BMJ Open

An informed shared decision making programme for patients with type 2 diabetes in primary care: cluster randomised controlled trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-024004
Article Type:	Research
Date Submitted by the Author:	04-May-2018
Complete List of Authors:	Buhse, Susanne; University of Hamburg, Faculty of Mathematics, Informatics and Natural Sciences, Health Sciences and Education Kuniss, Nadine; Jena University Hospital, Department of Internal Medicine III, Endocrinology and Metabolic Diseases; Diabetes Centre Thuringia Liethmann, Kathrin; University of Hamburg, Faculty of Mathematics, Informatics and Natural Sciences, Health Sciences and Education; University Medical Center Schleswig Holstein, Institute of Medical Psychology and Sociology Müller, Ulrich; Jena University Hospital, Department of Internal Medicine III, Endocrinology and Metabolic Diseases Lehmann, Thomas; Universitätsklinikum Jena, Institute of Medical statistics Mühlhauser, Ingrid; University of Hamburg, Faculty of Mathematics, Informatics and Natural Sciences, Health Sciences and Education
Keywords:	PRIMARY CARE, Diabetes Mellitus, Type 2, Decision Support Techniques, Patient Education as Topic, Health Educators, Health Knowledge, Attitudes, Practice

An informed shared decision making programme for patients with type 2 diabetes in primary care: cluster randomised controlled trial

Susanne Buhse[1], Nadine Kuniss[2,3], Kathrin Liethmann[1,4], Ulrich A Müller[2,3], Thomas Lehmann[5,] Ingrid Mühlhauser[1]

[1]Health Sciences and Education, University of Hamburg, Hamburg, Germany,

[2]Department of Internal Medicine III, Endocrinology and Metabolic Diseases, Jena University Hospital, Jena, Germany

[3]Diabetes Centre Thuringia, Jena, Germany

[4]Institute of Medical Psychology and Sociology, University Medical Center Schleswig Holstein, Kiel, Germany

[5]Centre for Clinical Studies, Jena University Hospital, Jena, Germany

Susanne Buhse, senior researcher

Nadine Kuniss, research fellow

Kathrin Liethmann, psychologist

Ulrich Alfons Müller, professor of internal medicine

Thomas Lehmann, biostatistician

Ingrid Mühlhauser, professor of health sciences and education

Corresponding author: Susanne Buhse, Email: Susanne.Buhse@uni-hamburg.de

University of Hamburg, Faculty of Mathematics, Informatics and Natural Sciences, Health Sciences and Education, Martin-Luther-King-Platz 6, 20146 Hamburg

Word count of main text: 4230 words

Keywords

Diabetes Mellitus, Type 2; Decision Making; Decision Support Techniques; Patient Education as Topic; Health Knowledge, Attitudes, Practice; Evidence-Based Medicine; Hypertension; Family Practice; Health Educators; Physicians, Primary Care

Abstract

Objective To translate an informed shared decision making programme (ISDM-P) for patients with type 2 diabetes from a specialized diabetes centre to the primary care setting.

Design Patient-blinded, two-arm multicentre, cluster RCT of 6 months follow-up; concealed randomisation of practices after patient recruitment and acquisition of baseline data.

Setting 22 general practices providing care according to the German Disease Management Programme (DMP) for type 2 diabetes.

Participants 279 of 363 eligible patients without myocardial infarction or stroke.

Interventions The ISDM-P comprises a patient decision aid, a corresponding group teaching session provided by medical assistants and a structured patient-physician encounter. Control group received standard DMP care.

Primary and secondary outcome measures Primary endpoint was patient adherence to antihypertensive or statin drug therapy by comparing prescriptions and patient-reported uptake after 6 months. Secondary endpoints included informed choice, risk knowledge (score 0 to 11 from 11 questions) and prioritised treatment goals of patients and doctors.

Results ISDM-P: 11 practices with 151 patients; standard care: 11 practices with 128 patients; attrition rate: 3.9%. There was no difference between groups regarding the primary endpoint. Mean drug adherence rates were high for both groups (80% for antihypertensive and 91% for statin treatment). More ISDM-P patients made informed choices regarding statin intake, 34% vs 3%, Odds Ratio [OR] 16.6 (95% CI 4.4 to 63.0), blood pressure control, 39% vs 3%, OR 22.2 (5.3 to 93.3) and HbA1c, 43% vs 3%, OR 26.0 (6.5 to 104.8). ISDM-P patients achieved higher levels of risk knowledge, with a mean score of 6.96 vs 2.86, difference 4.06 (2.96 to 5.17). In the ISDM-P group, agreement on prioritised treatment goals between patients and doctors was higher, with 88.5% vs 57%.

Conclusions Informed shared decision making is absent in standard care. The ISDM-P could be successfully implemented in general practices.

Trial registration ISRCTN77300204

Strengths and limitations of this study

- This cluster RCT followed the UK MRC framework for complex interventions and is the final step of the development and evaluation of an informed shared decision making programme (ISDM-P) for patients with type 2 diabetes.
- Efficacy of the ISDM-P was demonstrated in a former RCT under high fidelity conditions in a diabetes centre. In this cluster RCT, the ISDM-P was integrated into routine care by addressing implementation barriers.
- The cluster RCT was meticulously designed and conducted with a low drop-out rate; practices were only randomised after completion of patient recruitment and acquisition of baseline data.
- It was planned to keep the patients blinded, but it was impossible to keep the health care providers (practices) blinded.
- Since there is no gold standard to assess SDM in routine care, the patient-held sheet for personal treatment goals might be used as a surrogate indicator for SDM in diabetes care.

