diabetes care. Soon after its launch the care group approach became subject to controversy, as it was sometimes perceived as expensive and bureaucratic rather than as adding value to the delivery of diabetes care and patient wellbeing. Therefore, our first and second research questions concerned a general evaluation of the care group approach. Our findings demonstrated that care group participation by general practitioners (GPs) is associated with significantly better monitoring in line with GP guidelines – i.e., monitoring of biomedical and lifestyle-related target indicators – in people with type 2 diabetes (see chapter 2). Moreover, systematic monitoring of these indicators is associated with better HbA1c levels (see chapter 3), indicating that care group participation by GP practices is related to the improvement of patient outcomes.

With regard to systematic monitoring within a structured primary care setting, other studies of structured primary diabetes care in the Netherlands demonstrated that the percentage of participants undergoing at least one annual test of diabetes parameters increased strongly over the years (1, 2). Furthermore, the Dutch care group approach shares characteristics with diabetes care settings in several countries such as Germany and the United States (US). In Germany, a nationwide disease management program for people with type 2 diabetes was implemented in 2003 (3). To promote adherence to treatment goals and self-management, German physicians use routine monitoring data in combination with their professional knowledge and experience (4). After four years of follow-up, overall mortality, medication use and hospital costs were significantly lower for individuals who participated in the program than for other insured individuals with similar health profiles who were not in the program. These results suggest that the German disease management program is a successful strategy for improving chronic illness care (4). Moreover, other studies showed that despite the increase in costs - due to an improved life expectancy - this program is cost-effective (5) and that patient

satisfaction was higher in participating practices (6). Nevertheless, the German and Dutch systems differ concerning task delegation to nurse practitioners; in Germany, experience with the transfer of responsibilities to non-physician health care personnel are scarce (7), although task delegation on specific activities such as home visits and assessment of mental health is growing (8). Therefore, even though German disease management outcomes are mostly in line with our findings, caution is warranted regarding generalisability to the Dutch system.

A Comprehensive Primary Care program (CPC) was launched in the US in 2012 (9). As a part of the CPC program, practices receive support when implementing planned care concerning chronic conditions such as diabetes. The CPC program provides practices with a robust learning system, as well as data feedback to guide their decision making (10). In addition, practices are provided with in-person tailored assistance by staff members and other supplemental support, such as training of care managers. In other words, the practical impact of the care protocol on GP practices and the availability of collective support are quite similar to the Dutch approach.

In contrast to our findings, early studies on the effects of CPC found only modest advancements in health outcomes (11, 12). However, it must be noted that early evaluations of the Dutch care group approach revealed – besides missing data due to registration problems - considerable room for improvement of individual monitoring and at most a modest improvement of diabetes-related health outcomes (13, 14). Limited clinical achievements during the early years might have been related to logistic challenges. To illustrate, producing the reports that primary care practices used to assess quality development required a significant investment of time and resources, together with a focus on continuous improvement (15). In other words, the outcomes of these CPC evaluations do not by definition contradict our findings.

Interestingly, besides minimal improvements in individuals' monitoring, further evaluation of the CPC approach revealed substantial achievements in primary care delivery. Those accomplishments included care management for high-risk patients, enhanced access to GP care and improved coordination of care transitions (16). These perceived improvements in the delivery of care may clarify the promising outcomes of recent research. For example, in 2015 and 2016 practices participating in the CPC initiative outperformed benchmark practices on indicated preventive care such as monitoring high blood pressure and LDL management (17). Furthermore, primary care professionals providing more comprehensive care had lower hospitalisation rates and decreased emergency department visits (18). In short, the CPC program is associated with an improvement of several essential elements of care delivery,

and in general terms these findings are in line with the evaluation of our approach concerning monitoring and health outcomes of people with diabetes.

Several factors might be hypothesised to explain the mainly positive findings of structured primary care in the Netherlands and comparable systems in Germany and the US. First, systematic monitoring improves insight into the health of people with type 2 diabetes who participate in these programs. As a result, a decline in diabetes-related health is quickly detected, which enables timely adjustment of diabetes care and thus limits worsening of health outcomes. Second, digital systems that register diabetes-related health outcomes also allow insight into people missing consultations. Since missing consultations might lead to uncontrolled diabetes and thus a higher risk of diabetes complications (19, 20), targeted efforts to deliver appropriate diabetes care to these people might lead to substantial health gains. Third, a care protocol with collective support might alleviate the complexity of diabetes care. To illustrate, an in-depth evaluation of US practices participating in the CPC program revealed a strong preference for one-on-one, in-person coaching. Furthermore, practice staff appreciated advice adjusted to their job roles, practice organisation and the electronic health record system and other digital systems used in their practice (9).

Moreover, the removal of financial incentives is associated with an immediate decline in performance on registration of care parameters (21); in other words, financial incentives concerning proportions of individuals with monitoring as recommended might be associated with better delivery of care. To summarise, considering our findings in the context of current international literature, providing structured primary diabetes care within a collectively supported approach is associated with improved quality of diabetes care and positive clinical outcomes.

Tailoring of care to specific populations: perceived diversity

As described above, structured diabetes care within a care group setting is generally associated with improved monitoring and better health outcomes. However, these positive effects might be not equally applicable to all people regardless of background. In light of numerous studies (22-26), we can assume that the uptake and outcomes of diabetes care are related to certain personal characteristics. Therefore, in the following section we elaborate on differences between populations as regards tailoring of diabetes care.

The care process and outcomes in different socioeconomic groups

Socioeconomic deprivation is an established, important risk factor for health illiteracy, impaired use of health facilities, difficulties with lifestyle adjustment and diabetes-related complications

(27-36). Our study within a care group setting showed that socioeconomic status (SES) is not associated with structural monitoring (see chapter 4). On average, HbA1c levels in the urban and suburban advantaged categories did not significantly differ from the intermediate category, but worse HbA1c levels were found in the deprived category. Furthermore, in all categories, people monitored as recommended had better HbA1c levels than incompletely monitored people. SES does affect the association between recommended monitoring and HbA1c: in the deprived category, monitoring-related HbA1c differences were significantly greater than those found in the intermediate category. This indicates that systematic monitoring of biomedical and lifestyle indicators is important in all socioeconomic groups, but for deprived populations in particular.

The possibilities regarding comparison of our findings to other care group-like approaches to type 2 diabetes care are limited. Concerning the association between socioeconomic status and monitoring completeness, our crude findings – which suggest significantly lower monitoring in deprived neighbourhoods and better monitoring in advantageous neighbourhoods – are in line with previous findings in other settings. For example, a German study reported that people with a low educational level had a higher probability of receiving medication than highly-educated people, but a lower probability of receiving innovative anti-hyperglycaemic medication (37). Nevertheless, our adjusted results indicate that within the care group setting, monitoring completeness is more closely associated with physical patient characteristics—age, diabetes duration, gender—or practice factors rather than with socioeconomic status. These findings might be explained by the focus of the care group setting: collectively supported, structured diabetes care focused on the systematic monitoring of biomedical health parameters in combination with lifestyle counselling.

In other settings, lifestyle counselling is often limited or incompletely delivered in deprived populations (38-40). Some studies suggest that patient characteristics such as age, gender or disease duration affect consultation attendance (41, 42). In addition to these patient-related factors, insufficient monitoring of lifestyle in deprived populations can also be attributed to barriers at the level of health care providers. Examples include frequently reported doubts among health professionals regarding the effectiveness of lifestyle counselling in these populations in general, fear of negatively affecting the relationship with the patient and a lack of confidence in personal professional skills to coach these populations successfully (40, 43, 44). Within the care group approach, however, primary care providers are supported and educated with regard to the delivery of lifestyle counselling in their population. Considering that an equal proportion of people in the deprived and advantageous categories received recommended monitoring, it might be argued that the care group approach removes an important barrier to

full delivery of diabetes care regardless of SES. Nevertheless, at the level of individual practices, various strategies could be applied to improve consultation attendance in general such as a written or SMS reminder shortly before the scheduled appointment or immediate contact by telephone in case of a no-show (45).

Our finding that monitoring-related HbA1c differences are significantly greater in the deprived category compared to the intermediate category might be explained by several factors that underline the importance of sufficient attention for lifestyle adjustment. For instance, deprived populations are generally embedded in an unhealthy environment, such as lower availability of public green space (46, 47) and high levels of air pollution (48). In addition, among those in lower SES categories, diabetes-related unhealthy behaviours might be explained from the perspective of health literacy. Health literacy refers to social and communication skills that enable a person to understand health information and apply it adequately in daily life (49). In deprived populations, health cognitions and beliefs are often inadequate. For example, numerous studies among deprived populations have found a lack of disease-related knowledge and inappropriate beliefs or the inability to apply diabetes knowledge in daily life (50-52). In addition, overweight might be seen as normal (53) or, specifically among certain cultural minorities, as an expression of beauty (54-56) and health (57). On the other hand, using a bicycle or walking as a form of transportation instead of driving a car might be seen as a sign of poverty (58, 59). Furthermore, individual language skills affect the accessibility of evidence-based health information (40, 60).

All the elements described above, which are essential parts of health literacy, are known to influence diabetes-related lifestyle behaviours and, consequently, health outcomes. Moreover, confidence in one's ability to control circumstances, also known as self-efficacy (61), together with the availability of social support, is important for behavioural change (62-65). These factors are generally weaker in residents of deprived SES areas (62) and this weakness is thus associated with higher health risks (66). An unhealthy environment combined with limited health literacy and social-psychological constraints makes it challenging for people with a deprived SES to adopt and maintain a healthy lifestyle.

To conclude, the absence of an association between socioeconomic status and monitoring can be explained by the fact that the care group approach successfully tackles a variety of known factors related to both population characteristics as well as care providers. Structural monitoring might also improve people's sense of self-efficacy and social support, thus contributing to significantly better diabetes-related health outcomes specifically in deprived populations. In

view of our finding that monitoring as recommended is particularly important for people in deprived populations, modifying care to meet population needs is clearly warranted. Specific attention should be paid to monitoring vulnerable people, including overcoming the barriers and daily struggles regarding the adoption of a healthier lifestyle that these people face.

Dispensing with protocol and encouragement of self-management in different populations

As discussed earlier in this dissertation, it is recommended that people with diabetes develop an adequate level of self-management: this can be defined as an ability to manage the symptoms, treatment, physical and psychosocial consequences and lifestyle changes inherent to living with diabetes (67). Given that this ability varies substantially between individuals (62-64), sufficient focus on self-management improvement is required when tailoring diabetes care. Although a certain degree of flexibility in the delivery of care is allowed in the diabetes protocol, the protocol is sometimes experienced as a barrier to personalised care (68). The 'Free of protocol' study, which was described in chapter 5, aimed to identify key conditions for successful tailoring of care. Practices were allowed to depart from the diabetes care protocol and to select one or more interventions inspired by a toolkit comprising a wide range of nationally-approved self-management interventions. Using qualitative methods, we studied experiences of departure from protocol and the implementation process within each practice, regardless of intervention choice, and subsequently determined essential conditions for successful implementation.

