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

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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).

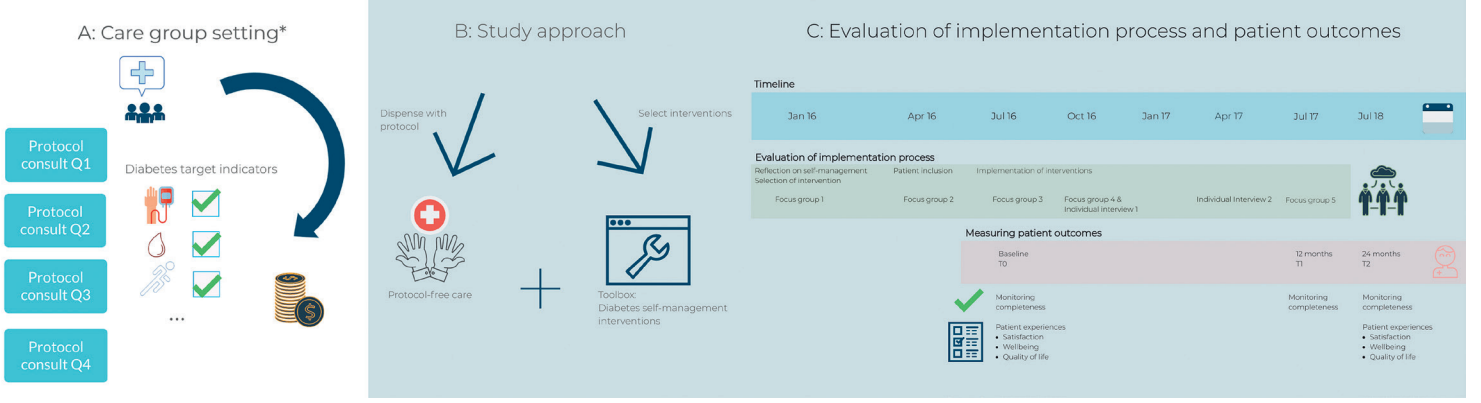

Figure 1. Overview of care group setting, study approach and study outcomes

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.

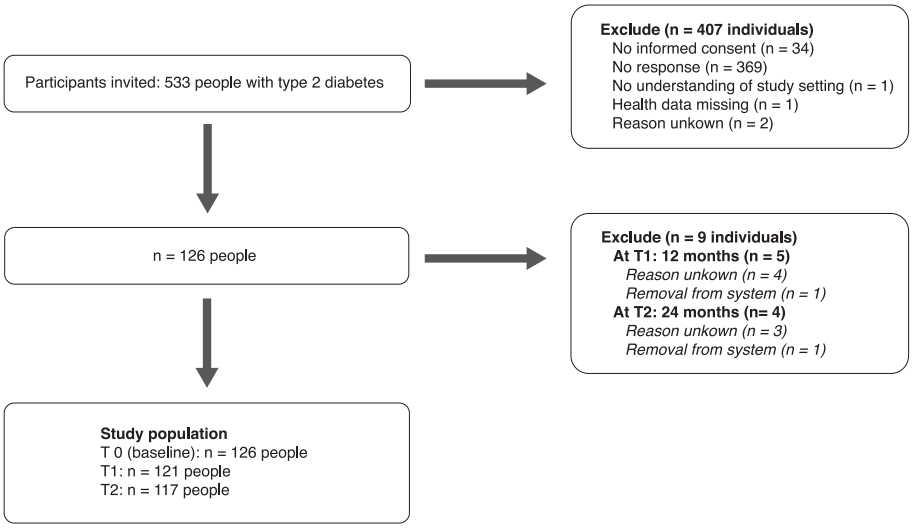

Figure 2. Flowchart of patient inclusion

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.

