Data supplement

S1 Study procedure and registration

Practices were either allocated to the ISDM-P or to standard intervention (control). A research associate of the Jena University Hospital (NK) explained documentation forms and gave instructions to the control group. The intervention groups were trained for the ISDM-P by a research fellow (SB) and a psychologist (KL) of the University of Hamburg.

Patients received diabetes information material from their practices: an evidence-based patient decision aid for the ISDM-P group, and an extract of the German National Disease Management Guideline for the control group.

For ISDM-P patients, an appointment for the group teaching was made within 2 to 4 weeks after receiving the decision aid. Some practices provided a teaching session in the evening for patients with a full-time job or who were often away for work. When an appointment failed, a new one was made. At the end of the teaching session, patients documented their preferences on treatment goals regarding statin uptake, smoking cessation, systolic blood pressure level and HbA1c values on the documentation sheet. In addition, they were asked to document their personally most important treatment goal. Within one week after the teaching session, patients had a consultation with their GP to discuss their preferences, using the documentation sheet. As a result, the GP documented the goals they agreed on in the same documentation sheet (in a column next to the column where the patient had already documented his or her goals). In case of any deviation from the patient's goals, reasons were documented on the same sheet. Patients kept the original sheet; one copy was stored in the patient record at the practice, and another copy in the study folder.

At six months follow-up, the primary endpoint was assessed.

The study was approved by the ethics committee of the Medical Association of Thuringia in April 2014. In December 2014, the first family practice was enrolled in the study, and the first patient was enrolled in December 2014. The study was submitted to registration in February 2015 (ISRCTN77300204). The detailed study protocol was published in March 2015 [1]. In order to avoid time constraints, recruitment of practices was started earlier. This had no influence on study results, as practices were randomised after registration and publication of

the study protocol. Randomisation of the first 12 clusters was performed in June 2015. Therefore, all practices and patients were randomised after study registration and well after publication of the study protocol.

Deviations from the protocol

In our study protocol, adequate knowledge was defined as a score above the median. For the cluster RCT, however, the cut-off that was predefined for the proof-of-concept RCT (e.g., having at least 8 correctly answered questions, out of 11) was used. We additionally calculated adequate knowledge according to the protocol. Results were consistent with the cut-off used in the RCT; significantly more ISDM-P patients had adequate risk knowledge than those in the control group (71% versus 8%; p <0.001).

It was planned to use Fisher's exact test to compare the groups in case of binary outcomes. However, this univariate comparison does not account for cluster effects in the trial. Therefore, generalised mixed models were fitted, with intervention as a fixed effect, and practices as a random effect. For the same reason, linear mixed models were used rather than unpaired *t*-tests, which had been planned in the study protocol.

The title of this publication slightly differs from the title of the protocol ("An informed shared decision making programme on the prevention of myocardial infarction for patients with type 2 diabetes in primary care: protocol of a cluster randomised, controlled trial"). Our intervention is about more than just prevention of myocardial infarction. It also includes information about other diabetes related complications. Therefore, the current and correct title is "An informed shared decision making programme for patients with type 2 diabetes in primary care: cluster randomised controlled trial".

S2 Intervention characteristics

Components	ISDM-P	Control intervention
Training for the providers	Participants: 4 to 6 GPs, plus the MA(s) employed in the participating practices	Not offered
	Duration: approx. six hours	
	Elements: curriculum for teaching sessions, concept of SDM for GPs and MAs together; Didactic lectures and role playing for GPs and MAs separately	
Information for patients	Topic: DA on the prevention of myocardial infarction in type 2 diabetes [2]	Topic: Brief extract of the German National Disease Management Guideline on the treatment of patients with type 2 diabetes, patients' version [3]
	Date of delivery: 2 to 4 weeks before teaching session	Date of delivery: 2 to 4 weeks before practice visit
	Core elements: Evidence-based patient information on heart attack risk, risk factors and different preventive options; combinations of 100 stick-figure pictograms and bar graphs; and user guide for risk estimation	Core elements: Recommendations related to treatment targets and a link to the full version of the guideline [3]
Patient teaching module	Participants: 4 to 6 patients per group	Not offered
	Duration: 90 minutes	
	Core elements: DA on the prevention of myocardial infarction and diabetes related complications [2], corresponding curriculum and media, provided by trained MAs	

Consultation with GP	Duration: approx. 10 minutes	Optional standard consultation with physician
	Core elements: patient-held sheet for the documentation of individual treatment goals; ISDM-P consultation guideline to structure the conversation	

Adapted from the study protocol [1]
ISDM-P = Informed Shared Decision Making Programme; GPs = general practitioners; MA = medical assistant; SDM = shared decision making; DA = decision aid

S3 patient-held sheet for documentation of treatment goals.

