Shared decision making in primary care: process evaluation of the intervention in the OPTIMAL study, a cluster randomised trial

Ouden, H. den; Vos, R.C.; Pieterse, A.H.; Rutten, G.E.H.M.

Primary Care Diabetes 16 (2022) 375–380

Contents lists available at ScienceDirect

Primary Care Diabetes

journal homepage: www.journals.elsevier.com/primary-care-diabetes

Original research

Shared decision making in primary care: Process evaluation of the intervention in the OPTIMAL study, a cluster randomised trial

Henk Den Ouden [a,*], Rimke C. Vos [b], Arwen H. Pieterse [c], Guy E.H.M. Rutten [d]

[a] Julius Centre for Health Sciences and Primary Care, University Medical Centre Utrecht, The Netherlands
[b] Public Health and Primary Care/LUMC Campus The Hague, Leiden University Medical Center, The Hague, and Julius Center for Health Sciences and Primary Care, University Medical Centre Utrecht, Utrecht University, The Netherlands
[c] Medical Decision Making, Department of Biomedical Data Sciences, Leiden University Medical Center, The Netherlands
[d] Julius Center for Health Sciences and Primary Care, University Medical Centre Utrecht, Utrecht University, The Netherlands

ARTICLE INFO

Keywords:
Shared decision making
Primary care
Type 2 diabetes
Decision aid

ABSTRACT

Aims: To analyse the performance of a Shared Decision Making (SDM) intervention, we assessed perceived and experienced SDM in General Practitioners (GPs) and patients with type 2 diabetes (T2DM).
Methods: Cluster-Randomised Controlled Trial (cRCT) testing the effect of a decision aid. Opinions and experienced role regarding SDM were assessed in 72 patients and 18 GPs with the SDM-Q-9 (range 0–45) and Control Preferences Scale (CPS, 0–5), and observed SDM with the OPTION5 (0–20). SDM at baseline was compared to 24 months' follow-up using paired t-tests.
Results: At baseline, perceived levels of SDM did not significantly differ between GPs and patients with T2DM (difference of 2.3, $p = 0.24$). At follow-up, mean patients' perceived level of SDM was 7.9 lower compared to baseline ($p < 0.01$), whereas GPs' opinions had not changed significantly. After both visits, mean CPS scores differed significantly between patients and GPs. OPTION5 scores ranged between 6 and 20.
Conclusion: Patients and GPs perceived similar baseline levels of SDM. Two years later, patients perceived less SDM, while GPs did not change their opinion. SDM was appropriate immediately after training, but perhaps GPs fell back in old habits over time. We recommend repeated SDM training.

1. Introduction

The management of type 2 diabetes mellitus (T2DM) requires a multitude of decisions, each one entailing different combinations of possible therapeutic or adverse effects [1,2]. Therefore, T2DM patients need to be involved in determining the management strategy most consistent with their preferences and values [3]. Shared Decision Making (SDM) is a healthcare decision making model that promotes patient involvement, and has been identified as the crux of patient-centred care [4]. In SDM, both parties share information and expertise: the physician shares medical information about options and their benefits and risks, and T2DM patients share their preferences and values [5]. But how to implement SDM in daily practice? It has been demonstrated that general practitioners (GPs) can learn to deliver patient-centred care [6,7], and that options can be made clearer to patients using decision aids [8]. With regard to SDM, there is broad consensus about two core physician competencies that should be acquired during training. The first is *relational competence*, involving the creation of a favourable environment for communication, and an appropriate interaction during the clinical encounter. The second is *risk communication competence*, including discussion of uncertainty in treatment outcomes, and effective communication about benefits and risks of different treatment options [6,8,9]. Charles et al. [10] highlighted the need for bidirectional information exchange, participation of both parties in deliberation and agreement about the resulting treatment plan. They developed their framework in the acute setting in which typically one-time decisions are made. Their framework is one of the most-often cited basis for later frameworks [5]. In 2006, Montori et al. modified it to make it applicable to the care of people with chronic conditions [11]. This modification stressed the need for an ongoing partnership between GP and patients with T2DM and the

* Corresponding author at: Julius Centre for Health Sciences and Primary Care, University Medical Centre Utrecht, Str. 6.131, PO Box 85500, 3508 GA Utrecht, The Netherlands.
E-mail addresses: H.denOuden@umcutrecht.nl, hendrikdenouden@outlook.com (H. Den Ouden), r.c.vos@lumc.nl (R.C. Vos), A.H.Pieterse@lumc.nl (A.H. Pieterse), G.E.H.M.Rutten@umcutrecht.nl (G.E.H.M. Rutten).

https://doi.org/10.1016/j.pcd.2022.02.006
Received 30 July 2021; Received in revised form 18 November 2021; Accepted 17 February 2022
Available online 18 March 2022

Table 1
Characteristics of patients in the intervention group at the first visit (n = 72). Values are means (SD) or percentages unless stated otherwise.