Introduction

Diabetes guidelines explicitly recommend shared decision making (SDM) to help patients and physicians to make informed choices and to select the treatment that best fits individual patient needs, values and preferences.[1 2] Patients increasingly want to participate in making decisions about their health, and they have the right to be involved.[3] However, SDM is not yet implemented in diabetes care[4], and a number of barriers have been identified that are hindering this.[5] While many clinicians believe that they already practice SDM, they in fact do not involve patients in treatment decision making.[5 6] Physicians are used to deciding what they consider best for their patients. Even if healthcare professionals are aware of such misconceptions about SDM, organisational structures (and mainly time constraints) are often perceived as barriers for patient involvement. Another challenge is the generally poor science literacy among health professionals and patients, and a lack of competencies for communicating and understanding risk information.[7-9] Finally, there is a paucity of evidence-based patient information material such as decision aids or drug facts boxes, which display probabilities of benefits and harms of options and are the basis for informed decision making.[10 11] There are only a few projects on decision aids and SDM in diabetes care; these address different treatment regimens,[12] statin treatment,[13-15] oral antidiabetic agents,[16 17] starting insulin injections,[18] or prevention of macro- and microvascular complications.[19] Results about efficacy or implementation are ambiguous.

We have developed an informed shared decision making programme (ISDM-P) for patients with type 2 diabetes that targets implementation barriers.[20 21] The ISDM-P comprises an evidence-based patient decision aid, a corresponding teaching session provided by specially trained medical assistants (MAs) and a structured patient-physician encounter. MAs and doctors are trained to provide risk information and to conduct consultations based on SDM principles. The ISDM-P is designed to be easily integrated in the structured treatment and teaching programme[22-25] used in the German Disease Management Programme (DMP).[26] We have compared the ISDM-P to a structurally equivalent control intervention in a proof-of-concept

randomised controlled trial at a single diabetes centre.[21] About half of the ISDM-P patients, but none of the patients in the usual care group, attained adequate risk knowledge to make informed decisions. Nonetheless, patients' treatment preferences were not adequately considered by physicians in decision making. Although physicians expressed a positive attitude towards SDM, they had not been specifically trained in SDM. Therefore, we developed additional programme components to facilitate SDM-based patient-physician consultations.[27]

In the present study, we investigated whether the results of the pilot RCT[21] could be repeated in terms of implementation conditions. The aim was to translate the optimised ISDM-P to the primary healthcare setting.

Methods

Study design and patient involvement

The study was a two-arm, multicentre cluster randomised controlled trial with six months follow-up. According to international standards for the development and evaluation of complex interventions, we additionally focused on the implementation process.[28-31] A detailed protocol has been published.[27]

In order to address patient and public involvement, patients participated in the development of the intervention material. After publication of the study we will write a plain language summary and design a leaflet for distribution to patient groups. It will also be available on the project website (www.diabetes-und-herzinfarkt.de).

Context and setting

The study took place in 21 primary care practices in East Germany (Free State of Thuringia and Saxony-Anhalt) and one in the city of Hamburg. Practices were included if they provided structured teaching and treatment according to the German DMP for type 2 diabetes.[32 33] Patient education was provided by diabetes educators or MAs with special training in diabetes

education.[34] All practices gave informed consent. A more detailed description is given in the protocol.[27]

Participants

Patients between 40 and 69 years who had been diagnosed with type 2 diabetes, had HbA1c levels of <9% and had previously participated in structured DMP teaching sessions were included. Exclusion criteria were a history of ischemic heart disease (ICD I20-I25) or stroke (ICD I63), proliferative retinopathy, chronic kidney disease stage 3 or higher or care by a legal guardian. All participants gave informed written consent.

Study recruitment

A total of 307 general practices of the study regions were informed about the project by mail (Figure). Two weeks later, the practices were called and asked whether they were interested in participating in the study. Supported by the research associate, MAs and general practitioners (GPs) of each practice screened the patient records for eligibility. Patients of the included practices were then informed about the study by a letter and invited to participate during the next consultation with their GPs. After patients who were willing to participate had given informed consent, baseline data were retrieved directly from patients and supplemented by standard data extracted from the electronic patient records.

Concealed external randomisation of practices (cluster) started only after conclusion of patient recruitment and collection of baseline data at the study centre.

The study was approved by the ethics committee of the Medical Association of Thuringia in April 2014. In December 2014, the first family practice and the first patients were enrolled. The last practice was enrolled in August 2015, and the last patient, in April 2016. The overall trial end date should have been July 2016, but as some practices required more time for patient

recruitment, data collection was completed in March 2017. Please refer to data supplement: S1 Study procedure and registration, for in depth detail of this.

Intervention

The ISDM-P comprises a number of interrelated components (data supplement S2).[27] Those components that had already been tested in the proof-of-concept RCT[21] were: 1) an evidence-based patient decision aid about the primary prevention of myocardial infarction and other diabetes-related complications [20]; 2) a structured group teaching session provided by MAs; and 3) a provider training for MAs. The additional components developed for implementation in routine care were: 4) a patient-held documentation sheet with patient-defined treatment goals, to be shared and discussed by the patient with the GP; and 5) a six-hour training to prepare GPs for consultations in terms of SDM.[27]

The ISDM-P addresses various facilitators and barriers of SDM implementation.[5 35 36] In the patient-teaching session, MAs provided evidence-based risk information and assured that the patients understood it by using question cards to identify knowledge gaps and to repeat content, if necessary. Further, they helped patients to set individual treatment goals and to document them on the patient-held sheet. The sheet ensured that individual patient set goals were discussed in the subsequent patient-physician encounter. Finally, both, patients and GPs documented their common goals on the patient-held sheet. A copy remained in the patient record. Please refer to data supplement S3 for details on the sheet – note that this has been translated from German to English.