Date: ___ / ____ / ____

My treatment goals

		Please fill in after the teaching session ☺	**Treatment agreement** Completed by GP during encounter
Statins	**Uptake**	☐	☐
	No statins	☐	☐
Smoking	**Quit smoking**	☐	☐
	Continue smoking	☐	☐
	Non-smoker	☐	
Blood glucose	**HbA1c-level**	**_____ %**	_____ %
Blood pressure	**Systolic blood pressure**	**_____ mmHg**	_____ mmHg

What option is most important to you?

(Please check one only)

• **Statin intake**	☐	☐
• **Smoking cessation**	☐	☐
• **Achievement of HbA1c goal**	☐	☐
• **Achievement of blood pressure goal**	☐	☐

Comment if goals deviate from patient's goals (completed by GP)

S4 Risk knowledge and realistic expectations after intervention.

Outcome	ISDM-P group (n = 136)	Control group (n = 109)	adjusted difference [95% CI]; P value	MI: adjusted difference [95% CI]; *p* value	ICC
Risk knowledge (primary endpoint) (score 0–11)	6.96 (2.55)	2.86 (1.87)	4.06 [2.96 to 5.17]; <0.001	3.7 [2.7 to 4.8]; <0.001	0.208
Realistic expectations (score 0–5)	3.09 (1.45)	0.92 (1.01)	2.18 [1.67 to 2.69]; <0.001	2.0 [1.5 to 2.5]; <0.001	0.108

Values are given as means (standard deviation); CI = confidence interval; ICC = intracluster coefficient; ISDM-P = Informed Shared Decision Making Programme; MI = multiple imputation (n = 279)

S5 Patients' estimation of individual heart attack risk after intervention

Heart attack risk	ISDM-P group	Control group	Adjusted OR [95% CI]; *p* value
Correct estimation	87/131 (66.4)	13/96 (13.5)	12.69 [5.47 to 29.39]; <0.001
Overestimation	26/131 (19.8)	79/96 (82.3)	0.05 [0.03 to 0.11]; <0.001
Underestimation	18/131 (13.7)	10/96 (4.2)	2.79 [1.01 to 7.74]; <0.001

Values are given as patient number (percentage); CI = confidence interval; ISDM-P = Informed Shared Decision Making Programme; OR = odds ratio

S6 Calculated risk and patients' estimated risk of myocardial infarction

	ISDM-P group	Control group
Calculated risk of myocardial infarction	11.9% (4.2)	11.5% (4.6)
Patients' estimated risk	14.5% (11.8)	41.6% (26.2)

Values are given as mean (standard deviation); ISDM-P = Informed Shared Decision Making Programme

S7 Achievement of treatment goals at 6 months of follow-up.

Outcome	ISDM-P	Control intervention	Adjusted OR [95% CI]; *p* value	MI: adjusted OR [95% CI]; *p* value
Statins	109/127 (85.8)	87/100 (87.0)	0.9 [0.3 to 2.7]; 0.899	0.95 [0.4 to 2.5]; 0.921
Blood pressure[a]	119/127 (93.7)	99/110 (90)	1.6 [0.5 to 5.3]; 0.476	0.8 [0.3 to 2.2]; 0.683
HbA1c[a]	126/133 (94.7)	98/110 (89.1)	2.1 [0.7 to 6.6]; 0.201	1.2 [0.4 to 3.6]; 0.792
Smoking	8/22 (36.4)	4/13 (30.8)	1.4 [0.3 to 6.8]; 0.688	1.4 [0.2 to 8.1]; 0.736

Values are given as patient number (percentage); CI = confidence interval; ISDM-P = Informed Shared Decision Making Programme; HbA1c = glycated hemoglobin; MI = multiple imputation (n = 279); OR = odds ratio
[a]Achievement was defined as having reached a value between 80% and 120% of the defined goal

S8 Patients' prioritised treatment goals

Prioritised goal	ISDM-P n = 135	Control n = 113	Adjusted OR [95% CI]; *p* value
Blood pressure control	38 (28.1)	14 (12.4)	3.0 [1.2 to 7.3]; 0.015
Glucose control	59 (43.7)	54 (47.8)	0.8 [0.4 to 1.7]; 0.529
Statins	6 (4.4)	9 (8.0)	0.5 [0.1 to 2.1]; 0.336
Stop smoking	9 (6.7)	4 (3.5)	1.5 [0.5 to 4.4]; 0.451
No prioritisation	23 (17.0)	32 (28.3)	0.5 [0.2 to 1.3]; 0.150

Values are given as patient number (percentage); CI = confidence interval; ISDM-P = Informed Shared Decision Making Programme; OR = odds ratio

S9 Process evaluation

The implementation success of the ISDM-P may depend on the complex interactions between components and terms and conditions of the setting. Based on the framework by Grant et al. [4], underlying processes involving clusters and patients were monitored to explore barriers and to promote factors in implementing the ISDM-P.