Physical characteristics	
Male sex — n (%)	39 (54.2)
Age (years)	70.0 (5.7)
Duration of type 2 diabetes (years)	10.2 (2.3)
Education high/middle/low	16.7%/31.9%/51.4%
Living alone — n (%)	17 (24.2)
Current smoking — n (%)	8 (11.1)
Body weight (kg)	83.8 (14.8)
HbA1c (mmol/mol) median (IQR)	49.0 (10)
Systolic blood pressure (mmHg)	138.1 (14.3)
Diastolic blood pressure (mmHg)	78.0 (10)
Total cholesterol (mmol/l) median (IQR)	4.0 (1.2)
LDL-cholesterol (mmol/l) Median (IQR)	2.2 (1.2)
Medication	
Oral diabetes medication — n (%)	61 (84.7)
Insulin — n (%)	8 (11.1)
Statin — n (%)	55 (75.9)
Other lipid regulating drugs — n (%)	5 (6.9)
Blood pressure lowering drugs — n (%)	60 (83.3)
Comorbidities	
Cardiac — n (%)	15 (20.8)
Stroke — n (%)	3 (4.2)
Chronic lung disease — n (%)	5 (6.9)
Peripheral arterial disease — n (%)	5 (6.9)

recognition that decisions in chronic care can be revised.

The American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) published a decision cycle to manage hyperglycaemia in T2DM patients, to be used during consultations. It integrates current lifestyle, comorbidities, clinical characteristics, and issues such as patient preferences, motivation, diabetes-related distress, depression, and financial resources. SDM is explicitly integrated in the cycle and the cycle requests smart goals to be set [12].

We conducted a Cluster-Randomised Controlled Trial (cRCT, the OPTIMAL study) with a follow-up of 24 months to assess to what extent the implementation of SDM, based on the framework by Montori et al., would affect the proportion of T2DM patients who achieve all their treatment targets (glucose, systolic blood pressure, and LDL-cholesterol) [13]. Furthermore, we were interested in the experienced SDM 24 months after training, to evaluate the sustainability of the effect of SDM training. SDM was introduced using two elements: a decision aid for T2DM patients, combined with a training of GPs. Here we evaluate the SDM-process during the trial, aiming to answer the following research questions:

1. Did GPs and patients differ in their opinions regarding the extent to which SDM occurred during consultations at baseline and at 24 months follow-up?
2. Which decisional role did GPs and patients experience in making the final decision at baseline and at 24 months follow-up?
3. To what extent did the GPs adhere to the study protocol regarding the SDM elements?

2. Methods

2.1. Study design

The full details on the rationale and design of the study are described elsewhere [13,14]. In short, the OPTIMAL study was a Cluster-Randomised Controlled Trial (cRCT) with three annual reviews by the GP (at baseline and at 12- and 24-months follow-up). The intervention aimed at fostering SDM about diabetes treatment targets by means of a decision aid and SDM training for the GPs. The decision aid was designed according to the International Patient Decision Aids Standards [15], and based on the results of the ADDITION study, which ran between 2002 and 2009 [16] (see below).

The study protocol was registered at ClicialTrials.gov (NCT02285881) and was approved by the Medical Ethical Committee of the University Medical Centre Utrecht (Protocol number: 11–153). All patients provided informed consent before entering the study.