In the study, departure from protocol was mostly experienced as positive, and although one practice felt a lack of clarity about what to do, three practices reported that it stimulated reflection on the improvement of self-management in their population. This resulted in a multiplicity of views on tailored care. In other words, a departure from protocol was a powerful incentive for reflection on adjustment of care to population needs.

As a result of contrasting views on tailored care, practices selected different self-management interventions. For instance, a practice in a deprived neighbourhood, aiming to improve show-up at consultations, decided not to depart from protocol, but to instead invest in protocol compliance. By contrast, a practice situated in an extremely advantageous area felt that tailoring diabetes care implied implementing a digital personalised health intervention that enabled people to monitor their health proactively at home and to personalise consultations at the ward. This practice chose a recently launched digital patient portal that, although not included in the official toolkit, came with the important benefit that it was already integrated into the GP's electronic medical health record system and was thus presumably easy to

implement in diabetes primary care. One practice emphasised the exploration of individual's views in order to determine which interventions could contribute to the tailoring of care. In other words, there was not a single 'magic bullet' intervention that enabled universal tailored care; in most practices, selection of interventions was strongly related to perceived preferences of the practice population. Moreover, in three of the four participating practices we perceived a high level of commitment to implementing the chosen interventions.

To summarise, a focus on needs and preferences within the practice population and the practice team fuelled the dedicated implementation of self-management interventions. Team collaboration was an additional key condition for successful implementation. Furthermore, the example of the digital patient portal, which showed insufficient readiness for implementation, underlined the importance of feasibility in the successful implementation of the selected intervention.

Despite numerous evaluations of self-management interventions in current literature, evidence concerning factors that affect successful implementation is scarce (69). In our study, the majority of the participating practices were highly committed to the implementation of their selected interventions. Interestingly, however, another study on the difficulties concerning the implementation of self-management interventions points to a general lack of commitment towards self-management among physicians (70). This analysis is mirrored in the results of a large-scale British evaluation of a self-management intervention in chronic care, where implementation stranded due to competing demands. The authors concluded that besides feasible training, additional incentives are required to enhance the engagement of practices with self-management interventions (71). These conclusions are in line with our results concerning the need for time to reflect on self-management implementation and dispensing with protocol. To add, a follow-up study found several barriers, such as the 'time-consuming' and 'too disruptive' character of the intervention (72). Furthermore, implementation was perceived as a top-down initiative from managerial level (73). In other words, the commitment of practices to implementation of the self-management intervention was limited. Considering that successful implementation requires that factors related to providers themselves and the organisational context receive adequate attention (74), the British findings underline the merits of 'a freedom to choose' approach to self-management interventions that allows matching to the preferences of practice staff.

Nevertheless, a review of the implementation of self-management interventions in primary asthma care identified key elements of effective interventions: these included active

engagement of patients, training and motivation of professionals and an organisation in which self-management is valued (75). In addition, according to Canadian GPs, collaboration with team members such as nurse practitioners is essential because it enables optimal care – although it might be difficult for GPs to adjust their perception of 'being the only one who can do that' (76). From a nurse practitioners' perspective, several factors affect the level of team collaboration. For instance, having a clear mandate from the GP, internally as well as towards people with diabetes, and role clarity are essential for successful team collaboration. Several barriers were reported, including vagueness about role expectations and lack of communication (77). With regard to feasibility, problems with implementation due to technical obstacles were reported in other studies (78, 79). Our findings underline the fact that successful implementation requires forethought regarding the readiness of interventions before implementation. To summarise, we identified a range of key conditions related to tailoring diabetes care to different people.

Concerning the experiences of those immediately affected by dispensing with protocol and care tailoring, we found that the number of individuals being monitored as recommended decreased. In addition, we observed a slight decline in people's satisfaction with diabetes care, in line with a study demonstrating that lower consultation frequency is associated with decreased satisfaction among well-controlled people with diabetes (80). This highlights the importance of tailoring care appropriately to people's needs and preferences from the perspective of positive health, which defines health as the ability to adapt and self-manage in the context of physical, mental and social wellbeing (81). In other words, for people with diabetes, maintaining optimal health requires sufficient attention for not only physical aspects of their disease, but also for related mental and social aspects of life. Hypothetically, coaching on these broader aspects of positive health and wellbeing might improve self-management and diabetes care-related satisfaction.

A positive, health-oriented view of diabetes care resonates from the perspective of population health management (82), which incorporates population needs as an essential pillar of adequate care and defines outcomes in terms of the Triple Aim (better quality of care, improved patient outcomes and reduction of costs). When physical, social and mental characteristics and population preferences are considered the starting point for selecting and implementing diabetes-related self-management interventions, it may be possible to increase the effectiveness of interventions and, consequently, the health and self-management skills of target populations. In addition, effective interventions might improve professionals' job satisfaction and even the cost-efficiency of delivered care. To conclude, in view of the

socioeconomic and cultural diversity of populations, adapting care to a specific population might contribute to optimal health and diabetes-related self-management skills.

Methodological considerations

In the following sections, we will elaborate on the strengths and weaknesses of the methods applied in this dissertation.

Cohort study

In chapters 2, 3 and 4, we used data from the ELZHA cohort. Despite the advantages of randomised clinical trials (RCTs) concerning the elimination of bias (83), our pragmatic observational design – which is quite common in research regarding primary diabetes care (84-86) – has several merits. Firstly, since we were able to include registry data covering virtually all GPs that participated in the ELZHA care group, controversial aspects with regard to RCTs (83) could be avoided. Specifically, the large-scale evaluation of structured diabetes care within a care group approach would be very difficult to realise within an RCT design. Care group participation implies fundamental reforms within a practice, such as task delegation to a practice nurse, the introduction of quarterly diabetes consultations for individual people including all logistical demands that emerge, together with the implementation of a computerised decision-making support system. Finding sufficient practices that were motivated to improve diabetes care and that nevertheless would accept the risk of being assigned to a control condition would have been challenging. In addition, GP practices might vary with regard to professional and system-related views on the role of GPs in health care (87), which can affect organisation and delivery of care. Moreover, depending on further characteristics of GPs, preferences concerning organisation of care might also vary (88). Thus, it might be doubted to what extent findings derived from a selection of practices within an RCT setting are applicable to all practices in the field (83). In contrast to RCT-related limitations, our study enabled the inclusion of virtually all practices in the ELZHA care group, which contributed to the generalisability of our findings.

Second, our study design did not interfere with daily routines in GP practices, as we simply evaluated the processes and outcomes of care as registered in practices without any additional study-related demands. As a result, our findings reflect actual practice. In addition, we corrected our analyses for GP practice and confounders such as age and diabetes duration, further contributing to the validity of our findings.

Nevertheless, there are some limitations that should be mentioned. First of all, since no control group could be included it is not possible to prove causal relationships. Thus, it cannot be ruled out that improved monitoring was caused by other 'contextual' factors, such as increased monitoring awareness conveyed by professional courses or magazines, rather than by care group participation. Second, considerable numbers of individuals had to be excluded. Most exclusions were for objective reasons. For instance, to avoid bias caused by moving or referral to secondary diabetes care during the course of the study period, individual people were excluded if they received less than one year of structured diabetes care at the same GP practice. In addition, since monitoring guidelines were defined for those below the age of 80 years, older people had to be excluded. Exclusion of these groups allowed optimisation of our real-life evaluation of the care group-related protocol.

Besides the exclusion criteria mentioned above, missing information on other variables such as age and prescribed diabetes medication were also important reasons for exclusion. In studies that use routine data, inconsistencies or missings in the coded data are common (89). Within Dutch primary care, date of birth is used as a key registration variable and it is therefore very unlikely that this information would not have been registered in electronic health records in our study. Furthermore, as a quarterly analysis of registered diabetes care in all practices required complex technical systems and procedures, it is reasonable to assume that technical problems caused most missing age data. While we should be aware of the risk of bias in the data, the large size of our study population excludes meaningful distortion of our findings.

In addition, concerning prescribed diabetes medication, it was not possible to determine whether missing data on medication prescriptions reflected a correct absence of medication treatment or was simply attributable to erroneously missing data. To avoid incorrect inferences, we decided to exclude those with missing information on medication. It is also not known how many people with diabetes actually participated in the diabetes care protocol while not receiving any diabetes-related medication treatment. As a result, it was difficult to assess the degree of incorrect exclusion of people without medication prescriptions, and consequently, whether bias might have risen. Given this uncertainty, we emphasise that our findings concerning recommended monitoring and HbA1c levels cannot be generalised to people without any medication prescription. In other words, our findings are mostly applicable to a population aged younger than 80 years, receiving care for at least one year at the same practice, and having medication prescriptions.

Furthermore, missing registration of care indicators did not necessarily imply that care was not delivered. For instance, missing data might have been caused by technical problems or a lack of time to properly register care rather than absence of care. Thus, people erroneously considered 'incompletely monitored' might have contributed to underestimation in the associations found.

Prospective mixed-methods study

In chapter 5 of this dissertation, a prospective 'Free of Protocol' study using qualitative and quantitative methods was conducted.

Merits of a mixed-methods approach

The process of dispensing with protocol, reflections on the tailoring of care and the implementation process were all monitored within an action research setting (90) using focus groups in combination with individual ward interviews. This qualitative information was combined with quantitative measures examining the experiences of people with diabetes concerning departure from protocol and tailoring of care. With regard to the qualitative study, the focus group resulted in lively discussions between GPs and nurse practitioners of all participating practices. They challenged each other concerning the development of ideas on tailored care, the choice of self-management interventions and, subsequently, plans to implement the selected interventions. Additional individual interviews allowed deeper insight into the proceedings of the implementation process. Experiences of individual participants related to satisfaction, wellbeing, health status and monitoring of target indicators were also measured. This provided essential information concerning the impact of tailored care on participating patients. The combination of process monitoring and individual measures allowed a balanced, triangular insight into the impact of dispensing with protocol and tailoring care on practices and people with diabetes.

Selection of practices and people

The practices included in our study reflected existing diversity regarding practice size and socioeconomic neighbourhood. Practices were invited to participate if their organisation met care group-related quality standards. These quality standards included meeting monitoring targets for diabetes and enrolment in care protocols for at least one other condition such as chronic obstructive pulmonary disease (COPD). Although these criteria might be considered reliable indicators of quality of care for individuals, it might be questioned to what extent they truly reflected the quality of organisation.