Comparison

The control group received standard care supplemented with a brief extract of the patients' version of the German National Disease Management Guidelines on the treatment of patients with type 2 diabetes, with a link to the full version of the guideline.[37]

Outcome measures

The primary outcome measure was adherence to antihypertensive or statin therapy, operationalised as adherence to prescribed medication as documented in the patients' records at the six-month follow-up. Our hypothesis was that patients would be more adherent when they defined personal treatment goals. For more details on selection of the primary endpoint, please refer to the protocol.[27]

A blinded external study assistant conducted telephone interviews with all patients to assess the primary endpoint after 6 months. She was specifically trained by the psychologist who co-authored the study (KL) to perform the interview. A standardised interview guide was used. Patients were considered to have been adherent if their answers were consistent with the prescription documented in the patients' record.

Secondary endpoints included: 1) informed choices about statin treatment, blood pressure control, glucose control and smoking cessation; 2) risk knowledge; 3) realistic expectations about individual heart attack risks and effects of preventive options; 4) achievement and 5) prioritisation of treatment goals.[27]

The adapted multi-dimensional parameter *informed choice*[38] tests for adequate knowledge (e.g., correctly answering 8 out of 11 items of the validated questionnaire [27]) and achievement of treatment goals. A patient with adequate knowledge and who had achieved the personal treatment goal was considered as having made an informed choice. How well the treatment goals (including prioritisation of goals) of patients and GPs matched was assessed as an indicator of SDM. In addition, changes in medication prescriptions and clinical parameters, including HbA1c levels, cholesterol and blood pressure, was assessed from baseline to follow-up.

Sample size

It was assumed that 80% of patients in the ISDM-P group would adhere to prescriptions of antihypertensive and statin medication, as compared to 60% of the control group.[27] An intra-cluster correlation coefficient (ICC) of 0.03, and a mean cluster size of 13 patients, were estimated. Using estimations of 1.36 for design effect (DE), 80% power, 5% significance level and a 20% drop-out rate, the calculated sample size was 306 patients distributed over 24 practices (clusters).

Randomisation and blinding

Concealed randomisation was performed in blocks of four practices, after patient recruitment and collection of baseline data, by the Centre for Clinical Studies at the Jena University Hospital. Blinding of practices was not feasible. However, an attempt to conceal allocation for patients was made. At follow-up, patients were asked *"In your opinion, did you receive new or more-of-the-same information?"* Assessment of the primary endpoint, data entry and analyses were kept blinded against study allocation.

Statistical analysis

Statistical analyses were carried out by intention-to-treat.[27] For main endpoints, missing data was imputed using the method of multiple imputations. Therefore, an extensive set was used of baseline covariates and, when appropriate, outcome specific variables, i.e., blood pressure, age, gender, graduation status and prescribed medication.

Generalised mixed models were fitted to compare the groups with respect to rates of adherence, informed choice and individual goal achievement, with intervention as a fixed effect and practices as a random effect. Cluster-adjusted OR and 95% confidence intervals (CI) were calculated. We used linear mixed models to compare study groups regarding average differences between planned and achieved values of blood pressure and HbA1c, the level of knowledge, realistic expectations and change of clinical parameters (from baseline to 6-months

follow-up). Cluster-adjusted mean differences with 95% CI were calculated. No central laboratory analysis was carried out for the study, as practices contract various laboratories. Deviations from the protocol are described in data supplement: S1.

Process of implementation

Barriers and facilitators of implementation were identified using the documentation from the MAs for the teaching sessions as well as interviews with MAs and GPs of each ISDM-P practice. Interviews focused on workload and attitudes towards the ISDM-P as well as on experiences with teaching, such as organisational aspects or use of teaching material.

Results

Of the 307 invited general practices, 22 were recruited; of the 363 eligible patients, 279 participated (with informed consent). Eleven practices (with 151 patients) were randomised to ISDM-P, and 11 practices (with 128 patients), to standard care (Fig. 1). Baseline characteristics were comparable between groups (Table 1). Fifteen patients of the ISDM-P group did not participate in the teaching session and eight were lost to follow-up. In the control group, three patients were lost to follow-up. About half of the patients in both groups thought they received the usual information. More patients in the ISDM-P group responded that they received new information (38% compared to 19%).

Primary outcome

At follow-up, 218 patients were prescribed antihypertensive drugs and 107 patients, statins. Adherence rates to antihypertensive and statin medications were high for both groups, with no difference between groups (Table 2). Missing data did not affect the results.

Secondary outcomes

More ISDM-P patients made informed choices regarding statin intake, blood pressure control and glucose control (Table 3). A total of 136 ISDM-P patients (90%) and 109 control group patients (85%) completed the knowledge test (score of 0 to 11). The mean score was 6.96 for ISDM-P, versus 2.86 for the control group (adjusted mean difference 4.06 [2.96 to 5.17]; <0.001). The mean score for the domain realistic expectations (score of 0 to 5) was 3.09 for ISDM-P patients, versus 0.92 for standard care patients (2.18 [1.67 to 2.69]; <0.001) (data supplement S4). Significantly more ISDM-P patients had adequate risk knowledge (Table 3).