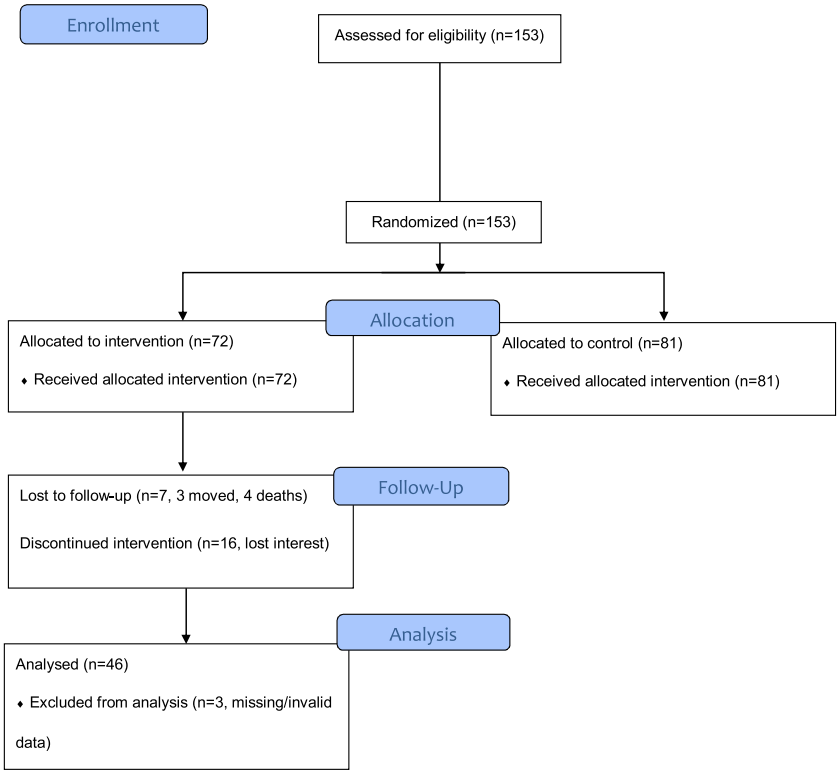

Fig. 1. CONSORT flow diagram of patient enrollment, allocation and analysis.

2.2. Practices and patients

All 79 practices that had participated in the ADDITION study were invited to participate in the OPTIMAL study. Of these, 35 practices responded, and in each practice one GP participated in the study. Practices were randomised, resulting in an intervention (n = 18) and a control (n = 17) group. Randomisation was executed at the research centre at practice-level, without stratification. All participating GPs included at least one person with T2DM with either of the following sets of characteristics: 1. Screen-detected with T2DM between 2002 and 2004, aged between 50–70 years at time of diagnosis, and participated in the ADDITION study; 2. Diagnosed with T2DM for eight to 12 years, aged between 60 and 80 years at study entry, and did not participate in the ADDITION study. Patients from outside the ADDITION study were allowed to participate, as long as they were comparable in terms of age and time since diagnosis (summarised in Table 1). Patients with a history of alcoholism, drug abuse, psychosis, personality disorder or another emotional, psychological or intellectual problem that was likely to invalidate informed consent, were excluded (Fig. 1). In order to assess the sustainability of the intervention, only participants from the intervention group are described and analysed here.

2.3. SDM intervention: development and content

The SDM intervention consisted of making a shared decision using a decision aid and training the GPs in SDM. Consequently, this decision aid first needed to be developed. Therefore, all GPs in the intervention group were approached twice. First, to develop the decision aid; under the guidance of an OPTIMAL study researcher, 15 GPs working in OPTIMAL intervention practices had a discussion about SDM in five groups of three GPs. The purpose was to review the decision aid that the researchers had drafted. Several propositions about SDM were discussed. We checked whether the GPs thought more treatment targets would be achieved through SDM. Besides, the ADDITION study was once again explained and discussed with the GPs, to determine to what extent they agreed with the conclusions of the study and to know the background of the decision aid. Specifically, the ADDITION study included screen detected T2DM patients and compared an intensive multifactorial treatment with less intensive usual care according to national guidelines. The intensive treatment was associated with a significant increase in prescribed medications and a non-significant 17% reduction of cardiovascular events and death after five years. The rate of cardiovascular events seemed to diverge after four years of follow-up. It was concluded that intensified treatment and treatment according to national guidelines can theoretically be equally effective. Following this session, the decision aid was finalised. Secondly, all participating GPs from the intervention group received a one-hour training, during which the definitive decision aid was presented and explained. The study protocol was discussed and SDM principles were reviewed to foster a common understanding of SDM processes.

The final decision aid described both treatment options, indicating their possible beneficial and adverse effects. The more intensive regime aimed for stricter treatment targets, and the less intensive regime aimed for less strict targets, meaning less medication. The different thresholds and treatment targets were as follows. Less intensive therapy: blood pressure <140 mmHg; total cholesterol <4.5 mmol/L; in case of cardiovascular disease <3.5 mmol/L; HbA1c < 53 mmol/mol; stop smoking and a shared decision about weight loss. Intensive treatment: blood pressure <135/85 mmHg; total cholesterol <3.5 mmol/L; HbA1c < 48−53 mmol/mol; stop smoking and if BMI > 27 five percent weight loss [13].

In the first step of the decision aid T2DM patients could choose between usual or intensified diabetes care and secondly to prioritise which treatment targets they would like to achieve first; it provided a systematic ranking of the five treatment targets. Patients made a treatment decision based on their preference and prioritised treatment goals during the first consultation. Patients who had been treated according to the Dutch guidelines, i.e., the less intensive regimen, in or outside the ADDITION trial, could change their therapy to the intensified treatment, and vice versa. Following that choice, the patients were not allowed to switch between the intensive and less intensive treatment during the study period. The decision aid was used again during the 12 months follow-up visit, providing the patient the possibility to change treatment priorities. After the last visit at 24 months follow-up, patients could change treatment intensity and re-evaluate their priorities.

Patients in the control group received treatment-as-before, as they were used to in or outside the ADDITION study.