In addition, the relatively limited inclusion of people with diabetes could have led to bias, although no differences in response rates were observed between deprived and populations within these four practices. The current quality of care might also explain the limited response of people eligible for study participation - that is, the current care group protocol already provides some room for tailoring of care, which might have reduced willingness to participate in a new 'care tailoring' project. Nevertheless, within this setting, we can only speculate about the exact motives for and possible consequences of non-participation.

Generalisability of findings

Besides the selection of practices and the limited number of those enrolled, other factors might have affected the generalisability of our findings. Firstly, we chose a prospective observational design which, in contrast to an RCT, cannot control for possible confounding. Despite this concession, important arguments from a practice point of view supported an observational design rather than an RCT. Our design allowed active enrolment of all GP practices that met inclusion criteria and aimed to tailor diabetes care. Assigning these practices to a control condition - which would have led to the continuation of current care and likely hampered care innovation in receptive practices - was thus avoided. For the same reason, the risk of being assigned to a control condition might have been perceived by practices as a barrier for study participation.

GP teams reported that dispensing with protocol and the freedom to select interventions themselves enabled tailoring of care. The absence of a control group, however, prevents any causal inference regarding the development of people's outcomes.

Furthermore, our findings were obtained within four different practices that all met internal care group-related quality standards. It is unclear how the implementation process would have worked in other practices. More specifically, it is difficult to assess to what extent our findings can be attributed to practice characteristics, such as quality of organisation or quality of care delivery. We cannot rule out that individual care providers' characteristics affected the implementation processes, although we strived to objectify our analysis as much as possible by using a theoretical framework that systematically explores organisation-related elements of implementation processes.

Outcome measure 'monitoring as recommended'

In our prospective study 'Free of Protocol' (see chapter 5), we observed a significant decrease in the number of people being monitored as recommended two years after dispensing

with protocol. From the perspective of professional GP guidelines, this could at first sight be interpreted as an adverse outcome or an indication of insufficient care. However, when we consider that the study population consisted of people with stable, well-controlled diabetes for at least one year, this raises the question whether measuring every year all key diabetes parameters, including lifestyle-related indicators, adds clinical value for these people. This contrasts with the ELZHA cohort studies described in chapters 2, 3 and 4, which included data from all people with diabetes participating in a structured primary care protocol.

Since GP guidelines are defined for the general population, our findings as described in chapters 2, 3 and 4 are applicable to the population in its totality. With regard to the prospective study, one might argue that for this relatively well-controlled population, annual measuring of BMI and level of physical exercise is not by definition necessary. However, insight is lacking concerning the clinical impact of our operationalisation within different populations. Thus, to understand whether monitoring recommendations for stable and well-controlled people could indeed be loosened without negative consequences, further exploration of appropriate monitoring within this population is indicated.

Implications and recommendations for clinical practice

Our findings yielded important insights and allow us to offer the following recommendations to improve primary diabetes care:

A. To allow structuring of care, use a protocol that provides systematic support for implementation

Tailoring of diabetes care requires a firm foundation. Our findings demonstrated that structured care within the collective ELZHA care group setting was associated with a noticeable improvement of registered individual monitoring. Furthermore, because monitoring as recommended was associated with better HbA1c levels, particularly in deprived groups, improved monitoring is clinically relevant. Therefore, based on the content of the ELZHA approach, we advocate that care providers should be provided with a clear protocol that summarises essential components of diabetes care, combined with collective support concerning implementation. In addition, practices should be visited at least once a year by care group nurses specialised in diabetes care to stimulate adequate implementation. Collective support should include task delegation to nursing practitioners,

effective team collaboration, assistance concerning the use of an automatised monitoring system and professional courses. The frequency of practice visits should also be adjusted to the needs and preferences of practices. Since competing demands may compromise compliance within a GP practice, even when staff personnel are well trained (71), additional incentives are recommended to encourage the implementation and application of the care protocol.

B. Tailoring of care: explore people's needs, work as a team and use feasible interventions

If solid implementation and delivery of a diabetes protocol have been achieved, tailoring individual care can be initiated. Our 'Free of protocol' study found that departure from protocol can be a powerful incentive for practices to reflect on the tailoring of care. Several key facilitators of successful implementation were determined, and the first step was the exploration of the needs and preferences of individual people.

As illustrated by our experiences within study practices, there is more than one way to explore different people's perspectives. Practices used different strategies, varying from organising a specific panel group to general communication with individual patients. In the latter case, appropriate communication skills are crucial to obtaining reliable insights. However, GPs (91) as well as practice nurses (40, 92) traditionally have limited training in communication skills and some scepticism has been noted concerning the long-term effect of communication training (93). Therefore, it is advisable that constant attention is devoted to appropriate training that matches the needs of individual care providers and sufficient maintenance of communication skills.

Besides adequate communication with people about their needs in the light of their diabetes, solid collaboration within the GP team – including GPs, nurse practitioners and other staff members - is recommended. This is particularly important when selecting appropriate interventions, as study practices have different 'comfort zones' concerning the implementation of interventions. For instance, in view of the likely impact on their practice organisation and the delivery of care, one practice preferred to select a single intervention targeted to the study population. Conversely, other practices aimed to tailor care for all those with diabetes, regardless of study enrolment. In other words, there are many options when tailoring care and awareness of team preferences is desirable. The process of implementation of an intervention might also affect all levels of practice organisation, as became apparent with the SMS reminder service where GPs, nurse practitioners and

medical assistants were involved. In that case, the commitment of all team members to the implementation process contributed to the success of the intervention, and we therefore recommend effective collaboration between GPs, nurse practitioners and other staff members.

Given that a GP practice is a multidisciplinary organisation embracing many different roles and levels of knowledge, skills and responsibilities, building a strong team can be very challenging. Clarification of daily practical and logistical processes and facilities within a GP organisation, and developing a model for integration and adequate management of these processes, is likely to require specific expertise. If practices are facing difficulties regarding team collaboration, they might consider seeking external expertise to overcome these obstacles. Care groups might also provide these services to practices.

Finally, the feasibility of an intervention is an important condition for successful implementation. In our 'Free of protocol' study, the feasibility of the selected interventions appeared to be diverse. Two practices chose interventions that were - with a considerable investment of time and effort - feasible to implement. The invested energy resulted in excellent implementation and, subsequently, high responsiveness of people with diabetes. In contrast, the digital patient portal, for which feasibility was only assumed, appeared insufficiently tested in practice. As a result, despite the best efforts of the practice that concentrated solely on this intervention, implementation stranded in practical and technical problems. Therefore, we recommend selecting only those interventions with proven feasibility in comparable settings. Considering that the feasibility of eHealth in particular is not always readily apparent, collaboration with experts on technical and user-related experiences is recommended.

To summarise, for the successful implementation of self-management interventions, we recommend conscientious exploration of people's needs, solid team collaboration and the selection of interventions with proven readiness for implementation. Following these steps will increase opportunities in the tailoring of care.

C. Avoid to lose the sight on individual people

Tailoring of care can take different forms, depending on the needs and preferences of individual people. For people with well-controlled diabetes, care adjustment might include a reduction of consultations. It is not yet clear whether a decline in monitoring equates to an increased risk of diabetes-related health complications or, conversely, suggests that

monitoring guidelines may need to be reconsidered. Importantly, we observed a long-term decrease concerning individual satisfaction with diabetes care. Therefore, until we have a sufficient understanding of appropriate monitoring for well-controlled people and the merits of registering BMI and physical exercise, we recommend continuing with (at least) one annual check of all diabetes-related biomedical target indicators and lifestyle indicators (the latter, for example, with mobile eHealth applications), combined with incentives to adequately register the delivery of care.

D. Keep in mind the need to reach people from deprived socioeconomic groups

We observed that monitoring was not associated with socioeconomic status and that appropriate monitoring is associated with better HbA1c levels, specifically among socioeconomically deprived people. This underlines the need for appropriate access to structured diabetes care in deprived populations. In these groups, improved compliance might be realised with tailored interventions. For instance, in our 'Free of protocol' study, a practice serving a deprived population aimed to reduce the no-show rate at consultations by implementing an SMS reminder service (see chapter 5).

Another practice, located in an area including both deprived and advantageous SES groups, chose to collaborate with community workers in order to reach as many people as possible. In deprived areas, usual primary care facilities such as availability of individual consultations at ward, smoking cessation counselling, or dieticians' support are often insufficient to encourage people to adopt healthy behaviour. As illustrated by this practice, collaboration with networks of community services might provide opportunities to reach people. For instance, social workers and debt counsellors often have a dense network among vulnerable populations or know where to find community centres that are frequented by this group. As social deprivation and risk of medical problems are interrelated, collaboration with the social and community domain might further encourage creative approaches to bridging care gaps. Therefore, we recommend that GP practices with deprived populations actively seek out social and community stakeholders in their own neighbourhood and explore opportunities for collaboration.

Recommendations for future research

As explained above, a better understanding is required of the causal relationships between collectively supported diabetes protocols, individual monitoring and health outcomes. Currently, the majority of Dutch people with low-complex diabetes are enrolled in a care group-related diabetes protocol. For several reasons, it will be methodologically challenging to realise a (randomised) setting that includes representative intervention and control groups without exposure to care group conditions. Nevertheless, since care groups vary concerning the amount of implementational support provided to practices, it would be interesting to compare practices receiving full collective support versus practices participating in less active care groups.

In addition, hypothetically, the needs of practices concerning collective support could differ. For instance, population-related characteristics such as local socioeconomic deprivation might affect practices' needs for support. Practice needs might also be related to organisational aspects such as practice size and nurse practitioners' educational level. Therefore, further research on the determination of support needs in practices is necessary to optimise collective support and thus the delivery of primary diabetes care.

Furthermore, finding a balance between protocolised diabetes care and tailoring diabetes care is a delicate matter that requires a sensitive approach. Specifically, while a diabetes protocol has important merits in terms of monitoring completeness, a properly implemented protocol might be experienced as a barrier to adapting care to individual needs and preferences. In our study, we were able to use an internal care group-related quality standard to assess which practices were suitable. Nevertheless, a more general, solid understanding is required of characteristics that reflect whether a practice is ready to depart from protocol. When valid characteristics can be determined, the risk of losing the benefits of the protocol can be limited, and it also enables care groups to coach practices appropriately towards the tailoring of care and maintenance of high-quality delivery of diabetes care.

A more thorough analysis focused on individuals regarding the effect of exposure to tailored care is also warranted. Firstly, right now it is unclear whether tailored care in our study was associated with an undesirable decline in individual monitoring, or conversely whether our definition of 'monitoring in line with GP guidelines' might need adjustment in stable, well-controlled people. A clear answer to this topic will contribute to the appropriate interpretation of these findings and, thus, subsequent recommendations for clinical practice. Secondly, to optimally adjust diabetes care to people's personal preferences, a better understanding of

people's satisfaction with care group-supported diabetes care is needed. People's satisfaction with diabetes care declined slightly during the process of care tailoring. Since having diabetes is a long-term problem, accompanied by a slow deterioration of health and an inevitable decrease in wellbeing, it is important to determine whether tailored care can positively affect satisfaction with diabetes care.