References

1. Krag MO, Hasselbalch L, Siersma V, Nielsen AB, Reventlow S, Malterud K, et al. The impact of gender on the long-term morbidity and mortality of patients with type 2 diabetes receiving structured personal care: a 13 year follow-up study. Diabetologia. 2016;59(2):275-85.
2. Wong CK, Wong WC, Wan YF, Chan AK, Chan FW, Lam CL. Effect of a structured diabetes education programme in primary care on hospitalizations and emergency department visits among people with Type 2 diabetes mellitus: results from the Patient Empowerment Programme. Diabet Med. 2016;33(10):1427-36.
3. Type 2 diabetes in adults: management. United Kingdom: National Institute for Health and Care Excellence; NICE guideline 2015.
4. Riordan F, McHugh S, Harkins V, Kearney P. Long term outcomes and mortality among patients enrolled in a structured primary care-led diabetes programme. In: Medicine SfS, editor. 61st Annual Scientific Meeting, University of Manchester, 5–8 September 2017: J Epidemiol Community Health; 2017.
5. Nielen M, Poos, R., en Korevaar, J. Diabetes mellitus in Nederland. Prevalentie en incidentie: heden, verleden en toekomst. Utrecht: Nivel; 2020.
6. Ineen. Transparante ketenzorg diabetes mellitus, COPD en VRM: rapportage zorggroepen 2014. Op weg naar genuanceerde rapportage van zorg.: Ineen; 2015.
7. Rutten GEHM DGW, Nijpels G, Houweling ST, Van de Laar FA, Bilo HJ, Holleman F,Burgers JS, Wiersma Tj, Janssen PGH. NHG-Standaard Diabetes mellitus type 2 (derde herziening). Huisarts en Wetenschap 2013;56(10):512-25.
8. Ineen. Transparante ketenzorg diabetes mellitus, VRM, COPD en astma: rapportage zorggroepen 2019. Spiegel voor het verbeteren van chronische zorg.: Ineen; 2020.
9. Struijs JN, Van Til JT, Baan CA. Experimenteren met de keten-dbc diabetes: de eerste zichtbare effecten. Bilthoven: RIVM; 2009. p. 19-62.
10. van Hateren KJ, Drion I, Kleefstra N, Groenier KH, Houweling ST, van der Meer K, et al. A prospective observational study of quality of diabetes care in a shared care setting: trends and age differences (ZODIAC-19). BMJ Open. 2012;2(4).
11. van Bruggen S, Rauh SP, Bonten TN, Chavannes NH, Numans ME, Kasteleyn MJ. 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). BMJ Open. 2020;10(4):e033085.
12. van Bruggen S, Rauh SP, Kasteleyn MJ, Bonten TN, Chavannes NH, Numans ME. 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). BMJ Open. 2019;9(3):e027208.