For estimating personal heart attack risk, 131 ISDM-P and 96 standard care patients participated. The absolute difference of the patient estimated individual risks and objective risks was greater in the control group (5.5% versus 31.1%; adjusted difference –25.6% [–30.4% to –20.8%]; <0.001). This result was confirmed after multiple imputation of missing data. Notably, most patients in the control group overestimated their personal heart attack risk (data supplement S5 and S6).

There was no difference between groups with respect to meeting treatment goals at follow-up. Most patients in both groups achieved their goals regarding statins (85.8% of ISDM-P patients versus 87% of control group patients), blood pressure (93.7% versus 90%), and HbA1c (94.7% versus 89.1%) (data supplement S7). No substantial changes within groups from baseline to follow-up were observed for HbA1c levels, systolic blood pressure values, total cholesterol levels, LDL cholesterol levels or medication prescriptions (data not shown).

Prioritisation of treatment goals differed significantly between groups. More ISDM-P patients prioritised blood pressure control rather than HbA1c targets (28% versus 12%; $p < 0.015$) (data supplement S8).

Matching of treatment goals of GPs and patients were higher for the ISDM-P group (Table 4). Significant differences in favour of the ISDM-P group were found for treatment goals regarding blood pressure values, HbA1c-levels and the prioritised goal. These results remained unchanged after multiple imputation of missing data.

Process evaluation

Characteristics of practices, such as numbers of employed MAs, GPs and patients, were comparable between groups (data supplement S9).

ISDM-P patient teaching module

Overall, 35 teaching sessions were provided by ISDM-P practices. MAs conducted 2 to 6 sessions that lasted between 50 and 120 minutes. Group sizes varied from one to seven patients. MAs stated that they felt well prepared for the ISDM teaching module. Role playing and question cards related to the content of the ISDM-P were identified as facilitators for training success. Before the study, MAs were unfamiliar with risk communication. Some MAs and some patients indicated that there was too much statistics to explain/understand, while a few patients stated that there was not enough information about statistics. Overall, MAs felt that patients were appreciative for the opportunity to participate in the decision making process and to define their own treatment goals.

ISDM-P consultations

Patients consulted their GPs directly after the teaching session or within one to three weeks afterwards. The consultations lasted between 5 and 20 minutes (mean 11.4 minutes). GPs stated that the patients had been well prepared for decision making by their MAs, which was *"better than expected"* and *"better than usual"*. They experienced changes in communication following the ISDM-P teaching module. One GP stated that former consultations were more *"instructive, demanding, and in some ways authoritarian"*, and found that after training, patients and professional teams "*meet on an equal footing"*.

Workload

MAs described the efforts of training and practicing for the teaching module as similar as for standard DMP patient education modules. Most GPs and MAs described the overall workload as appropriate. GPs considered the intended distribution of work within the team as helpful and

reduced workload. Most practices would provide the ISDM-P in routine care if it was covered by health insurances. See supplement S9 for more details.

Discussion

Statement of principle findings

Results from our pilot single centre RCT[21] were confirmed in this multicentre cluster RCT. The programme could be translated from a university-based diabetes centre to everyday primary care. ISDM-P patients were more likely to make informed choices, while the standard care control group did not make informed decisions. The ISDM-P group showed increased knowledge and realistic expectations regarding their individual cardiac risk and probabilities of the benefits and harms of preventive treatment options. Treatment goals between patients and their physicians were more matched for the intervention group. The patient-held documentation sheet of personal treatment objectives supported patients and GPs in deliberating treatment goals and preferences. In fact, better informed patients appeared to trigger more rational evidence-based goal setting among physicians. Contrary to our predefined hypotheses, adherence to medication was very high overall in this study population, making further improvements undetectable. Overall, we believe that the ISDM-P was successfully implemented in the general practices.

Strengths and weaknesses of the study

Our study has several strengths. The intervention has been developed and evaluated according to the UK MRC framework for complex interventions.[28] Efficacy was demonstrated in an RCT under high fidelity conditions.[21] Findings of the RCT and qualitative process data were used to optimize the ISDM-P.[27] A recent publication has reviewed important barriers of SDM.[5] Our programme already addresses these barriers.

In order to facilitate integration into everyday practice, the structure and duration of the ISDM-P teaching session were adapted to standard teaching modules of the DMP.[22-25] The cluster RCT

was meticulously designed and conducted with a low drop-out rate. Additional qualitative methods were used to gain insight into implementation processes.