Given the demands that diabetes care places on a GP practice on a daily basis, staff need to be adequately prepared to sustain diabetes care. Since task delegation from GPs to nurse practitioners, an important part of care group- supported diabetes care, might be related to a decline in job satisfaction (94), better insight might improve job satisfaction among GPs within a care group setting.

Moreover, as we noticed that among some GPs the care group approach is viewed as expensive, a careful evaluation of costs in relation to clinical benefits is also recommended.

Conclusion

Based on this dissertation, we can conclude that within diabetes care carried out in general practices, a collectively supported care protocol is associated with better monitoring of people with diabetes. Furthermore, improved monitoring is associated with better health outcomes, regardless of the socioeconomic status of the individuals concerned. In other words, systematic and ongoing monitoring for all is recommended, with specific attention for alleviation of existing barriers to monitoring in deprived socioeconomic populations.

When practices meet quality standards for the delivery of chronic care, room becomes available for departure from protocol and the tailoring of diabetes care. The needs and preferences of the population and of the practice should both be considered. Furthermore, effective team collaboration and feasibility of specific interventions both require attention. To avoid losing contact with those needing diabetes care, we recommend one annual consultation with monitoring of all target diabetes indicators. Thus the road may be opened to optimal, individualised primary diabetes care.

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7

Background

Type 2 diabetes mellitus (T2DM) is a chronic condition that occurs when the body cannot effectively use insulin. The function of insulin is to ensure that glucose in the blood, derived from the digestion of food, is taken up by cells throughout the body. Too little or too much glucose in the blood can cause both short-term and long-term health problems, some of which can be very serious. Insensitivity to insulin leads to a higher than normal level of HbA1c, a blood measurement that gives an indication of the amount of glucose in the blood. Over time, a structurally elevated HbA1c level can cause serious harm, resulting in heart and cardiovascular diseases, blindness, limb amputation and early death. Fuelled by an aging population and a growing prevalence of (serious) overweight, the number of T2DM cases has risen dramatically worldwide. The Netherlands is no exception.

The steep increase in T2DM cases in the Netherlands has begun to affect the delivery of care in Dutch general practice. In order to catch and treat risks of health deterioration at an early stage, effective diabetes care requires frequent monitoring of diabetes-related health parameters such as HbA1c. In addition, many people need support regarding weight loss, quitting smoking and increasing their physical exercise – in other words, help developing a healthier lifestyle. To achieve and maintain a healthy lifestyle, people must develop the ability to effectively manage their T2DM. This is known as 'self-management', and frequent coaching is often needed to encourage the development of self-management skills. Given these many demands, diabetes care places considerable pressure on general practice.

In order to improve primary diabetes care in the Netherlands, in 2007 a 'local care group' system was initiated. The goal of care groups is to tackle problems that hinder the delivery of diabetes care, such as time pressure, difficulties staying up-to-date in the face of an expanding diabetes population and challenges concerning task delegation from general practitioner (GP) to nurse practitioner. The care group approach entails offering specific services to participating GP practices, including a structured care protocol. This care protocol consists of four diabetes consultations for each diabetes patient in the GP practice. Diabetes consultations comprise monitoring of specific biomedical blood parameters (such as HbA1c and cholesterol) and the encouragement of self-management skills in order to stimulate a healthy life style. Practices receive support concerning implementation of the care protocol and task delegation from GPs to nurse practitioners. Furthermore, many care groups facilitate the use of digital systems that are linked to electronic health records. These systems help provide a clear picture of the diabetes care delivered by a GP practice to an individual patient. Another important function of care groups is to support GPs during negotiations with healthcare insurance companies. For

example, care groups negotiate with insurance companies regarding the contents of the care protocol, reimbursements and targets concerning care provision, such as the percentage of people with at least one systolic blood pressure measurement per calendar year.

In the last few years, doubts have been raised regarding the care group approach. Some people feel that care groups add little clinical value to patient care, while bringing high costs and an additional bureaucratic load. A structured care protocol can also seem to be a barrier if the aim is to tailor diabetes care to people's individual needs.

In this thesis, we first studied the association between adherence to a structured diabetes protocol and patient outcomes. We then investigated what practices actually require when seeking to adjust care to patient needs. With that aim in mind, we explored the effect of dispensing with protocol and the key conditions for successful implementation of self-management interventions. Finally, we measured patient outcomes with regard to treatment satisfaction, quality of life and monitoring.

Findings of this dissertation

A structured care protocol has added value for people with diabetes

We first investigated whether care group participation is associated with improvement of diabetes monitoring (chapter 2). Monitoring was defined as 'appropriate' if during a calendar year at least one measurement was registered for each of three biomedical target indicators (HbA1c, systolic blood pressure, cholesterol) and three lifestyle-related target indicators (body mass index, smoking behaviour and physical exercise). This definition is based on the professional GP guidelines for type 2 diabetes care in the Netherlands and is referred to here as 'recommended monitoring'.

To get a picture of the effect of care group participation on recommended monitoring, we conducted two analyses. The first was carried out using data from all six practices that joined the Eerstelijns Zorggroep Haaglanden (ELZHA) care group, a care group in The Hague and suburbs, in January 2014. In 2019, this care group was integrated with other local GP organisations to become the Haaglandse Dokters (Hadoks) organisation. In the new practices that joined in January 2014, we explored whether the number of people receiving recommended monitoring was higher at the end of 2014 compared with January of that year. This was indeed the case, and recommended monitoring was found to be substantially higher at the end compared to the beginning of 2014.

Second, we examined whether recommended monitoring at one year in these new practices differed from that in experienced practices which had participated in the care group for at least three years. This analysis found no significant differences between new and experienced practices. To summarise, practices likely undergo an intensive learning process when they join a care group and appear to reach the same level as experienced practice within a year.

Chapter 3 explores the added value of recommended monitoring for people with diabetes. We therefore compared HbA1c levels in people with recommended versus incomplete monitoring with regard to calendar year 2014. Professional GP guidelines in the Netherlands define maximum HbA1c values for three distinct patient groups. These three groups are characterised by risk profiles related to age, treatment characteristics and the duration of diabetes. Group one consists of people younger than 70 years, as well as older people with only metformin monotherapy prescription, and has a maximum value of 53 mmol/mol. Group two includes people older than 70 years who require more diabetes medications but have had the disease for less than ten years. The maximum value in this group is 58 mmol/mol. The third group includes the most vulnerable people – older than 70 years, on intense medication prescription and a disease duration of more than 10 years – and has a maximum value of 64 mmol/mol.

We compared the HbA1 levels of people with recommended and incomplete monitoring in all three groups. We found that the HbA1c levels in people with recommended monitoring are significantly circa 2 mmol/mol lower compared to incomplete monitoring. In other words, recommended monitoring is far more than merely an administrative procedure; it actually reflects better real-world HbA1c levels.

Outcomes differ between distinct groups with diabetes

Health benefits are the highest among socioeconomically vulnerable people

The Hague and its suburbs are characterised by large differences in socioeconomic status (SES). To investigate the impact of SES we compared advantageous and deprived neighbourhoods with regard to recommended monitoring, HbA1c levels and the association between these factors. This study is described in chapter 4.

For the purposes of this study, all practices in The Hague received a so-called 'deprivation score', which is registered by The Hague municipality and divided into three categories: deprived, advantageous or intermediate. The suburbs of The Hague (Wassenaar, Leidschendam-Voorburg and Voorschoten) were assigned to a 'suburban advantageous' category.

When advantageous and deprived neighbourhoods were compared to the intermediate category, we found that all areas of The Hague, together with advantageous suburban areas, were comparable in terms of recommended monitoring. Despite this finding, HbA1c levels were significantly lower in the deprived category (a difference of circa 2 mmol/mol).

We also examined whether SES categories differed with regard to the association between monitoring and HbA1c levels. Differences in HbA1c level between people with recommended versus incomplete monitoring were greater in the deprived group, to the extent of approximately 3 mmol/mol, whereas a circa 1 mmol/mol difference was found in the intermediate category. In other words, within a care group setting people in the deprived category derive the most benefit from recommended monitoring.

In view of the fact that a vulnerable SES is an established factor lowering the chance of favourable health outcomes, for example due to limited health literacy, this is an interesting finding. We know from scientific literature that professionals sometimes face difficulties when providing care to diabetes patients with a vulnerable SES, specifically in terms of lifestyle coaching. GPs and nurse practitioners often express doubt concerning the added value of lifestyle coaching and their personal ability to provide appropriate support to this group. Furthermore, professionals might hesitate for fear of negatively affecting their relationship with the patient. Nonetheless, appropriate monitoring of biomedical indicators and an adequate focus on lifestyle coaching is reflected in substantially better HbA1c levels, especially in this group.

Tailoring care to different groups: 'Free of protocol'

As described in chapter 5, four GP practices that were classified as well-organised according to Hadoks quality standards, participated in the 'Free of protocol' initiative. This study was designed to stimulate the development of tailored care for people with diabetes, and entailed investigating the effects of protocol-free care and the key conditions for successful implementation of self-management interventions.

Participating practices had the opportunity to dispense with the structured care protocol in a relatively safe population – people with a comparatively good HbA1c level who had received structured diabetes care for at least a year. Practices could choose one or more interventions from a broad variety of self-management options inspired by a nationally approved 'toolkit'. Practices subsequently prepared an implementation plan based on practice-specific insights and used this plan as the basis for implementation.

We examined practices' experiences with protocol-free care by organising group meetings and interviews with individual practice members at the practice location. This allowed us to evaluate the proceedings of the implementation process in each practice. In addition, we mapped the experiences of individual patients with protocol-free care and the self-management interventions as implemented by the practices. Patients filled out written questionnaires measuring satisfaction with diabetes care, general wellbeing and self-rated health. We also determined the extent to which the number of people with recommended monitoring remained at an appropriate level.

This study revealed the following findings:

Effect of protocol-free care: room for reflection concerning 'tailored care'

The opportunity to dispense with a structured diabetes protocol was experienced in most practices as liberating. However, there was also some uncertainty and with protocol compliance no longer necessary, some practices experienced difficulties defining suitable care for their patients. Nevertheless, most practices indicated that departure from protocol created room to reflect on how diabetes care in their practice could be optimally tailored.

Practices differed with regard to SES neighbourhood and, correspondingly, patient characteristics such as health literacy. This diversity was mirrored in the self-management interventions chosen; these ranged from an SMS reminder service to improve attendance of a vulnerable SES population at diabetes consultations, to a digital portal - in an advantageous neighbourhood - that enabled people to independently monitor their health outcomes and to proactively prepare for a diabetes consultation.