13. Elissen AM, Duimel-Peeters IG, Spreeuwenberg C, Spreeuwenberg M, Vrijhoef HJ. Toward tailored disease management for type 2 diabetes. Am J Manag Care. 2012;18(10):619-30.
14. Mainous AG, 3rd, Tanner RJ, Scuderi CB, Porter M, Carek PJ. Prediabetes Screening and Treatment in Diabetes Prevention: The Impact of Physician Attitudes. J Am Board Fam Med. 2016;29(6):663-71.
15. Rushforth B, McCrorie C, Glidewell L, Midgley E, Foy R. Barriers to effective management of type 2 diabetes in primary care: qualitative systematic review. Br J Gen Pract. 2016;66(643):e114-27.
16. Lawton R, Heyhoe J, Louch G, Ingleson E, Glidewell L, Willis TA, et al. Using the Theoretical Domains Framework (TDF) to understand adherence to multiple evidence-based indicators in primary care: a qualitative study. Implement Sci. 2016;11:113.
17. Correa VC, Lugo-Agudelo LH, Aguirre-Acevedo DC, Contreras JAP, Borrero AMP, Patino-Lugo DF, et al. Individual, health system, and contextual barriers and facilitators for the implementation of clinical practice guidelines: a systematic metareview. Health Res Policy Syst. 2020;18(1):74.
18. LHV. Het roer gaat om: Tussenrapportage 2016. 2016.
19. Eaton S, Roberts S, Turner B. Delivering person centred care in long term conditions. BMJ. 2015;350:h181.
20. American Academy of Family Physicians, American Academy of Pediatrics, American College of Physicians, American Osteopathic Association. Joint principles of the patient-centered medical home. Washington, DC: Patient-Centered Primary Care Collaborative; 2007.
21. Wermeling PR, Janssen J, Gorter KJ, Beulens JW, Rutten GE. Six-monthly diabetes monitoring of well-controlled patients: experiences of primary care providers. Prim Care Diabetes. 2013;7(3):187-91.
22. Powers MA, Bardsley J, Cypress M, Duker P, Funnell MM, Hess Fischl A, et al. Diabetes Self-management Education and Support in Type 2 Diabetes: A Joint Position Statement of the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics. Diabetes Care. 2015;38(7):1372-82.
23. Richards T, Coulter A, Wicks P. Time to deliver patient centred care. BMJ. 2015;350:h530.
24. Beck J, Greenwood DA, Blanton L, Bollinger ST, Butcher MK, Condon JE, et al. 2017 National Standards for Diabetes Self-Management Education and Support. Diabetes Care. 2017;40(10):1409-19.
25. World Health Organization. Coronavirus disease (COVID-19): Advice for the public. 2020.
26. Toolkit Zelfmanagement-ondersteuning voor zorgprofessionals. Leusden, The Netherlands: Zelfzorg Ondersteund!; 2015.

27. Kroese FM, Adriaanse MA, Vinkers CD, van de Schoot R, de Ridder DT. The effectiveness of a proactive coping intervention targeting self-management in diabetes patients. Psychol Health. 2013;29(1):110-25.
28. Coulter A, Entwistle VA, Eccles A, Ryan S, Shepperd S, Perera R. Personalised care planning for adults with chronic or long-term health conditions. Cochrane Database Syst Rev. 2015(3):CD010523.
29. Rosenzweig JL, Taitel MS, Norman GK, Moore TJ, Turenne W, Tang P. Diabetes disease management in Medicare Advantage reduces hospitalizations and costs. Am J Manag Care. 2010;16(7):e157-62.
30. Shah BR, Hwee J, Cauch-Dudek K, Ng R, Victor JC. Diabetes self-management education is not associated with a reduction in long-term diabetes complications: an effectiveness study in an elderly population. J Eval Clin Pract. 2015;21(4):656-61.
31. Steinsbekk A, Rygg LO, Lisulo M, Rise MB, Fretheim A. Group based diabetes self-management education compared to routine treatment for people with type 2 diabetes mellitus. A systematic review with meta-analysis. BMC Health Serv Res. 2012;12:213.
32. Carroll C, Patterson M, Wood S, Booth A, Rick J, Balain S. A conceptual framework for implementation fidelity. Implement Sci. 2007;2:40.
33. Slaughter SE, Hill JN, Snelgrove-Clarke E. What is the extent and quality of documentation and reporting of fidelity to implementation strategies: a scoping review. Implement Sci. 2015;10:129.
34. Sun X, Guyatt GH. Interventions to enhance self management support. BMJ. 2013;346:f3949.
35. Kennedy A, Rogers A, Bowen R, Lee V, Blakeman T, Gardner C, et al. Implementing, embedding and integrating self-management support tools for people with long-term conditions in primary care nursing: a qualitative study. Int J Nurs Stud. 2014;51(8):1103-13.
36. Kadu MK, Stolee P. Facilitators and barriers of implementing the chronic care model in primary care: a systematic review. BMC Fam Pract. 2015;16:12.
37. Baker R, Camosso-Stefinovic J, Gillies C, Shaw EJ, Cheater F, Flottorp S, et al. Tailored interventions to address determinants of practice. Cochrane Database Syst Rev. 2015(4):CD005470.
38. Wensing M. The Tailored Implementation in Chronic Diseases (TICD) project: introduction and main findings. Implement Sci. 2017;12(1):5.
39. Municipality of The Hague. Den Haag in Cijfers. The Hague, The Netherlands 2015.
40. Baxter P, Jack S. Qualitative case study methodology: study design and implementation for novice researchers. The Qualitative Report. 2010;13(4).