2.4. Outcome measures

The GPs' and patients' perceived levels of SDM were measured at baseline and at 24-months follow-up, using the validated Dutch translations of the SDM-Q-9-Doc (physician version) and SDM-Q-9 (patient version) questionnaires [17–19]. Both questionnaires include nine items to be answered on a six-point Likert-type scale, ranging from 0 (completely disagree) to 5 (completely agree) (Table 1). The total scores range from 0 to 45, with higher scores representing more perceived SDM; the questionnaire developers did not describe thresholds for poor SDM.

The perceived actual role in making the final decision at baseline and at 24-months follow-up was assessed using the modified Control Preferences Scale (CPS) [20]. The CPS consists of five role descriptions, which for the patients are the following: 1: "I made my decision alone", 2: "I made my decision alone, considering what my doctor said", 3: "I shared the decision with my doctor", 4: "My doctor decided, considering my preferences", 5: "My doctor made the decision". The role descriptions are mirrored for the GP. A score of 3 may be considered as describing a shared decision-making process. The modified patient-version of the CPS has shown good reliability and validity [21]. Participants (GPs and patients) were asked to complete a paper-based questionnaire after their first and last visit, and were given a return envelope. Participants in both groups will be asked to complete and return the following questionnaires at baseline and after 24 months at home.

Observed SDM was assessed using the OPTION5. The OPTION 5-item observation measure is a coding scheme of how much SDM occurred from an observer's perspective. Independent observers rate recordings of actual consultations using the 5 items, scored on a zero (no effort made by clinician to involve the patient) to four (exemplary effort) scale. Item scores are added and higher total scores imply higher total imply higher degrees of SDM. Total scores range from 0 to 20 [22]. Two independent observers (one psychologist and one GP, both experienced in assessing audiotapes of GP consultations on SDM) applied the scheme directly to the audiotapes. For that purpose, GPs were asked to audiotape one first consultation with a self-selected participant.

2.5. Statistical analyses

Descriptive statistics (means, standard deviations) were used to report patient characteristics, GP and patient scores on the questionnaires, and OPTION5 scores, per practice. The median with interquartile range was reported for HbA1c, total cholesterol and LDL-cholesterol, as a normal distribution could not be confirmed. We defined low, medium and high education levels as having completed only elementary school, secondary education, and university (of applied sciences), respectively. We evaluated the differences in levels and correlation of perceived SDM (SDM-Q-9) and decisional roles (CPS) between GPs and patients who completed the intervention, both at baseline and at 24 months follow-up, using paired t-tests. This same approach was used to evaluate the differences in levels and correlation of perceived levels of SDM (SDM-Q-9) and decisional roles (CPS) between baseline and follow-up for GPs and patients. The differences between the drop-outs and completers

Table 2
Mean (SD) item scores on the SDM-Q-9 (patients[a]) and SDM-Q-Doc (GPs) at baseline and 24-months follow-up.

	Item	Baseline (n=46)	Follow-up (n=46)
1.	**My doctor made clear that a decision needs to be made.**	3.2 (1.9)	2.6 (2.0)
	I made clear to my patient that a decision needs to be made.	3.8 (1.2)	3.7 (1.1)
2.	**My doctor wanted to know exactly how I want to be involved in making the decision.**	3.6 (1.6)	3.0 (2.0)
	I wanted to know exactly from my patient how he/she wants to be involved in making the decision.	3.7 (0.9)	3.5 (1.1)
3.	**My doctor told me that there are different options for treating my medical condition.**	3.8 (1.6)	2.8 (1.9)
	I told my patient that there are different options for treating his/her medical condition.	3.7 (1.0)	3.7 (1.1)
4.	**My doctor precisely explained the advantages and disadvantages of the treatment options.**	4.3 (1.2)	2.7 (2.0)
	I precisely explained the advantages and disadvantages of the treatment options to my patient.	3.6 (1.1)	3.6 (1.1)
5.	**My doctor helped me understand all the information.**	4.3 (1.2)	3.4 (1.9)
	I helped my patient understand all the information.	4.0 (0.8)	4.0 (1.0)
6.	**My doctor asked me which option I prefer.**	4.4 (1.2)	3.3 (2.3)
	I asked my patient which treatment option he/she prefers.	4.1 (1.0)	4.0 (1.0)
7.	**My doctor and I thoroughly weighted the different treatment options.**	4.3 (1.2)	2.9 (2.0)
	My patient and I thoroughly weighed the different treatment options.	3.7 (0.9)	3.4 (1.1)
8.	**My doctor and I selected a treatment option together.**	4.2 (1.3)	3.3 (2.2)
	My patient and I selected a treatment option together.	4.0 (1.0)	3.6 (1.1)
9.	**My doctor and I reached an agreement in how to proceed.**	4.4 (1.2)	3.2 (2.0)
	My patient and I reached an agreement on how to proceed.	4.1 (0.8)	3.9 (1.1)
Total		36.6 (9.9)	28.6 (14.2)
		34.3 (7.0)	32.8 (8.3)

* Patient items and scores are shown in grey shading
[a] Patient items and scores are shown in grey shading.

were evaluated with the independent samples t-test.