Key conditions for successful implementation of self-management interventions

- An eye for the needs of the patient population

Although patient needs differed considerably between practices, for practices a clear view of patient needs was a strong incentive to carry out a thorough implementation process. When the implementation process took more time than foreseen or if practical or logistical setbacks arose, keeping the patient perspective in mind seemed to provide practices with sufficient incentive to finish the task.

- Collaboration within the practice team

Strong collaborations between different GP practice disciplines – GPs, nurse practitioners, medical assistants – was very important to the implementation process. Extensive discussion concerning the intended intervention(s), the development of an implementation plan supported by all team members and sufficient consideration given to logistical processes all contributed to a smooth implementation.

- Feasibility of interventions

We found that instruments need to function appropriately. This was not the case with the digital patient portal, the implementation of which was hindered by technical shortcomings from the perspective of both the care provider as well as the patient. This intervention was not part of the toolkit, but was chosen because it had recently become available and was already integrated with the electronic diabetes management system used by all practices. However, during the course of the study it became apparent that it was not yet ready for daily practice use. Keeping in mind that appropriate assessment requires specific technical expertise combined with insight into user experiences, assessment of the feasibility of eHealth instruments can be difficult for GP practices. Therefore, when considering this approach we recommend collaboration with expert academic centres that have sufficient specific knowledge and can provide independent advice.

Impact on people with diabetes

We found that the number of people with recommended monitoring declined over the study period. At first sight, this appears worrying. However, it also raises the question of the extent to which the definition 'monitoring as recommended' is applicable to people with a long-term, stable HbA1c level that remains below the recommended maximum value. In addition, patient satisfaction also decreased slightly, underlining the importance of sufficient focus on patient needs with regard to diabetes care.

Our results reflect the international discussion of why self-management interventions so often appear of limited value. Some have suggested that, given the urgencies of daily practice, GP practices often assign insufficient priority to the careful implementation of interventions in research settings. Others suggest that different kinds of incentives are required to encourage appropriate implementation. In our opinion, our studies reveal some of those incentives: the ability to depart from care protocol and the freedom to choose interventions that fit the practice and the specific patient population. These factors appear to be important motivators for practices to maintain focused efforts and to achieve a good implementation.

Remarkably, and despite satisfaction with many of the implemented measures, overall satisfaction concerning patient outcomes declined slightly over time. With regard to the present study and given our study setting, no causal inferences can be drawn as we cannot determine the extent to which diminished satisfaction was related to the study setting itself. Nevertheless, other work indicates that a reduction in consultations is associated with lower satisfaction. Furthermore, the number of people receiving recommended monitoring also declined. In the context of Dutch professional GP guidelines, this appears at first sight to be an unfavourable outcome. Nonetheless, given the fact that enrolment in the study was dependent on stable diabetes control, one might question whether these individuals really need annual monitoring of all target indicators. Until this question is resolved satisfactorily, we recommend at least one annual diabetes consultation.

Conclusions and recommendations

A number of conclusions can be drawn from the studies described in this dissertation.

Firstly, our cohort studies clearly show that the participation by GPs in a care group adds value for patients: the number of people with recommended monitoring in accordance with GP guidelines increases considerably. While it can never be ruled out that care has been delivered but is not registered as such, perhaps due to technical reasons, a clear difference is apparent in the HbA1c levels of people with recommended versus incomplete monitoring: people with recommended monitoring have significantly better HbA1c levels. This finding allows us to conclude that structured diabetes care, with collective support in a care group setting, is associated with better patient outcomes.

Furthermore, weaker socioeconomic differences are apparent in a structured care setting, as equal numbers of people receive recommended monitoring regardless of the SES neighbourhood. Importantly, the deprived category derived the greatest benefit from recommended monitoring, showing higher than average monitoring-related HbA1c differences. This finding argues for care that is as closely tailored to people's needs as possible. Once practices have properly organised structured care, protocol-free care might encourage further tailoring of care. Consideration of the needs of patients, appropriate collaboration within the practice team and implementation-ready interventions can all contribute to personalised care delivered with dedication and commitment.

Taken together, these conclusions also raise new questions and chapter 6 provides several recommendations for follow-up research. All studies in this dissertation were, following careful consideration, based on an observational study design. The downside of this approach is that we could not determine the extent to which the care group setting contributed one-by-one to better monitoring, or in turn, if better monitoring directly results in favourable HbA1c outcomes.

To obtain deeper insight into the effects of collective support and a structured care protocol on health outcomes, additional research is welcome. Given the diversity in individual practices with regard to factors such as type of organisation, practice size and educational level of nurse practitioners, a better understanding of the requirements and experiences of individual practices is needed. It cannot be ruled out that practices differ concerning needs for support in the delivery of diabetes care. Moreover, support from the care group perspective is characterised by providing practices with structure on the one hand and flexibility on the other. To find an optimal balance between structure and flexibility that recognises the diversity of practices, we endorse a better understanding of when practices are ready for departure from protocol.

There are also indications that task delegation to nurse practitioners is associated with lower work satisfaction amongst GPs. To achieve sustainable diabetes care in the future, more research into factors that contribute to improved satisfaction is also recommended.

Our studies provided fresh insight regarding the association between diabetes care within a care group setting and patient outcomes. Given perceptions of the care group system as expensive and of limited cost-effectiveness, we would also encourage the systematic investigation of financial costs in relation to clinical outcomes.

Based on our overall findings, we propose the following roadmap:

A roadmap to strong, personalised diabetes care

1. **Work from a solid base**

   When implementing structured diabetes care, use a protocol that provides systematic support

2. **Look before you leap: determine the shape of tailored patient care in your own practice**

   Take the necessary time to consider the question of what 'tailored care' will mean for patients in your own practice; actively explore patient needs and values, ensure smooth collaboration within your team and carefully consider the feasibility of interventions within the practice

3. Don't forget the individual patient

Regardless of the selected intervention, make certain that every patient is seen at least once a year

4. Keep in mind the specific SES-dependent care needs

Take into account that 'personalised care' for people with a vulnerable SES background might mean that these individuals need extra support concerning their diabetes care

This roadmap is intended as a summary for GP practices that wish to provide optimal diabetes care. When working from a solid base, care that accommodates patients' needs is an achievable goal.

Samenvatting (Nederlands)

Achtergrond

Diabetes type 2 is een chronische aandoening. Deze ontstaat wanneer het lichaam insuline niet goed kan gebruiken, waardoor de spiegel van HbA1c (een bloedwaarde die iets zegt over de hoeveelheid glucose in het bloed) in het bloed stijgt. Als de HbA1c-spiegel structureel te hoog blijft, kan dat ernstige gevolgen hebben zoals hart- en vaatziekten, blindheid, amputatie van ledematen en vroegtijdig overlijden. Wereldwijd neemt het aantal patiënten met diabetes type 2 sterk toe. Deze groei wordt verklaard door diverse factoren, zoals de vergrijzing en een toename van het aantal mensen met (ernstig) overgewicht. Nederland vormt hierop geen uitzondering.

De sterke groei van het aantal diabetespatiënten heeft haar weerslag op de Nederlandse huisartsenzorg, oftewel de 'eerste lijn'. Goede diabeteszorg vereist regelmatige controle op gezondheidsparameters, zoals HbA1c, zodat het risico op complicaties vroegtijdig kan worden opgemerkt en behandeld. Daarnaast hebben veel patiënten begeleiding nodig rondom gewichtsverlies, stoppen met roken en stimulering van lichaamsbeweging ' kortom, het verwerven van een gezondere leefstijl. Om tot een gezonde leefstijl te komen én die met succes te behouden, hebben patiënten het vermogen nodig om op adequate wijze de regie te voeren over het leven met hun aandoening. Dit vermogen om zelf de regie te voeren wordt ook wel zelfmanagement genoemd. Regelmatige begeleiding is van belang om de zelfmanagementvaardigheden bij patiënten te versterken. Vanwege al deze factoren vormt de diabeteszorg een aanzienlijke belasting voor de huisartsenpraktijk.

Om de diabeteszorg in de eerste lijn te verbeteren zijn vanaf 2007 regionale zorggroepen opgericht. Deze zorggroepen hebben als doel om bekende barrières rondom de uitvoering van diabeteszorg te slechten, zoals gebrek aan tijd, moeite om het overzicht te bewaren over de almaar uitdijende diabetespopulatie en knelpunten bij delegatie van zorgtaken naar de praktijkondersteuner. Zorggroepen bieden specifieke voorzieningen aan huisartsenpraktijken, waaronder een gestructureerd zorgprotocol. Dit zorgprotocol omvat jaarlijks vier consulten bij de huisartsenpraktijk voor iedere diabetespatiënt, waarbij aan diabetes gerelateerde zorg wordt geleverd. Onderdeel hiervan vormt bijvoorbeeld controle van specifieke biomedische bloedwaarden (zoals HbA1c en cholesterol) en – ten behoeve van een gezonde leefstijl - aandacht voor versterking van zelfmanagementvaardigheden. Praktijken ontvangen hulp bij de implementatie van het zorgprotocol, onder andere rondom taakdelegatie van huisartsen naar praktijkondersteuners. Daarnaast faciliteren veel zorggroepen digitale systemen die gekoppeld zijn aan huisarts-informatiesystemen, om laagdrempelig inzicht te verkrijgen in de

diabeteszorg die patiënten vanuit de huisartsenpraktijk ontvangen. Ook dienen zorggroepen als belangenbehartiger van huisartsen richting zorgverzekeraars. Zo onderhandelen zorggroepen met zorgverzekeraars over de inhoud van het zorgprotocol, de vergoeding daarvan alsmede doelstellingen ten aanzien van geleverde zorg, zoals het percentage patiënten met bijvoorbeeld een bloeddrukbepaling.

De afgelopen jaren zijn er in toenemende mate twijfels geuit ten aanzien van zorggroepen. Er leeft het gevoel dat zorggroepen, ondanks de kosten en bureaucratie die daarmee gemoeid zijn, weinig klinische relevantie hebben. Ook wordt ervaren dat het diabetesprotocol het lastig maakt om de zorg af te stemmen op behoeften van individuele patiënten.

Voor dit proefschrift is eerst de relatie tussen het volgen van een gestructureerd diabetesprotocol en de uitkomsten voor patiënten bestudeerd. Daarnaast hebben we onderzocht wat praktijken nodig hebben om zorg op de behoeften van hun patiënten af te stemmen. Daartoe hebben we het effect van loslating van het zorgprotocol en randvoorwaarden voor succesvolle implementatie van zelfmanagementinterventies geëvalueerd. Tevens hebben we de uitkomsten op patiëntniveau ten aanzien van tevredenheid, kwaliteit van leven en monitoring gemeten.