1. Processes involving clusters (primary care practices)

Baseline characteristics of clusters (practices)

	ISDM	**Control**
Primary care practices	n = 11	n = 11
Mean number of general practitioners (GPs) in each practice (SD)	1.9 (0.9)	1.9 (1.2)
Mean number of medical assistants (MAs) in each practice (SD)	3.4 (1.5)	2.9 (1.5)
MAs	n = 12	n = 12
Mean age, years (SD)	42.1 (8.8)	40.3 (10.8)
Female sex	12	10
Weekly working time, hours (SD)	33.2 (8.9)	33.3 (12.0)
Years of professional experience, mean (SD)	15.8 (9.2)	13.8 (9.0)
Physicians	n = 12	n = 12
Mean age (SD)	42.9 (5.9)	50.2 (6.5)
Female sex	7	8

Recruitment of clusters	
Recruitment of practices	Facilitators: Most practices that agreed to participate in our study had previously attended a special training course at the Jena University Hospital in order to provide the DMP structured treatment and teaching programme for patients with type 2 diabetes, which is covered by health insurances. Barriers: Only 22 of 307 practices that were invited gave informed consent. The main reason for not participating was that healthcare teams did not offer DMP patient teaching modules, even though this has been defined as an essential part of diabetes care. Patients are usually sent to specialised diabetes practices that provide patient teaching. The ISDM-P addresses the entire practice team. As treatment goals to be negotiated and defined in the teaching sessions are further discussed in the consultation with the GP, outsourcing the teaching module might not work in this disconnected concept.
Delivery to clusters (practice teams)	
Intervention, intervention delivery as intended	Facilitators: Training for providers and the corresponding material were pre-tested and optimised with GPs and diabetes educators of the Jena University Hospital, Germany. All ISDM-P trainings (n = 6) were performed by the same research fellow (SB) and a psychologist (KL). The training sessions took place at the Jena University Hospital following a structured curriculum and protocol. All trainings were conducted according to the curriculum and protocol. Role playing was used to train ISDM skills and to ensure that the team was well prepared for the teaching session and the consultation. MAs are familiar with role playing

	from former trainings for the DMP structured teaching programme. The role play took less time than expected. Therefore, duration of the training was reduced from six hours to four or five hours. A reason for that was a small group size in all trainings. Participants appreciated time saving. Barriers: It was difficult to arrange a mutual training appointment for some practices because the time to recruit all patients for the study varied between the practices. Hence, three practice teams were trained individually. In two instances, two or four practice teams were trained together. One team (of one GP and one MA) was trained at the practice site. The GP and MA declined role playing. It was therefore impossible to check if they were adequately prepared to provide the ISDM-P.
Response of clusters	
Knowledge and comprehension	Facilitators: Role playing and question cards During training, problems were discussed within the groups. At the end of the training, MAs answered the question cards that were also used in the patient teaching session. Incorrect answers were corrected and explained. MAs stated that they felt well prepared for the ISDM-P teaching module. We did not directly assess MAs' and GPs' knowledge of the probabilities of benefits and harms of preventive options regarding diabetes-related complications after the training. However, ISDM-P patients' high level of knowledge and realistic expectations indicated that MAs had sufficient skills to provide risk

	information to patients in an understandable manner. Barriers: The MA who declined role playing mentioned some trouble with explaining benefits of statin intake during one patient teaching session. She felt that patients were not motivated anymore to follow the teaching session. We did not directly assess MAs' and GPs' knowledge.

2. Processes involving patients with type 2 diabetes

Recruitment and reach in individuals	
Recruitment procedure	Facilitators: A research associate explained and handed over a guide to GPs and MAs on how to recruit patients and collect baseline data. Supported by the research associate, MAs or GPs of each practice screened the patient records for eligibility. All patients who met inclusion criteria were informed about the study by a letter from their GP and were invited to participate during the next consultation. In order to minimize selection bias, practices were randomised to either ISDM-P or standard care only after recruitment and assessment of baseline data. Barriers: 84 patients did not want to participate in the study. Reasons were too much effort and no interest.
Delivery to patients	
Fidelity of the ISDM-P teaching	A total of 35 teaching sessions were provided by ISDM-P practices. MAs conducted 2 to 6 sessions that