3. Results

At 24 months follow-up, 23 out of 72 patients had dropped out of the study and three patients had incomplete data (Fig. 1). At baseline, the average age of the intervention participants with T2DM was 71 (SD 5.6) years. At baseline, the 23 drop-outs did not significantly differ in age (72 (SD 5.5) vs 70 (SD 5.5) years, $p = 0.10$) or self-reported SDM score (31.7 (SD 12.5) versus 36.6 (SD 9.8), ($p = 0.08$)) compared to completers. Significantly more women (65%) than men dropped out of the study ($p = 0.02$).

The mean item scores on the SDM-Q-9 and SDM-Q-Doc questionnaires are summarised in Table 2. The differences between baseline and follow-up scores appear to be more substantial in patients compared to GPs, with a maximum reduction of 1.6 in patients (item 4) and a maximum reduction of 0.4 in GPs (item 8).

The mean scores on the SDM-Q-9, SDM-Q-Doc and CPS questionnaires are summarised in Table 3.

At baseline, GPs' and patients' perceptions of SDM levels did not significantly differ: the mean difference was 2.3 ($p = 0.24$, Table 4). At 24-months follow-up, the perceived SDM level was lower in patients compared to GPs (−4.6; $p = 0.07$). In patients, it had decreased significantly and was −7.9 lower ($p < 0.01$) than at baseline, whereas the GPs' perceived level of SDM remained more or less unchanged (difference of −1.3 ($p = 0.34$)) at 24-months follow-up. There was no significant correlation between initial and follow-up scores.

After both visits, the mean CPS score differed significantly between patients and GPs, with −1.3 ($p < 0.01$) at baseline and −0.6 ($p = 0.05$) at 24 months follow-up (Table 4). At 24-months follow-up, the patients' CPS score had increased with 0.7 ($p = 0.04$), whereas GPs' CPS scores decreased with on average −0.6 ($p = 0.11$). There was no significant correlation between initial and follow-up scores.

Nine GPs audiotaped a consultation. The mean OPTION5 score was 16.6. Three practices had a score of 20 after consensus and one practice scored below 10 after consensus. The practice with the lowest OPTION5 score did not have the lowest score on the questionnaires among the tested practices (Table 3).

4. Discussion

This study shows that GPs and patients did not significantly differ in

Table 3
Mean scores (SD) of SDM-Q-9, OPTION-5 and CPS of patients (completers) and GPs per practice in the intervention group. Patient scores are on the upper line, physician scores on the lower line.