Bevindingen van dit proefschrift

Gestructureerd diabetesprotocol heeft meerwaarde voor patiënten met diabetes

Allereerst hebben wij onderzocht of zorggroepdeelname in algemene zin samengaat met een verbetering van de monitoring van patiënten (zie hoofdstuk 2). De monitoring van patiënten werd daarbij als goed beschouwd wanneer er gedurende een kalenderjaar minimaal één meting is bepaald van drie biomedische kernindicatoren (HbA1c, systolische bloeddruk en cholesterol) alsmede drie leefstijlgerichte kernindicatoren (BMI, rookgedrag en lichaamsbeweging). Deze definitie is gebaseerd op de NHG-richtlijnen voor diabetes type 2 en is in het onderzoek samengevat als 'aanbevolen monitoring'.

Om een beeld te krijgen van het effect van zorggroepdeelname op de aanbevolen monitoring, hebben we twee analyses uitgevoerd. De eerste analyse had betrekking op de zes praktijken die in januari 2014 toetraden tot de Eerstelijns Zorggroep Haaglanden (ELZHA) – een zorggroep in Den Haag en omgeving die in 2019 met een aantal andere regionale huisartsenorganisaties is gefuseerd tot Haaglandse Dokters (Hadoks). Bij deze nieuwe praktijken hebben we onderzocht of het aantal patiënten met aanbevolen monitoring aan het eind van 2014 hoger was ten

opzichte van januari 2014. Dit bleek het geval; de aanbevolen monitoring was aan het eind van kalenderjaar 2014 aanzienlijk hoger dan bij aanvang van het jaar.

Daarna is onderzocht of voor deze nieuwe praktijken na een jaar zorggroepdeelname de aanbevolen monitoring verschilde van ervaren praktijken, die minimaal drie jaar deelnamen aan de zorggroep. Uit deze analyse bleek dat er aan het eind van kalenderjaar 2014 geen verschil meer was tussen ervaren en nieuwe praktijken wat betreft het aantal patiënten met aanbevolen monitoring. Kortom, wanneer praktijken zich aansluiten bij een zorggroep, maken ze in het eerste tijd waarschijnlijk een intensief leerproces door. Na een jaar bevinden ze zich op hetzelfde niveau als ervaren praktijken.

Hoofdstuk 3 gaat in op de vraag wat de meerwaarde van aanbevolen monitoring voor patiënten is. Daartoe zijn voor kalenderjaar 2014 de HbA1c-uitkomsten van patiënten met aanbevolen monitoring vergeleken met de uitkomsten van patiënten met incomplete monitoring. De NHG-richtlijnen rapporteren een grenswaarde met betrekking tot het HbA1c-niveau voor drie groepen diabetespatiënten. Deze groepen zijn ingedeeld op basis van een risicoprofiel dat afhankelijk is van de leeftijd van de patiënt, het type behandeling en de duur van de diabetes. Voor patiënten jonger dan zeventig jaar alsmede oudere patiënten die alleen metformine-monotherapie gebruiken, is de geadviseerde maximumwaarde 53 mmol/mol. Voor patiënten boven de zeventig jaar die zwaardere diabetesmedicatie gebruiken maar korter dan tien jaar diabetes hebben, ligt de grens bij 58 mmol/mol. De derde categorie betreft de kwetsbaarste patiënten - ouder dan zeventig, met zwaardere medicatie gebruiken én langer dan tien jaar de diagnose van diabetes ' ligt de grenswaarde bij 64 mmol/mol.

In alle drie de groepen hebben we de HbA1c-niveaus van patiënten met aanbevolen monitoring vergeleken met incompleet gemonitorde patiënten. Uit de resultaten blijkt dat in alle drie de groepen de HbA1c-waarde van patiënten met aanbevolen monitoring significant ongeveer 2 mmol/mol lager ligt dan bij de incompleet gemonitorde patiënten. Met andere woorden: aanbevolen monitoring weerspiegelt niet alleen een administratieve realiteit, maar is daadwerkelijk een indicatie voor betere HbA1c-uitkomsten.

Uitkomsten zijn verschillend voor groepen diabetespatiënten

Bij sociaal-economisch kwetsbare patiënten is de gezondheidswinst het grootste

De regio Haaglanden wordt gekenmerkt door grote diversiteit ten aanzien van sociaal-economische status (SES). Daarom betrof de volgende stap een vergelijking van welvarende

en kwetsbare gebieden ten aanzien van de aanbevolen monitoring, de HbA1c-uitkomsten én de relatie tussen die twee elementen. Dit onderzoek is beschreven in hoofdstuk 4.

Voor dit onderzoek zijn alle Haagse huisartsenpraktijken op basis van een zogenaamde 'achterstandsscore', die de gemeente Den Haag registreert, toegekend aan drie categorieën: kwetsbaar, welvarend of gemiddeld. Daarnaast zijn de omliggende randgemeenten (Wassenaar, Leidschendam-Voorburg en Voorschoten) ondergebracht in de categorie 'welvarende periferie'.

Vervolgens zijn de welvarende en de kwetsbare Haagse gebieden alsmede de welvarende periferie vergeleken met de gemiddelde categorie. We zagen dat de aanbevolen monitoring in zowel de Haagse als perifere welvarende categorie niet significant verschilde van de gemiddelde categorie. Wel was het HbA1c in de achterstandscategorie significant ongunstiger dan in de gemiddelde categorie; het verschil betrof ongeveer 2 mmol/mol.

Ook hebben we onderzocht of de SES-categorieën verschilden ten aanzien van de relatie tussen monitoring en HbA1c-niveau. Het HbA1c-verschil tussen goed en onvolledig gemonitorde patiënten was significant groter in de kwetsbare groep: dit bedroeg ruim 3 mmol/mol, terwijl het verschil in de gemiddelde categorie ruim 1 mmol/mol was. Oftewel: binnen de zorggroepsetting heeft de kwetsbare categorie het meeste baat bij aanbevolen monitoring.

Gegeven het feit dat kwetsbare SES bekend staat als een factor die de kans op gunstige(re) gezondheidsuitkomsten belemmert, bijvoorbeeld vanwege beperkte gezondheidsvaardigheden bij de patiënt, is dit een interessante bevinding. Vanuit de wetenschappelijke literatuur weten we dat bij zorgverleners soms sprake is van barrières rondom de zorg voor diabetespatiënten met een kwetsbare SES, met name op het gebied van leefstijlbegeleiding. Zo hebben huisartsen en praktijkondersteuners vaak twijfels over het effect van leefstijlbegeleiding en hun eigen vermogen om goede begeleiding kunnen bieden. Ook is er terughoudendheid vanwege angst dat de relatie met de patiënt dan op het spel komt te staan. Adequate monitoring van biomedische indicatoren én voldoende aandacht voor leefstijlbegeleiding wordt echter - juist in deze groep - weerspiegeld in aanzienlijk betere HbA1c-waarden.

Zorg op maat voor verschillende groepen patiënten: 'Protocol los'

Zoals in hoofdstuk 5 is beschreven, hebben vier huisartsenpraktijken die de organisatie van hun ketenzorgprogramma's volgens de kwaliteitsstandaard van zorggroep ELZHA uitstekend op orde hadden, deelgenomen aan het onderzoeksproject 'Protocol los'. Doel van dit project

was om ontwikkeling van zorg op maat bij diabetespatiënten te stimuleren. Daartoe is het effect van protocolvrije zorg geëvalueerd en is onderzocht wat randvoorwaarden zijn voor succesvolle implementatie van zelfmanagementinterventies.

Deelnemende praktijken konden het ketenzorgprotocol loslaten bij een relatief veilige populatie - patiënten die al minimaal een jaar gestructureerde diabeteszorg ontvingen met een relatief gunstig HbA1c. Ze konden één of meerdere interventies kiezen, geïnspireerd door een landelijk erkende 'toolkit' met een breed aanbod aan zelfmanagementinterventies. Vervolgens maakten de praktijken naar eigen inzicht een implementatieplan. Dat plan vormde de basis voor de daadwerkelijke implementatie. Door middel van groepsbijeenkomsten en interviews op locatie met individuele praktijken is onderzocht hoe praktijken de protocolvrije zorg ervoeren. Ook is op die wijze het verloop van het implementatieproces in iedere praktijk geëvalueerd.

Daarnaast is in kaart gebracht hoe patiënten de protocolvrije zorg en de geïmplementeerde zelfmanagementinterventies ervoeren. Bij patiënten zijn aan het begin en na afloop van het project vragenlijsten afgenomen die de tevredenheid met de diabeteszorg, algemeen welbevinden en ervaren gezondheid in kaart brachten. Bij patiënten is ook gemeten in hoeverre de aanbevolen monitoring op peil bleef.

Uit deze studie kwamen de volgende bevindingen naar voren.

Effect van protocolvrije zorg: ruimte voor reflectie t.a.v. zorg op maat

De meeste praktijken ervoeren de kans om het ketenzorgprotocol los te laten als bevrijdend. Tegelijkertijd gaf het soms ook onzekerheid. Nu het ketenzorgprotocol wegviel, werden praktijken immers op zichzelf teruggeworpen, en op hun eigen inschatting van wat de juiste zorg voor hun patiënten was. Niettemin gaven de meeste praktijken aan dat het loslaten van het protocol ruimte creëerde om na te denken over de vraag hoe de zorg in de eigen praktijk het beste kon worden afgestemd op hun patiënten.

De praktijken verschilden ten aanzien van SES-regio en daarmee met betrekking tot patiëntkenmerken zoals gezondheidsvaardigheden. Deze diversiteit werd weerspiegeld in de gekozen zelfmanagementinterventies; deze liepen uiteen van een sms-service in een kwetsbare SES-populatie om de opkomst bij het diabetesspreekuur te verbeteren tot - in een welvarende wijk - een digitaal portaal om patiënten de ruimte te geven zelfstandig vanuit huis hun gezondheidsuitkomsten te monitoren en het consult voor te bereiden.

Randvoorwaarden voor succesvolle implementatie van zelfmanagementinterventies

- Oog voor de behoeften van de patiëntpopulatie

Als praktijken duidelijk zicht hadden op de behoeften van patiënten - die per praktijk dus aanzienlijk konden verschillen - was dat een krachtige stimulans om het implementatieproces grondig aan te pakken. Wanneer het implementatieproces langer duurde dan voorzien, of er sprake was van praktische of logistieke tegenvallers, gaf de focus op het patiëntperspectief praktijken de energie om de schouders eronder te blijven zetten.

- Samenwerking binnen het praktijkteam

Een goede samenwerking tussen de verschillende geledingen van de huisartsenpraktijk – huisartsen, praktijkondersteuners, assistenten – was van groot belang voor het implementatieproces. Zorgvuldig overleg over de beoogde interventie(s), het bouwen van een implementatieplan dat gedragen werd door binnen alle lagen van het team, en voldoende afstemming ten aanzien van logistiek droeg bij aan een geoliede implementatie.