The weaknesses of the study include the inability to blind the study for the healthcare team for study allocation, due to the nature of the intervention. It also remains unclear to what degree patients were kept blinded. Further, we could not document the extent of SDM. There is no gold standard to quantify patient involvement,[27 39] and the use of decision aids does not accurately reflect SDM.[40] Video-taping and available instruments, such as MAPPIN'SDM, are not applicable for routine care conditions.[41] Thus, we had to define surrogate parameters. Risk knowledge is a prerequisite of informed SDM. Both RCTs showed that patients with standard care lack the necessary risk knowledge. Therefore, we used knowledge and informed choice as secondary endpoints. We hypothesised that successful ISDM would enable more patients to set and achieve realistic and personally defined treatment goals. However, patients were already well controlled at the beginning of the study. Study participants were followed in the German DMP for type 2 diabetes. All had received structured education and were closely monitored. The pilot RCT indicated lower adherence rates to statin prescriptions in the standard care group. Thus, we hypothesised that patients would be more adherent to medication when prescriptions were based on SDM principles. However, in the present cluster RCT, adherence to antihypertensive medication and statins was very high already under standard care. No changes from baseline to follow-up were observed for prescription rates or clinical parameters (such as levels of HbA1c, blood pressure and cholesterol). Thus, it is very likely that adherence was already high at baseline. Our patient-held documentation sheet improved matching of treatment goals between patients and GPs and therefore might be used as a surrogate indicator for SDM. This sheet is an integral part of the intervention for supporting patient participation and, at the same time, a tool for the documentation of common treatment goals.

Strengths and weaknesses in relation to other studies, discussing important differences in results

The S*tatin Choice Decision Aid* was tested regarding statin adherence in a specialised clinic,[14] one primary care centre,[13] and several primary care practices in Spain.[15] Improvement of adherence was only found in the specialised clinic.[14] The *Diabetes Medication Choice Decision Aid* had no impact on adherence,[17] while one study even reported a better outcome in the control group.[16] In all publications, adherence rates were very high already under standard care. This is consistent with our study.

In a recent cluster RCT from the Netherlands (OPTIMAL), an SDM intervention also aimed at enhancing patients' achievement of treatment goals.[12] Patients were asked to choose between an intensive treatment strategy according to the ADDITION protocol and a less intensive treatment based on guideline recommendations. The findings showed no significant difference between the groups. Almost half of the patients in the intervention group switched from less intensive to intensive treatment.[12] However, benefits from intensifying therapy in type 2 diabetes are questionable. In our previous RCT on the ISDM-P, more patients achieved their HbA1c level goals because they set slightly higher HbA1c targets after the teaching session.[21] We offered and supported patients to prioritise and set realistic treatment goals. GPs of the OPTIMAL trial found the decision aid helpful, but it remains unclear if patients understood the information.[12] Most of the ISDM-P consultations with the GP did not take longer than usual consultations, with a mean duration of about 11 minutes. The implementation trial of the S*tatin Choice Decision Aid* in Spain reported consultation times of almost 20 minutes without significant differences between intervention and control groups.[15] In our study, GPs just had to perform the last steps of the SDM process, as patients had been well prepared for decision making by MAs. Hence, GPs could discuss four health topics—blood glucose, blood pressure, statin use and smoking—and related treatment options with their patients in a single encounter. The duration of the group teaching session provided by MAs was comparable to other DMP teaching sessions.

Recently, Ballard et al. (2017) assessed the routine use of the *Statin Choice Decision Aid* and the *Diabetes Medication Choice Decision Aid* in a tertiary care centre under routine care.[40] Half of the clinicians used the statin choice decision aid and 9% the medication choice decision aid. Reasons for not using the material were lack of awareness that the tools were available, time constraints and attitudinal barriers, e.g. clinicians found the decision aids not helpful or not accurate.[40] Recommendations to address such barriers are workshops to improve SDM skills, development of brief evidence-based consultation tools, interventions to prepare patients in decision making and the development of measurements to be used in practice to identify knowledge gaps and preferences.[5] Our ISDM intervention already addresses all these aspects. The ISDM-P training included a demonstration of a patient teaching session and role play in order to help teams gain more insight into differences between usual counselling and SDM-based consultations. Our training took longer than trainings in other studies, but this time duration was perceived as appropriate by participants.

Meaning of the study: possible explanations and implications for clinicians and policymakers

In our study, we determined that patients under standard care did not have adequate risk knowledge to make informed decisions. Healthcare providers do not have access to education and patient information material which fulfil the criteria for evidence-based health information. The ISDM-P remedies this: it not only provides understandable and relevant risk information to healthcare personnel and patients, it also enables a patient-physician communication on equal footing and helps patients and GPs to pursue common treatment goals as recommended in DMP guidelines. Our study shows that the ISDM-P can be integrated in everyday practice without large extra effort. It meets the criteria to be covered by health insurance companies.

Unanswered questions and future research

Further research will focus on extending the ISDM-P concept to other clinical decisions. In particular, drug facts boxes on the increasing number of oral antidiabetic agents should be made available. Structured treatment and teaching programmes need to be updated and optimised based on criteria for evidence-based patient information and SDM.[22 25 42] Web-based formats allowing individual training and exchange with health care professionals have to be developed. This will also allow a more personalised selection of teaching modules on diabetes or hypertension care.

Current clinical practice guidelines do not provide well-structured information on benefits and harms of medication or other treatments that could readily be used within consultations with patients. Fact boxes or other decision tools should be considered in guideline development.[3 43] Finally, open access trainings in evidence-based medicine, risk information and SDM for healthcare providers are required. Maintaining and updating an entire ISDM treatment and teaching programme, will require an up-to-date online platform for patients and healthcare providers.

The implementation of the ISDM-P concept would meet national and international guideline recommendations as well as the patients' ethical and legal rights on true involvement in decision making.

Acknowledgements

We thank the medical assistants, physicians and participating patients of all 22 primary care practices. We also thank Susanne Kählau-Meier for her valuable support in data collection and administration as well as Veronica A. Raker for editing the manuscript.