GP (number of patients)	First visit			Follow-up	
	SDM-Q-9 (t = 0)	CPS (t = 0)	OPTION-5[a]	SDM-Q-9 (t = 24)	CPS (t = 24)
1 (n = 4)	35.8 (5.6)	n.d.	n.d.	20.0 (11.9)	2.3 (1.0)
	39.0 (2.2)	n.d.		32.5 (4.5)	3.3 (1.0)
2 (n = 1)	43.0 (n = 1)	1.0 (n = 1)	n.d.	18.0 (n = 1)	3.0 (n = 1)
	25.0 (n = 1)	5.0 (n = 1)		24.0 (n = 1)	4.0 (n = 1)
3 (n = 1)	27.0 (n = 1)	4.0 (n = 1)	n.d.	32.0 (n = 1)	4.0 (n = 1)
	33.0 (n = 1)	5.0 (n = 1)		35.0 (n = 1)	2.0 (n = 1)
4 (n = 5)	38.8 (6.1)	2.2 (0.8)	15	22.6 (13.5)	3.0 (0.7)
	33.4 (3.9)	4.2 (0.4)	16 (16)	32.3 (2.0)	1.0 (n = 1)
5 (n = 4)	29.0 (25.1)	3.0 (1.6)	6	22.3 (17.9)	3.0 (0.8)
	33.5 (13.3)	3.0 (0.0)	9 (9)	26.3 (6.2)	3.0 (1.4)
6 (n = 3)	40.0 (3.5)	1.7 (1.2)	20	39.7 (4.6)	2.7 (0.6)
	39.3 (6.4)	5.0 (0.0)	20 (20)	43.0 (1.0)	3.0 (0.0)
7 (n = 1)	35.0 (n = 1)	2.0 (n = 1)	n.d.	26.0 (n = 1)	4.0 (n = 1)
	36.0 (n = 1)	4.0 (n = 1)		33.0 (n = 1)	4.0 (n = 1)
8 (n = 3)	38.7 (7.6)	2.0 (1.0)	n.d.	22.0 (16.6)	3.7 (1.2)
	34.7 (6.1)	3.7 (1.5)		26.7 (1.5)	3.0 (1.4)
9 (n = 2)	41.5 (0.7)	n.d.	18	40.0 (2.8)	3.0 (0.0)
	35.0 (1.4)	n.d.	19 (19)	18.0 (25.5)	4.0(1.4)
10 (n = 4)	25.8 (19.0)	1.0 (0.0)	18	35.8 (14.6)	2.5 (1.0)
	31.5 (1.3)	3.0 (0.0)	18 (18)	41.3 (0.5)	3.0 (0.0)
11 (n = 1)	40.0 (n = 1)	n.d.	n.d.	38.0 (n = 1)	2.0 (n = 1)
	36.0 (n = 1)	n.d.		36.0 (n = 1)	4.0 (n = 1)
12 (n = 1)	40.0 (n = 1)	n.d.	n.d.	29.0 (n = 1)	2.0 (n = 1)
	34.0 (n = 1)	n.d.		41.0 (n = 1)	5.0 (n = 1)
13 (n = 3)	41.0 (6.1)	3.0 (n = 1)	n.d.	22.3 (22.5)	2.7 (0.6)
	35.7 (0.6)	3.0 (n = 1)		28.0 (1.7)	3.0 (0.0)
14 (n = 2)	36.5 (3.5)	2.0 (1.4)	15	36.0 (4.2)	2.0 (n = 1)
	26.5 (2.1)	2.5 (2.1)	16 (16)	30.5 (4.9)	2.0 (n = 1)
15 (n = 1)	44.0 (n = 1)	n.d.	20	41.0 (n = 1)	3.0 (n = 1)
	37.0 (n = 1)	n.d.	20 (20)	n.d.	n.d.
16 (n = 1)	31.0 (n = 1)	n.d.	20	45.0 (n = 1)	2.0 (n = 1)
	9.0 (n = 1)	n.d.	20 (20)	23.0 (n = 1)	3.0 (n = 1)
17 (n = 4)	43.0 (2.4)	2.8 (1.3)	n.d.	37.3 (8.1)	3.0 (n = 1)
	31.8 (1.5)	2.5 (0.6)		31.5 (2.1)	3.3 (0.6)
18 (n = 5)	34.2 (7.3)	n.d.	10	21.8 (19.1)	2.3 (1.2)
	41.0 (5.6)	n.d.	9 (11)	41.4 (3.0)	3.3 (0.6)
Total	36.6 (9.9)	2.3 (1.2)	16.6 (1.4)	28.6 (14.2)	2.8 (0.8)
	34.3 (7.0)	3.6 (1.1)		32.8 (8.3)	3.2 (1.0)
Missing/ invalid	n = 3[b]	n = 19	n.a.	n = 4[b]	n = 6
	n = 0	n = 19		n = 3	n = 14

n.d. = Not determined, n.a. = not applicable.

[a] Values of two independent observers, the value after consensus between both observers is indicated between brackets. Mean of the total was calculated from the consensus values.

[b] Three patients did not respond at the first visit and another four people did not respond after follow-up.

how much SDM they perceived during the first visit, when they first used the decision aid. However, patients experienced their role in making the final decision to be significantly more shared, while GPs experienced their own role to be more important. Regardless, we can conclude that both GPs and patients perceived to have shared the decision about treatment intensity, at the time they first used the decision aid. In contrast, patients perceived significantly less SDM during the follow-up visit 24 months later, while the GPs perceived the same level of SDM as during the first visit.

At first sight, perceived decisional roles and perceived levels of SDM seem contradictory: both patients' and GPs' experienced roles in making the final decision about treatment intensity during the 24 months' follow-up visit were almost identical and had both shifted significantly towards a shared decision [21]. However, decisional roles were not recorded for all the patients and GPs: the decisional roles were self-reported after the consultation, while perceived levels of SDM were assessed during the consultation. This may have led to self-report bias in the reported decisional roles.

Looking at the specific aspects of the decision-making process, differences between the consultation in which the decision aid was first used and the 24 months' months follow-up visit became apparent. In particular, GPs reported the largest reduction with regard to selecting the treatment option together. Possibly, the GPs' role became more important in the decision-making process during the intervention, which contradicts the reported decisional role. Patients reported to have been less informed by their GP during the follow-up visit. Taken together, these results suggest that GPs made less effort to explain the options well and to decide on the best treatment option together with the patient during follow-up. On the other hand it might be speculated that because a high degree of SDM took place at baseline, there was less need for a SDM discussion at follow-up. It is known that GPs perceive barriers to implement SDM consequently in daily practice [22–24]. Against this background, it would be valuable to study the effect of repeated SDM training on sustaining high levels of SDM.

Similar to a previous study, the participating GPs in the current study experienced their own role in the SDM process to be quite important [22]; they tended to limit SDM to only discussing treatment options and paid considerably less attention to other key elements of the SDM process. It appears that GPs should be more specifically trained to pay attention to other elements of the SDM process, in order to achieve a truly shared decisions with their patients. Patients' experiences at follow-up indicate the relevance of increasing GPs' awareness about what a shared decision making process entails, and how to involve patients actively in it.