- Voldoende haalbaarheid van interventies

Ook is gebleken dat de instrumenten goed moeten functioneren. Bij het digitale patiëntportaal was dat niet het geval: de implementatie werd belemmerd door technische tekortkomingen voor zowel de zorgverlener als de patiënt. Deze interventie maakte geen onderdeel uit van de toolkit; er was voor gekozen omdat deze net beschikbaar was gesteld, en aansloot op het elektronische diabeteszorgsysteem dat alle praktijken gebruikten. Het bleek nog onvoldoende geschikt voor implementatie in de praktijk. Voor huisartsenpraktijken kan het lastig zijn om e-health-instrumenten op hun geschiktheid te beoordelen. Dit vereist immers niet alleen specialistische technische kennis, maar ook inzicht in ervaringen van gebruikers. Daarom raden we aan om samenwerking te zoeken met academische expertisecentra die deze kennis in huis hebben en onafhankelijk advies kunnen geven.

Impact van protocolvrije zorg op maat op patiënten

Uit onze bevindingen bleek dat het aantal patiënten met aanbevolen monitoring gedurende de loop van het project daalde. In eerste instantie zou dat als zorgwekkend kunnen worden opgevat. Dit roept echter ook vragen op over de mate waarin onze definitie van monitoring zoals aanbevolen van toepassing is op patiënten met een langdurige en stabiele HbA1c-spiegel die onder de geadviseerde bovengrens blijft. Afgezien van dat punt nam ook de tevredenheid iets af. Dit onderstreept het belang van voldoende focus op de behoeften van de patiënt omtrent de diabeteszorg.

Onze bevindingen sluiten aan op een internationale discussie rondom de vraag waarom zelfmanagementinterventies vaak zo weinig lijken op te leveren. Daarin wordt onder andere naar voren gebracht dat huisartsenpraktijken– gegeven de hectiek van alledag - in onderzoekssettings vaak onvoldoende prioriteit geven aan zorgvuldige implementatie van interventies; en dat er andersoortige stimulansen benodigd zijn om adequate implementatie aan te moedigen. Naar onze overtuiging kan uit onze bevindingen worden geconcludeerd dat we die stimulansen hebben gevonden: het mogen loslaten van het ketenzorgprotocol en de vrijheid om zelf interventies te kiezen die passen bij de patiëntpopulatie én de eigen praktijk zijn voor de studiepraktijken belangrijke handvatten gebleken om de schouders te zetten onder het implementatieproces, en een uitstekende implementatie tot stand te brengen.

Ten aanzien van de patiëntuitkomsten valt op dat de tevredenheid van patiënten met de diabeteszorg, ondanks tevredenheid met de geïmplementeerde interventies, gaandeweg licht afnam. Met betrekking tot deze studie kunnen, gelet op de onderzoeksopzet, geen causale relaties worden vastgesteld; we kunnen dus niet bepalen in hoeverre de lagere tevredenheid veroorzaakt werd door de studie-opzet. Wel weten we vanuit bestaande literatuur dat er een relatie bestaat tussen consultreductie en verminderde tevredenheid. Daarnaast daalde ook het aantal patiënten met aanbevolen monitoring. Dat lijkt met het oog op de NHG-richtlijnen in principe een onwenselijke uitkomst. Gegeven het feit dat in deze studie patiënten werden geïncludeerd die een bewezen stabiele diabetesinstelling hadden, is het echter de vraag of voor deze patiënten daadwerkelijk jaarlijks een controle op alle kernindicatoren benodigd is. Zo lang dat nog niet duidelijk is, raden we voor deze patiënten vooralsnog minimaal één jaarlijks consult aan.

Conclusie en aanbevelingen

Aan de onderzoeken die in dit proefschrift beschreven zijn, kunnen een aantal conclusies worden verbonden.

Allereerst laat ons cohortonderzoek zien dat deelname van huisartsen aan een zorggroep meerwaarde heeft voor patiënten: het aantal patiënten dat systematisch wordt gemonitord volgens de NHG-richtlijnen neemt sterk toe. Hoewel het nooit uitgesloten kan worden dat zorg wel geleverd wordt maar bijvoorbeeld om technische redenen niet als zodanig geregistreerd is, blijkt er niettemin een duidelijk verschil te zijn in de HbA1c-uitkomsten van patiënten met aanbevolen dan wel incomplete monitoring: patiënten met aanbevolen monitoring hebben een significant gunstiger HbA1c. Hieruit kan worden geconcludeerd dat gestructureerde

diabeteszorg met collectieve ondersteuning vanuit een zorggroepsetting samengaat met betere patiëntuitkomsten.

In een gestructureerde zorgsetting blijkt bovendien dat er sprake is van minder sociaal-economische verschillen: ongeacht het SES-gebied is het aandeel patiënten met aanbevolen monitoring even groot. Wel heeft de kwetsbare categorie het meeste baat bij aanbevolen monitoring: het aan monitoring gerelateerde HbA1c-verschil is in die groep significant groter dan gemiddeld. Dit pleit voor zorg die zo veel mogelijk wordt afgestemd op de behoeften van groepen patiënten. Wanneer praktijken de organisatie van hun ketenzorgprogramma's goed op orde hebben, kan protocolvrije zorg een stimulans zijn tot reflectie op het thema 'zorg op maat'. Indien praktijken goed letten op de behoeften van hun patiënten, er sprake is van adequate samenwerking binnen het team en interventies geschikt zijn voor implementatie, leidt dit tot persoonsgerichte zorg die grondig en met veel betrokkenheid wordt geleverd.

Tegelijkertijd roepen deze conclusies ook nieuwe vragen op. Daarom worden in hoofdstuk 6 een aantal aanbevelingen gedaan voor vervolgonderzoek. Bij alle bovengenoemde onderzoeken is om belangrijke redenen gekozen voor een observationele studie-opzet. Daardoor kan bijvoorbeeld niet worden beoordeeld in hoeverre de zorggroepaanpak een-op-een leidt tot betere monitoring, en of betere monitoring de oorzaak is van gunstiger HbA1c-uitkomsten. Om het daadwerkelijke effect van collectieve ondersteuning en een gestructureerd zorgprotocol op gezondheidsuitkomsten beter te kunnen begrijpen, is vervolgonderzoek nodig.

Gelet op de variëteit in individuele praktijken ten aanzien van allerlei factoren - zoals type organisatie, praktijkomvang en opleidingsniveau van praktijkondersteuners - is er bovendien meer inzicht benodigd in de behoeften en ervaringen van individuele praktijken. Het is immers niet ondenkbaar dat praktijken verschillen wat betreft hun behoeften ten aanzien van ondersteuning bij de uitvoering van diabeteszorg. Daarnaast kenmerkt de ondersteuning vanuit zorggroepperspectief zich door het bieden van enerzijds houvast en anderzijds flexibiliteit. Om een optimale balans tussen houvast en flexibiliteit te vinden die recht doet aan de diversiteit van praktijken, is meer inzicht gewenst in de vraag wanneer praktijken er klaar voor zijn om het zorgprotocol los te laten.

In ons onderzoek 'Protocol los', waar afstemming van de zorg op de behoeften van patiënten centraal stond, daalde het aantal patiënten met aanbevolen monitoring na verloop van tijd significant. Zoals eerder besproken is het niet duidelijk in hoeverre lagere monitoring bij deze patiëntgroep - die 'fitte' diabeten betrof - een zorgelijke uitkomst is. Met het oog op

de diversiteit van de populatie patiënten met diabetes is het nader onderzoek naar optimale diabetesmonitoring in verschillende groepen patiënten wenselijk.

Er zijn aanwijzingen dat taakdelegatie naar praktijkondersteuners samengaat met een lagere werktevredenheid van huisartsen. Vanuit het perspectief van duurzame, toekomstbestendige diabeteszorg is diepgaander onderzoek naar factoren die de tevredenheid verbeteren van belang.

Tenslotte hebben we met dit onderzoek inzicht verkregen in de relatie tussen diabeteszorg binnen een zorggroepsetting en patiëntuitkomsten. Gegeven het feit dat de zorggroepsystematiek soms als duur en weinig kosteneffectief wordt gezien, wordt systematisch onderzoek naar de financiële kosten in verhouding tot de klinische uitkomsten aanbevolen.

Wanneer we teruggaan naar de uitkomsten van ons onderzoek, kunnen de bevindingen worden vertaald in onderstaand stappenplan.

Stappenplan: route naar sterke, persoonsgerichte diabeteszorg

1. Werk aan een solide basis

Gebruik een protocol met systematische ondersteuning bij de implementatie om de diabeteszorg te structureren

2. Bezint eer ge begint: ga na hoe zorg op maat bij patiënten en in de eigen praktijk gestalte kan krijgen

Neem de ruimte om te bezinnen op de vraag wat 'zorg op maat' voor patiënten in de eigen praktijk betekent; verken actief de behoeften van patiënten, draag zorg voor een goede samenwerking binnen het team en let erop dat interventies binnen de praktijk haalbaar zijn

3. Probeer te voorkomen dat patiënten uit zicht raken

Hoe de interventie er ook uit ziet, let erop dat iedere patiënt in ieder geval eens per jaar wordt gezien

4. Houd rekening met specifieke zorgbehoeften afhankelijk van SES

Wees erop alert dat voor 'zorg op maat' voor patiënten met een kwetsbare SES-achtergrond kan betekenen dat er behoefte is aan extra houvast ten aanzien van de zorg

Dit stappenplan is bedoeld als handreiking voor huisartsenpraktijken om optimale diabeteszorg te bieden, vertrekkend van een stevige basis naar zorg die recht doet aan de behoeften van de patiënt.

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De start van de samenwerking tussen LUMC en de Haaglandse huisartsen, waartoe drs. Leonie van Son en Mattijs in 2015 het voortouw namen, vormde de basis waaruit ook dit proefschrift kon ontstaan. Dr. Robert Jansen en drs. Gos de Vries, raad van bestuur van het tegenwoordige Hadoks, zagen het belang en hebben de lijn voortgezet: veel dank voor jullie betrokkenheid!

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"Speak low, if you speak love" (Shakespeare, 1598)
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About the author

After completing the Willem Lodewijk Gymnasium in 1997, Sytske van Bruggen (1979, Groningen) moved to Nijmegen to study psychology at the Radboud Universiteit. With the master thesis 'Werk in de zorg: zorgeloos werk?' she graduated in work and organisational psychology in 2004. Having completed the curriculum of clinical psychology as well, she also obtained the certificate 'Basisaantekening klinische psychodiagnostiek'. Besides her study, Van Bruggen was glad to finish courses in Italian speaking, grammar and writing at the department of Roman languages.

Van Bruggen always had a lively interest in the connection between research and practice. In January 2005, she started professional life with a practice-related job as a reintegration coach for school dropouts and people receiving welfare support. She was struck by the socioeconomic vulnerability, stress and the concurrent behavioural patterns among those people.