Contributors

The study was carried out in collaboration between all authors. SB and IM designed the study. SB and KL designed and tested the provider training. SB, NK and UAM were involved in the

planning, coordination and management of data acquisition at the study sites (primary care practices). TL did the statistical planning and analyses of the study. SB and IM wrote the first draft of the manuscript. NK, KL and UAM contributed to the draft of the manuscript. All authors critically revised the manuscript and approved the final version. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

Funding

This study was funded by the European Foundation for the Study of Diabetes (EFSD) on behalf of the European Association for the Study of Diabetes (EASD). NK's salary has been partly financed by the non-profit association "Diabeteszentrum Thüringen e.V." [Diabetes Centre Thuringia]. The EFSD and the Diabetes Centre Thuringia had no role in the design of the study, collection, analysis, and interpretation of data, and preparation and approval of the manuscript.

Competing interest

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: SB, NK, KL, and TL report grants from the EFSD during the conduct of the study; NK reports grant from the Diabetes Centre Thuringia during the conduct of the study; UAM and IM received no support from any organisation for the submitted work; all authors had no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Ethics approval

The study protocol was approved by the ethics committee of the Medical Association of Thuringia in April 2014 (ref: 29739/2014/31). All participants gave informed consent before taking part.

Data sharing

The corresponding author can be contacted to forward request for data sharing.

Transparency

The lead author (SB) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported. No important aspects of the study have been omitted. Discrepancies from the study as planned have been explained.

Copyright

References

[1] German Medical Association, National Association of Statutory Health Insurance Physicians, Association of the Scientific Medical Societies. Nationale VersorgungsLeitlinie Therapie des Typ-2-Diabetes – Langfassung 2013; Available from http://www.leitlinien.de/nvl/diabetes/therapie. Accessed 19 Mar 2018 [Guideline in German].

[2] Inzucchi SE, Bergenstal RM, Buse JB et al. Management of hyperglycemia in type 2 diabetes, 2015: a patient-centered approach: update to a position statement of the American Diabetes Association and the European Association for the Study of Diabetes. *Diabetes Care* 2015;38:140-49.

[3] Rutten GEHM, Alzaid A. Person-centred type 2 diabetes care: time for a paradigm shift. *Lancet Diabetes Endocrinol* 2017;Jun 9: doi: 10.1016/S2213-8587(17)30193-6.

[4] Rodriguez-Gutierrez R, Gionfriddo MR, Ospina NS et al. Shared decision making in endocrinology: present and future directions. *Lancet Diabetes Endocrinol* 2016;4:706-716.

[5] Joseph-Williams N, Lloyd A, Edwards A et al. Implementing shared decision making in the NHS: lessons from the MAGIC programme. *BMJ* 2017;357:j1744.

[6] Agoritsas T, Heen AF, Brandt L et al. Decision aids that really promote shared decision making: the pace quickens. *BMJ* 2015;350: g7624.

[7] Scholte op Reimer WJ, Moons P, De Geest S et al. Cardiovascular risk estimation by professionally active cardiovascular nurses: results from the Basel 2005 Nurses Cohort. *Eur J Cardiovasc Nurs* 2006;5:258-63.

[8] Mühlhauser I, Kasper J, Meyer G. Understanding of diabetes prevention studies: questionnaire survey of professionals in diabetes care. *Diabetologia* 2006;49:1742-1746.

[9] Gigerenzer G, Gaissmaier W, Kurz-Milcke E, Schwartz LM, Woloshin S. Helping doctors and patients to make sense of health statistics. *Psychol Sci Public Interest* 2007;8:53-96.

[10] Montori VM, Kunneman M, Brito JP. Shared decision making and improving health care: the answer is not in. *JAMA* 2017;318: 617-8.

[11] Stacey D, Legare F, Lewis K et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev* 2017;4:Cd001431.

[12] Den Ouden H, Vos RC, Rutten GEHM. Effectiveness of shared goal setting and decision making to achieve treatment targets in type 2 diabetes patients: a cluster-randomized trial (OPTIMAL). *Health Expect* 2017;20:1172-80.

[13] Mann DM, Ponieman D, Montori VM, Arciniega J, McGinn T. The statin choice decision aid in primary care: a randomized trial. *Patient Educ Couns* 2010;80:138-40.

[14] Weymiller AJ, Montori VM, Jones LA et al. Helping patients with type 2 diabetes mellitus make treatment decisions: statin choice randomized trial. *Arch Intern Med* 2007;167:1076-82.

[15] Perestelo-Perez L, Rivero-Santana A, Boronat M et al. Effect of the statin choice encounter decision aid in Spanish patients with type 2 diabetes: a randomized trial. *Patient Educ Couns* 2016;99:295-9.

[16] Mullan RJ, Montori VM, Shah ND et al. The diabetes mellitus medication choice decision aid: a randomized trial. *Arch Intern Med* 2009;169:1560-8.

[17] Karagiannis T, Liakos A, Branda ME et al. Use of the diabetes medication choice decision aid in patients with type 2 diabetes in Greece: a cluster randomised trial. *BMJ Open* 2016;6:e012185.

[18] Mathers N, Ng CJ, Campbell MJ, Colwell B, Brown I, Bradley A. Clinical effectiveness of a patient decision aid to improve decision quality and glycaemic control in people with diabetes making treatment choices: a cluster randomised controlled trial (PANDAs) in general practice. *BMJ Open* 2012;2:e001469.