sessions provided by MAs (assessed using diary entries of each teaching session and interviews with MAs after all teaching sessions were completed)	lasted between 50 and 120 minutes. The group size varied from one patient to seven patients. Facilitators: Teaching curriculum and documentation sheet for treatment goals MAs followed the teaching curriculum and used the corresponding material. They used the curriculum to prepare for the patient teaching and to structure the session. One of the materials was a magnet board with 100 orange and blue game pieces, representing people with or without myocardial infarction, to visualize patients' risks of myocardial infarction and the benefit of statin intake. It reminded participants of a game board, and a few MAs were worried that patients may feel that they were not being taken seriously by using the board. Only a few patients did not want to use the board. Overall, it was positively accepted by participants. MAs stated that the board was helpful to explain statistics, and they wish to keep using it. A total of 135 of 136 patients who participated in the ISDM teaching session defined individual treatment goals together with their MAs and subsequently discussed them with their physicians. The patient-held sheet to document individual treatment goals was the link between the teaching session and the consultation with the GP. Barriers: A few MAs indicated that there was *"too much statistics"* to explain to patients. They were afraid to overstrain their patients. Fifteen patients did not attend the teaching session because of time constraints due to work-related issues or for other personal reasons. Not all patients had read the decision aid.

	The teaching sessions were not video-recorded.
Fidelity of the ISDM-P consultations between patients and GPs (assessed using protocol entries of GP's consultations and interviews with GPs at the end of the study)	Patients consulted their GPs directly after the teaching session or within one to three weeks afterwards. A total of 95 ISDM-P consultations were protocoled (151 patients were randomised to ISDM-P). The consultations lasted between 5 and 20 minutes (mean 11.4 minutes). Facilitators: Consultation guideline and documentation sheet for treatment goals GPs stated that they used the ISDM-P consultation guideline to structure the conversation with the patients, and they considered the guideline to be helpful and time-saving. The patient-held sheet for the documentation of individual treatment goals was used to discuss the patients' personal treatment goals and to find a consensus. GPs said that they actively involved patients in the decision making process, and that patients knew their treatment goals. One GP said that former consultations were more "*instructive, demanding, and in some ways authoritarian"*, while patients and professional teams now *"meet on an equal footing"*. Barriers: We did not video record the consultations.
Response of patients regarding the ISDM-P	
Satisfaction with the ISDM-P, knowledge level, participation in	Facilitators: MAs said that patients appreciated the opportunity to participate in the decision making process and to define their own treatment goals. GPs stated that the patients were well prepared for

decision making	decision making by their MAs, which was “better than expected” and “better than usual”. GPs mentioned differences in communication before and after the ISDM-P teaching module. During the consultations, the patients asked more questions than usual, and these were distinct and more specific than normal; e.g., they asked for risk factors as well as for benefits and harms of treatment options. One GP said that patients were more well-informed, making the consultation much easier than before. Quantitative data showed that ISDM-P patients had better knowledge and realistic expectations regarding heart attack risk and preventive options, and that they made more informed choices. Matching of prioritised treatment goals between patients and physicians was better in the ISDM-P group. Barriers: A few patients gave feedback that there was too much statistics.

3. Other

Maintenance	
Integrating the ISDM-P in routine care, workload	Facilitators: Appropriate workload MAs described the efforts of training and practicing for the teaching module as similar as for DMP patient education modules. The overall workload was perceived as appropriate. Most GPs described the workload as appropriate. They considered the intended distribution of work within the team as helpful and reduced workload.

	Barriers: Budgetary allowance Most GPs stated that they will provide the ISDM-P in routine care if it will be covered by health insurances.
Unintended consequences	
MAs: stress, anxiety, tension within the team due to overburdening	One MA did not like to work with the magnet board. No other unintended consequences were mentioned in the interviews.
GPs: stress, anxiety, tension within the team due to overburdening	No unintended consequences were mentioned in the interviews.

References

[1] Buhse S, Mühlhauser I, Kuniss N, Müller UA, Lehmann T, Liethmann K et al. An informed shared decision making programme on the prevention of myocardial infarction for patients with type 2 diabetes in primary care: protocol of a cluster randomised, controlled trial. *BMC Fam Pract* 2015;16:43.

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[3] German Medical Association, National Association of Statutory Health Insurance Physicians, Association of the Scientific Medical Societies. PatientenLeitlinie zur Nationalen VersorgungsLeitlinie „Therapie des Typ-2-Diabetes“ 2015; Available from http://www.leitlinien.de/nvl/diabetes/therapie. Accessed 19 Mar 2018 [Patient guideline in German].

[4] Grant A, Treweek S, Dreischulte T, Foy R, Guthrie B. Process evaluations for cluster-randomised trials of complex interventions: a proposed framework for design and reporting. *Trials* 2013;14:15.