Looking for more theoretical challenges, Van Bruggen in February 2006 accepted a position as desk research editor at Elsevier's Weekblad, where she designed and conducted statistical analyses for studies such as 'De beste gemeenten' and 'De beste scholen'. Furthermore, she produced and wrote articles of various subjects. In September 2008, Van Bruggen took a sabbatical to reconnect with practice and travelled to the Westbank, where she volunteered in local community initiatives to improve work and social perspectives of disabled people. This period allowed insight into the perspective of other cultures concerning a meaningful life. In addition, Van Bruggen perceived how wellbeing, health behaviour and individuals' perceptions of the interrelation between behaviour and health outcomes are shaped by their cultural context.

After her return to the Netherlands, Van Bruggen was drawn to research again; in October 2009, she started as a project assistant in the Mantelzorg project at the department of ethics and law of the Leiden University Medical Center (LUMC). Having finalised that project in 2013, she became research policy officer at the Eerstelijns Zorggroep Haaglanden (Elzha), a care group of general practitioners (GPs) in the Hague and its suburbs - in 2019 integrated with two other local primary care organisations into Hadoks.

From 2015, Van Bruggen was able to combine her passions. To improve the connection between the perspective of local GPs and the academic community, Van Bruggen started as a liaison between Hadoks and the LUMC Campus The Hague. Next to this position, Van Bruggen has fulfilled several roles in the LUMC. From 2015 to 2019, she served as a board secretary of the interdisciplinary research consortium 'Health, prevention and the human life cycle' – that comprised an collaboration between several medical and social departments of Leiden University. In December 2016, Van Bruggen started with her PhD project. Currently, she is involved as a postdoctoral researcher in several projects on the LUMC Campus The Hague.

Portfolio

PhD courses

2021 Re-registration eBrok, NFU

2018 Basic Methods and Reasoning in Biostatistics

2018 Academic writing

2017 Presenting skills

2017 PhD Introductory Meeting

2016 Basic course on regulations and organisation of clinical trials (eBrok), NFU

Selection of scientific publications

2021 **Towards tailoring of primary diabetes care: mixed-methods study of key conditions for successful implementation of self-management interventions**
Van Bruggen S, Kasteleyn MJ, Rauh SP, Meijer JS, Busch KJG, Numans ME, Chavannes NH (under review)

2021 **Socioeconomic status is not associated with the delivery of care in people with diabetes but does modify HbA1c levels: An observational cohort study (Elzha-cohort 1)**
Van Bruggen S, Kasteleyn MJ, Bonten TN, Chavannes NH, Numans ME, Rauh SP. International Journal for Clinical Practice, 2021;00:e13962.

2020 **Association between GP participation in a primary care group and monitoring of biomedical and lifestyle target indicators in people with type 2 diabetes: a cohort study (ELZHA cohort-1)**
Van Bruggen S, Rauh SP, Bonten TN, Chavannes NH, Numans ME, Kasteleyn MJ. BMJ Open. 2020;10(4):e033085.

2019 **Association between full monitoring of physiological and lifestyle target indicators and HbA1c level in primary type 2 diabetes care: an observational cohort study (ELZHA-cohort 1)**
Van Bruggen S, Rauh SP, Kasteleyn MJ, Bonten TN, Chavannes NH, Numans ME. BMJ Open. 2019;9(3):e027208.

2016 **Problems experienced by informal caregivers with older care recipients with and without cognitive impairment**
Van Bruggen S, Gussekloo J, Bode C, Touwen DP, Engberts D, Blom JW. Home Health Care Services Quarterly, 35:1, 11-24, DOI: 10.1080/01621424.2016.114516

2015 **Reliability and validity of the dutch translation of the filial maturity measure in informal caregivers**
Van Bruggen S, Bode C, Ten Klooster PM, Lenferink LIM. Journal of Adult Development, 2015 (vol. 22, pp 138–147)

Submitted:

Perceptions about hypertension healthcare and therapy adherence on the level of healthcare providers and the healthcare system: a qualitative study using the Behavior Change Wheel and the Theoretical Domains Framework.
Van Grondelle SE, van Bruggen S, Meijer JS, Van Ittersum ATP, Van der Salm MCM, Veen-Reedijk B, Van Duin E, Mairuhu A, Bots M, Rutten GEHM, Vos HHM, Numans ME, Vos RC

The impact of the COVID-19 pandemic on delivery of primary diabetes care: experiences of healthcare providers in Europe
Van Bruggen S, Van Grondelle SE, Van der Zwan M, Jansen TN, Hart HE, Vos HMM, Numans ME, Domeyer P, Kalanghot M, Topsever P, Jansson SPO, Cos FX, Seidu S, Vos RC

The impact of the COVID-19 pandemic on HbA1c levels and experienced primary diabetes care by people with type 2 diabetes and healthcare providers in the Netherlands
Van Grondelle SE, van Bruggen S, Van der Zwan M, Jansen TN, Hart HE, Vos HMM, Numans ME, Vos RC

Delivery of primary diabetes care through video consultations during the COVID-19 pandemic: a mixed-methods study
Van Bruggen S & Van Grondelle SE, Van der Zwan M, Jansen TN, Hart HE, Vos HMM, Numans ME, Vos RC

Selection of other publications

2020 **Hadoks ketenzorgprogramma diabetes werkt!**
Interview in online newsletter Hadoks, May 2020

2018 **'Experimenteerruimte voor huisartsenpraktijken: Diabeteszorg zonder protocol'.** Interview in 'De Eerstelijns, March 2018, page 4-6.

2017 **Bilangual report 'Health, Prevention and the Human Life Cycle: Synergy added!** ***An insight into this unique Leiden collaboration between the medical and behavioral sciences***
Interviews with key representatives of all 8 disciplines that are affiliated to this consortium

2017 **'De diabetespatiënten in Leidschendam zijn de Challenge aangegaan. Al na acht weken zag ik het verschil, de gezondheid van m'n diabetespatiënten ging met sprongen vooruit!'**
Sytske van Bruggen. Article in online newsletter Elzha, May 2017

2015 **Project Transvaal: "Doordat de diabetesverpleegkundige bij Surinaamse diabeten thuis hun glucose prikte en direct de uitkomsten besprak, nam hun ziekte-inzicht enorm toe"**
Sytske van Bruggen. Article in newsletter Elzha, December 2015

2015 **Project Segbroek: ontmoeting en uitwisseling met medepatiënten die hun leefstijl succesvol hebben aangepast**
Sytske van Bruggen. Article in newsletter Elzha, December 2015

2008 **Redactie wetenschap: 'Geen pillendoosje maar een medicijntand'**
Sytske van Bruggen. Article on website Elseviers weekblad, July 2008

2007 **Redactie wetenschap: 'Voedingssuplementen mogelijk schadelijk'**
Sytske van Bruggen. Article on website Elseviers weekblad, October 2007

2007 **Alle scholen beoordeeld. Elsevier vergelijkt op basis van gegevens van de Inspectie van het Onderwijs alle middelbare scholen in Nederland. Toelichting bij de berekening van alle eindoordelen.**
Sytske van Bruggen en Arthur van Leeuwen, Elseviers Weekblad, January 2007, pag 33-39.

2006 **Hoe goed is uw gemeente? Vergelijk woongenot, voorzieningen, veiligheid, economische prestaties en de lasten. Wat iedere burger hoort te weten: vingerwijzingen voor bij de stembus**
Sytske van Bruggen en Arthur van Leeuwen, Elseviers Weekblad, February 2006, pag 22–25

Selection of oral and poster presentations

2021 'Towards tailoring of primary diabetes care: study of key conditions for successful implementation of self-management interventions'. Oral presentation for GPs at online NHG-Wetenschapsdag

2020 'Protocol los': preliminary results on patient level. Oral presentation at zesde Werkconferentie LUMC Campus Den Haag: Vitaliteit in onderzoek en praktijk.

Evaluation of structured local type 2 diabetes care: associations between care group participation and neighbourhoods and delivery of care. Oral presentation at zesde Werkconferentie LUMC Campus Den Haag: Vitaliteit in onderzoek en praktijk.

2019 'Protocol los': key conditions for successful implementation of self-management interventions in primary diabetes care. Oral presentation at Vijfde Werkconferentie LUMC Campus Den Haag: innovatie en onderzoek in de publieke gezondheidszorg in de regio Den Haag

Evaluation of structured local type 2 diabetes care: associations between care group participation and delivery of care . Oral presentation at Vijfde Werkconferentie LUMC Campus Den Haag: innovatie en onderzoek in de publieke gezondheidszorg in de regio Den Haag

2018 'Protocol los: als je loslaat heb je twee handen vrij'. Oral presentation at vocational course for GPs 'Vorderingen en praktijk'. Organisation: Boerhaave Nascholing, Leiden

'Protocol los'. Oral presentation at seminar of university of applied sciences, The Hague

A multidisciplinary Type 2 Diabetes care protocol within a primary care group leads to a higher proportion of fully-monitored patients (ELZHA cohort-1). Oral presentation at annual Meeting of North American Primary Care Research Group (NAPCRG), Chicago (Illinois), US.

Full monitoring of T2DM target indicators in primary care is associated with a lower HbA1c level (ELZHA cohort-1). Oral presentation at Annual Meeting of North American Primary Care Research Group (NAPCRG), Chicago (Illinois), US.

Implementation of self-management interventions within in a 'protocol free' GP setting: study design. Poster presentation at Annual Meeting of North American Primary Care Research Group (NAPCRG), Chicago (Illinois), US.

'Evaluatie effectiviteit eerstelijns DM2-ketenzorgprogramma'. Oral presentation for GPs at NHG-Wetenschapsdag Amsterdam.

'Protocol los: iedere patiënt z'n eigen plan!' Oral presentation for GPs at NHG-Wetenschapsdag Amsterdam.

2017 Protocol los: als je loslaat heb je twee handen vrij. Patiëntentop 'Zorg voor innoveren', Utrecht. Organisation: ZonMW

2016 Innovation in local healthcare: collaboration between Elzha and LUMC Campus The Hague. Oral presentation for secretary of Council of Ministers, The Hague

Grant

2018 Travel grant representing $1,000 to attend the Annual Meeting of the North American Primary Care Research Group

Selection of activities to encourage interdisciplinary exchange and collaboration between researchers and professionals in health care and social work

- Organisation of the annual Werkconferentie LUMC Campus The Hague (first edition in 2015, follow-up in 2016 and 2017), 100 – 150 attendants

- Organisation of Spring Event, offered by research consortium 'Health, prevention and the human life cycle' (editions 2015, 2016 and 2017), approximately 100 attendants, LUMC

- Organisation of symposium 'eHealth, what's in it for me?' offered by the research consortium 'Health, prevention and the human life cycle', approximately 600 attendants, Stadsgehoorzaal Leiden, September 2018