[19] Denig P, Schuling J, Haaijer-Ruskamp F, Voorham J. Effects of a patient oriented decision aid for prioritising treatment goals in diabetes: pragmatic randomised controlled trial. *BMJ* 2014;349:g5651.

[20] Lenz M, Kasper J, Mühlhauser I. Development of a patient decision aid for prevention of myocardial infarction in type 2 diabetes - rationale, design and pilot testing. *Psychosoc Med* 2009;6:Doc05.

[21] Buhse S, Mühlhauser I, Heller T et al. Informed shared decision-making programme on the prevention of myocardial infarction in type 2 diabetes: a randomised controlled trial. *BMJ Open* 2015;5:e009116.

[22] Grüsser M, Bott U, Ellermann P, Kronsbein P, Jörgens V. Evaluation of a structured treatment and teaching program for non-insulin-treated type II diabetic outpatients in Germany after the nationwide introduction of reimbursement policy for physicians. *Diabetes Care* 1993;16:1268-75.

[23] Kronsbein P, Mühlhauser, Jörgens V, Scholz V, Venhaus A, Berger M. Evaluation of a structured treatment and teaching programme on non-insulin-dependent diabetes. *Lancet* 1988;2:1407-11.

[24] Grüsser M, Hartmann P, Schlottmann N, Jörgens V. Structured treatment and teaching programme for type 2 diabetic patients on conventional insulin treatment: evaluation of reimbursement policy. *Patient Educ Couns* 1996;29:123-30.

[25] Müller UA, Müller R, Starrach A et al. Should insulin therapy in type 2 diabetic patients be started on an out- or inpatient basis? Results of a prospective controlled trial using the same treatment and teaching programme in ambulatory care and a university hospital. *Diabetes Metab* 1998;24:251-55.

[26] Busse R. Disease management programs in Germany's statutory health insurance system. *Health Aff (Millwood)* 2004;23:56-67.

[27] Buhse S, Mühlhauser I, Kuniss N 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.

[28] Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008;337:a1655.

[29] 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.

[30] Pfadenhauer LM, Gerhardus A, Mozygemba K et al. Making sense of complexity in context and implementation: the Context and Implementation of Complex Interventions (CICI) framework. *Implement Sci* 2017;12:21.

[31] Pinnock H, Barwick M, Carpenter CR et al. Standards for Reporting Implementation Studies (StaRI) Statement. *BMJ* 2017;356:i6795.

[32] Busse R, Blumel M, Knieps F, Barnighausen T. Statutory health insurance in Germany: a health system shaped by 135 years of solidarity, self-governance, and competition. *Lancet* 2017;390:882-97.

[33] Fuchs S, Henschke C, Blumel M, Busse R. Disease management programs for type 2 diabetes in Germany: a systematic literature review evaluating effectiveness. *Dtsch Arztebl Int* 2014;111:453-63.

[34] German Medical Association, National Association of Statutory Health Insurance Physicians, Association of the Scientific Medical Societies. Nationale VersorgungsLeitlinie Diabetes – Strukturierte Schulungsprogramme – Langfassung. Available from http://www.leitlinien.de/nvl/diabetes/schulungsprogramme 2012; Accessed 19 Mar 2018 [Guideline in German].

[35] Joseph-Williams N, Elwyn G, Edwards A. Knowledge is not power for patients: a systematic review and thematic synthesis of patient-reported barriers and facilitators to shared decision making. *Patient Educ Couns* 2014;94:291-309.

[36] Légaré F, Ratte S, Gravel K, Graham ID. Barriers and facilitators to implementing shared decision-making in clinical practice: update of a systematic review of health professionals' perceptions. *Patient Educ Couns* 2008;73:526-35.

[37] 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].

[38] Marteau TM, Dormandy E, Michie S. A measure of informed choice. *Health Expect* 2001;4:99-108.

[39] Gärtner FR, Bomhof-Roordink H, Smith IP, Scholl I, Stiggelbout AM, Pieterse AH. The quality of instruments to assess the process of shared decision making: A systematic review. *PLoS One* 2018;13:e0191747.

[40] Ballard AY, Kessler M, Scheitel M, Montori VM, Chaudhry R. Exploring differences in the use of the statin choice decision aid and diabetes medication choice decision aid in primary care. *BMC Med Inform Decis Mak* 2017;17:118.

[41] Kasper J, Heesen C, Köpke S, Fulcher G, Geiger F. Patients' and observers' perceptions of involvement differ. Validation study on inter-relating measures for shared decision making. *PLoS One* 2011;6:e26255.

[42] Mühlhauser I, Sawicki PT, Didjurgeit U, Jörgens V, Trampisch HJ, Berger M. Evaluation of a structured treatment and teaching programme on hypertension in general practice. *Clin Exp Hypertens* 1993;15:125-42.

[43] Mühlhauser I, Meyer G. Evidence base in guideline generation in diabetes. *Diabetologia* 2013;56:1201-9.

Tables

Table 1. Baseline characteristics of patients.