A number of limitations of the study should be noted. Overall, the number of participants was low. This decreases the changes of finding subtle differences between baseline and follow-up. Additionally, there was a high number of drop-outs, but they did not significantly differ in perceived levels of SDM at baseline compared to the completers. Perhaps the drop-outs lost their interest in the study because they already felt well-involved in making the treatment decision [25], did not believe their decision making could be improved, or did not have the time/-motivation to fill in the questionnaires. Furthermore, the OPTION5 scores are based on recordings of a self-selected consultation. Since this is susceptible to reporting bias, the OPTION5 scores are only reported and not discussed.

In conclusion, patients with T2DM and GPs perceived similar and high levels of SDM at the time they first went through the decision aid and made a decision about treatment intensity, which also was shortly after the GPs had received SDM training. Twenty-four months later, GPs perceived similarly high levels of SDM while patients perceived significantly less SDM. These results suggest that if the intervention was effective in helping achieve SDM shortly after GPs had been trained, boost sessions seem necessary to consolidate and understand key SDM elements and truly incorporate them into routine clinical practice.

Table 4
Paired t-test means (SD) of SDM-Q-9 and CPS in the intervention group, patient scores are on the upper line, physician scores on the lower line.

Pair	SDM-Q-9			CPS		
	First visit	24 months follow-up	Mean difference (95%CI, p-value)	First visit	24 months follow-up	Mean difference (95%CI, p-value)
Patient t = 0 vs patient t = 24	36.6 (9.9, n = 45)	28.6 (14.3, n = 45)	−7.9 (−3.8 to −12.0, p < 0.01)	2.3 (1.1, n = 23)	3.0 (0.9, n = 23)	0.7 (0.1–1.4, p = 0.04)
Doctor t = 0 vs doctor t = 24	34.1 (7.2, n = 44)	32.8 (8.3, n = 44)	−1.3 (−4.1 to 1.4, p = 0.34)	3.6 (1.1, n = 18)	2.9 (1.0, n = 18)	−0.6 (−1.4 to 0.2, p = 0.11)
Patient t = 0 vs doctor t = 0	36.6 (9.9, n = 45) 34.2 (7.1, n = 45)		2.3 (−1.6 to 6.2, p = 0.24)	2.3 (1.2, n = 27) 3.6 (1.1, n = 27)		1.3 (2.1–0.6, p < 0.01)
Patient t = 24 vs doctor t = 24		28.2 (14.4, n = 44) 32.8 (8.3, n = 44)	−4.6 (−9.6 to 0.4, p = 0.07)		2.7 (0.9, n = 28) 3.3 (1.0, n = 28)	0.6 (1.1–0.0, p = 0.05)

Conflict of interest

None.

Acknowledgments

The study was funded by a charitable foundation (Nuts OHRA) and no funding assistance was received from a commercial organization. The funding body has not any role in design, in the collection, analysis, and interpretation of data; in the writing of the manuscript; and in the decision to submit the manuscript for publication.