41. Bradley C. Diabetes Treatment Satisfaction Questionnaire (DTSQ). In: Bradley C, editor. Handbook of Psychology and Diabetes: a guide to psychological measurement in diabetes research and practice. Abingdon: Routledge; 1994. p. 111-32.
42. WHO. Info Package: Mastering depression in primary care. Regional Office for Europe, Psychiatric Research Unit. Frederiksborg: World Health Organisation; 1998.
43. Brooks R. EuroQol: the current state of play. Health Policy. 1996;37(1):53-72.
44. Bengtsson M. How to plan and perform a qualitative study using content analysis. NursingPlus Open. 2016;2:8-14.
45. Seidu S, Cos X, Brunton S, Harris SB, Jansson SPO, Mata-Cases M, et al. A disease state approach to the pharmacological management of Type 2 diabetes in primary care: A position statement by Primary Care Diabetes Europe. Prim Care Diabetes. 2021;15(1):31-51.
46. Corriere MD, Minang LB, Sisson SD, Brancati FL, Kalyani RR. The use of clinical guidelines highlights ongoing educational gaps in physicians' knowledge and decision making related to diabetes. BMC Med Educ. 2014;14:186.
47. Nokleby K, Berg TJ, Mdala I, Tran AT, Bakke A, Gjelsvik B, et al. Variation between general practitioners in type 2 diabetes processes of care. Prim Care Diabetes. 2021;15(3):495-501.
48. Hertroijs DFL, Elissen AMJ, Brouwers M, Schaper NC, Ruwaard D. Relevant patient characteristics for guiding tailored integrated diabetes primary care: a systematic review. Prim Health Care Res Dev. 2018;19(5):424-47.
49. Diabetes Care. Strategies for improving care. 2016. Contract No.: Supplement 1.
50. Powell BJ, Waltz TJ, Chinman MJ, Damschroder LJ, Smith JL, Matthieu MM, et al. A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project. Implement Sci. 2015;10:21.
51. Frow P, Nenonen S, Payne A, Storbacka K. Managing Co-creation Design: A Strategic Approach to Innovation. British Journal of Management. 2015;26(3):463-83.
52. Raynor DK. Health literacy. BMJ. 2012;344:e2188.
53. Huber M, Knottnerus JA, Green L, van der Horst H, Jadad AR, Kromhout D, et al. How should we define health? BMJ. 2011;343:d4163.
54. Huber M, van Vliet M, Giezenberg M, Winkens B, Heerkens Y, Dagnelie PC, et al. Towards a 'patient-centred' operationalisation of the new dynamic concept of health: a mixed methods study. BMJ Open. 2016;6(1):e010091.
55. Guthrie B, Roland M, Minchin M. Quality of Care in the United Kingdom after Removal of Financial Incentives. N Engl J Med. 2018;379(22):2179.
56. Hirst JA, Farmer AJ, Smith MC, Stevens RJ. Timings for HbA1c testing in people with diabetes are associated with incentive payments: an analysis of UK primary care data. Diabet Med. 2019;36(1):36-43.

57. Wermeling PR, Janssen J, Gorter KJ, Beulens JW, Rutten GE. Satisfaction of well-controlled type 2 diabetes patients with three-monthly and six-monthly monitoring. BMC Fam Pract. 2013;14:107.
58. Creswell J. Research design: Qualitative, quantitative and mixed methods approaches. 3 ed: Thousand Oakes, CA: Sage Publication Inc; 2009.

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.

Conflict of Interest Statement No potential conflicts of interest relevant to this article were reported.

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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