References

[1] S.I. Inzucchi, R.M. Bergenstal, J.B. Buse, M. Diamant, E. Ferrannini, D.R. Matthews, et al., Management of hyperglycemia in type 2 diabetes: a patient-centered approach: position statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD), Diabetes Care 35 (6) (2012) 1364–1379.
[2] M.J. Wilkinson, A.G. Nathan, E.S. Huang, Personalized decision support in type 2 diabetes mellitus: current evidence and future directions, Curr. Diab. Rep. 13 (2) (2013) 205–212.
[3] M.J. Davies, D.A. D'Allesio, J. Fradkin, W.N. Kernan, J.B. Buse, et al., Management of hyperglycemia in type 2 diabetes, 2018. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD), Diabetes Care 41 (12) (2018).
[4] J.M. Bae, Shared decision making: relevant concepts and facilitating strategies, Epidemiol. Health 39 (2017).
[5] H. Bomhof-Roordink, F.R. Gartner, A.M. Stiggelbout, A.H. Pieterse, Key components of shared decision making models: a systematic review, BMJ Open 9 (12) (2019).
[6] F. Legare, N. Moujiad-Ferdjaoui, R. Drolet, D. Stacey, H. Bastion, R. Thomson, et al., Core competencies for shared decision making training programs: insights from an international, interdisciplinary working group, J. Contin. Educ. Health Prof. 33 (4) (2013) 267–273, https://doi.org/10.1002/chp.21197.
[7] V. Coronado-Vasquez, C. Canet, M.T. Fajas Delgado-Morroquin, J. Gomez-Salgado, et al., Interventions to facilitate shared decision-making using decision aids with patients in Primary Health Care: a systematic review, Medicine (Baltimore) 99 (32) (2020).
[8] D. Stacey, F. Legare, N.E.K. Lewis, M.J. Barry, C.L. Bennet, L. Trevena, et al., Decision aids for people facing health treatment or screening decisions, Cochrane Database Syst. Rev. 12 (4) (2017).
[9] T. Agoristas, A.F. Heen, L. Brandt, P. Alonso-Coella, E.A. Akl, P.O. Vandvik, et al., Decision aids that really promote shared decision making: the pace quickens, BMJ 350 (2015) g7624.
[10] C. Charles, A. Gafni, T. Whelan, SDM in the medical encounter: what does it mean? (or it takes at least two to tango), Soc. Sci. Med. 44 (5) (1997) 681–692.
[11] V.M. Montori, A. Gafni, C. Charles, A shared treatment decision-making approach between patients with chronic conditions and their clinicians: the case of diabetes, Health Expect. 9 (1) (2006) 25–36.
[12] M.J. Davies, D.A. D'Alessio, J. Fradkin, W.N. Kernan, C. Mathieu, J.B. Buse, et al., Management of hyperglycemia in type 2 diabetes, 2018 a consensus report by the American Diabetic Association (ADA) and the European Association for the Study of Diabetes (EASD), Diabetes Care 41 (12) (2018) 2669–2701.
[13] H. den Ouden, R.C. Vos, C. Reidsma, G.E.H.M. Rutten, Shared decision making in type 2 diabetes with a support decision tool that takes into account clinical factors, the intensity of treatment and patient preferences: design of a cluster randomised (OPTIMAL) trial, BMC Fam. Pract. 16 (2015) 27.
[14] H. den Ouden, R.C. Vos, G.E.H.M. Rutten, Effectiveness of shared goal setting and decision-making to achieve treatment targets in patients with type 2 diabetes. A cluster randomised trial (OPTIMAL), Health Expect. 20 (5) (2017) 1172–1180.
[15] International Patient Decision Aids Standards Collaboration, Criteria for Judging the Quality of Patient Decision Aids, 2005. www.ipdas.ohri.ca/IPDAS_checklist.pdf.
[16] S.J. Griffin, K. Borch-Johnsen, M.J. Davies, K. Khunti, G.E.H.M. Rutten, T. Lauritzen, et al., Effect of early intensive multifactorial therapy on 5-year cardiovascular outcomes in individuals with type 2 diabetes detected by screening (ADDITION-Europe): a cluster-randomised trial, Lancet. 378 (9786) (2011) 156–167.
[17] S. Rodenburg-Vandenbussche, A.H. Pieterse, P.M. Kroonenberg, I. Scholl, T. van der Weijden, A.M. Stiggelbout, Dutch translation and psychometric testing of the 9-item shared decision making questionnaire (SDM-Q-9) and shared decision making questionnaire- physician version (SDM-Q-Doc) in primary and secondary care, PLoS One 10 (7) (2015).
[18] L. Kriston, I. Scholl, L. Holzel, D. Simon, A. Loh, M. Harter, The 9-item Shared Decision Making Questionnaire (SDM-Q-9). Development and psychometric properties in a primary care sample, Patient Educ. Couns. 80 (1) (2010) 94–99.
[19] I. Scholl, L. Kriston, J. Dirmaier, A. Buchholz, M. Härter, Development and psychometric properties of the Shared Decision Making Questionnaire—physician version (SDM-Q-Doc), Patient Educ. Couns. 88 (2012) 284–290.
[20] L.F. Degner, J.A. Sloan, P. Venkatesh, The control preference scale, Can. J. Nurs. Res. 29 (3) (1997) 21–43.
[21] J. Kasper, C. Heesen, S. Kopke, G. Fulcher, F. Geiger, Patients' and observers' perceptions of involvement differ. Validation study on inter-relating measures for shared decision making, PLoS One 6 (10) (2011).
[22] E.M. Driver, A.M. Stiggelbout, P.L.P. Brand, Shared decision making: physicians' preferred role, usual role and their perception of its key components, Patient Educ. Couns. 103 (2020) 77–82.
[23] A. Alsulamy, A.C.K. Lee, P. Thokala, T. Alessa, What influences the implementation of shared decision making: an umbrella review, Patient Educ. Couns. 103 (12) (2020).
[24] R.E. Pel-Little, M. Snaterse, N.M. Teppich, B.M. Buurman, F.S. Van Etten-Jamaluda, W.J.M. Scholte op Reimer, et al., Barriers and facilitators for shared decision making in older patients with multiple chronic conditions: a systematic review, BMC Geriatr. 21 (112) (2021).
[25] H. Doherr, E. Christalle, L. Kriston, M. Harter, I. Scholl, Use of the 9-item shared Decision Making Questionnaire (SDM-Q-9 and SDM-Q-Doc) in intervention studies — a systematic review, PLoS One 12 (3) (2017).