Characteristic	ISDM-P group (n = 151)	Control group (n = 128)
Women	67 (44.4)	59 (46.1)
Age, years	59.5 (6.5)	58.7 (7.9)
Duration of diabetes, years[a]	8.5 (6.5)	7.5 (6.2)
Systolic blood pressure, mmHg[b]	140 (15.1)	140 (16.0)
Diastolic blood pressure, mmHg[b]	81 (8.9)	84 (8.5)
Body mass index, kg/m^2 [c]	33.6 (5.3)	31.5 (6.7)
HbA1c, %[d]	7.0 (0.7)	7.0 (1.0)
Total cholesterol[b], mmol/l	5.2 (1.1)	5.3 (1.1)
HDL cholesterol[e], mmol/l	1.3 (0.4)	1.3 (0.4)
LDL cholesterol[e], mmol/l	3.2 (0.9)	3.4 (1.0)
Smoker (%)[f]	29 (19.2)	18 (14.5)
Diagnosis hypertension (%)[b]	134 (88.7)	115 (90.6)
Medication for blood pressure control (%)	129 (85.4)	104 (81.3)
Medication for glucose control	124 (82.1)	95 (74.2)
Insulin	36 (23.8)	28 (21.9)
Metformin	111 (73.5)	88 (68.8)
Sulfonylurea	21 (13.9)	10 (7.8)
Other antidiabetic agents	52 (34.4)	40 (31.3)
Statin medication	50 (33.1)	41 (32.0)
Participation in teaching session for hypertension[g] (%)	28 (21.1)	11 (10.1)
Graduation		
None	1 (0.7)	1 (0.8)
Junior high school	29 (19.2)	24 (18.8)
High school	93 (61.6)	86 (67.2)
Qualification for technical college or university	28 (18.5)	17 (13.3)

Values are given as patient number (percentage) or as means (SD); ISDM-P = Informed Shared Decision Making Programme;
[a]ISDM-P n = 151, control group n = 125; [b]ISDM-P n = 151, control group n = 127; [c]ISDM-P n = 150, control group n = 126; [d]ISDM-P n = 151, control group n = 128; [e]ISDM-P n = 150, control group n = 117; [f]ISDM-P n = 151, control group n = 124; [g]Patients with diagnosis of hypertension, ISDM-P n = 133, control group n = 109

Table 2: Primary endpoint: Adherence to antihypertensive and statin therapy

	ISDM-P group	Control group	adjusted OR [95% CI]; P value	MI: adjusted OR [95% CI]; *p* value	ICC
Antihypertensive drugs	96/118 (81.4)	71/90 (78.9)	1.2 [0.5 to 2.6]; 0.696	1.1 [0.5 to 2.4]; 0.812	0.176
Statins	51/58 (87.9)	43/45 (95.6)	0.4 [0.1 to 2.0]; 0.271	0.4 [0.1 to 1.4]; 0.139	0.000

Values are given as patient number (percentage); ISDM-P = Informed Shared Decision Making Programme; ICC = intracluster coefficient

Table 3: Informed choice and adequate knowledge

	ISDM-P group	Control group	Adjusted OR [95% CI]; P value	MI: adjusted OR [95% CI]; *p* value
Adequate knowledge[a]	61/136 (44.9)	3/109 (2.8)	29.3 [6.9 to 124.6]; <0.001	21.4 [6.8 to 67.4]; <0.001
Informed choice: statins	43/128 (33.6)	3/105 (2.9)	16.6 [4.4 to 63.0]; <0.001	6.2 [2.4 to 16.0]; <0.001
Informed choice: blood pressure	50/129 (38.8)	3/109 (2.8)	22.2 [5.3 to 93.3]; <0.001	10.0 [3.3 to 30.4]; <0.001
Informed choice: HbA1c	57/134 (42.5)	3/109 (2.8)	26.0 [6.5 to 104.8]; <0.001	11.5 [4.0 to 33.1]; <0.001
Informed choice: smoking	3/23 (13.0)	0/16 (0)	5.1 [0.2 to 135.1]; 0.322	-

Values are given as patient number (percentage); ISDM-P = Informed Shared Decision Making Programme; MI = multiple imputation (n = 279)

[a]at least eight out of eleven questions were correctly answered

Table 4: Match of treatment goals between physicians and patients

Treatment goal	ISDM-P group	Control group	Adjusted difference [95% CI]; P value	MI: adjusted difference [95% CI]; *p* value
Blood pressure[a]	3.06 mmHg (5.21)	6.89 mmHg (6.94)	–4.0 mmHg [–6.6 to –1.4]; 0.005	–3.1 [–5.6 to –0.5]; 0.019
HbA1c[b]	0.26% (0.33)	0.49% (0.49)	–0.2 [–0.4 to –0.1]; 0.003	–0.2 [–0.39 to –0.05]; 0.012
			Adjusted OR [95% CI]; P value	**MI: adjusted OR [95% CI]; P value**
Statins	114/127 (89.8)	81/104 (77.9)	2.4 [0.9 to 6.2]; 0.077	1.9 [0.7 to 4.8]; 0.181
Stop smoking	9/17 (52.9)	6/9 (66.7)	0.5 [0.1 to 4.0]; 0.537	0.6 [0.1 to 3.6]; 0.561
Prioritized goal	92/104 (88.5)	45/79 (57.0)	6.5 [3.0 to 14.4]; <0.001	2.6 [1.3 to 5.2]; 0.009

Values are given as patient number (percentage) unless stated otherwise. ISDM-P = Informed Shared Decision Making Programme; HbA1c = glycated haemoglobin; MI = multiple imputation (n = 279)
[a]adjusted mean difference between patients' treatment goals and physicians' treatment goals; values are means (standard deviation); ISDM-P n = 127, control group n = 95
[b]adjusted mean difference between patients' treatment goals and physicians' treatment goals; values are means (standard deviation); ISDM-P n = 133, control group n = 95

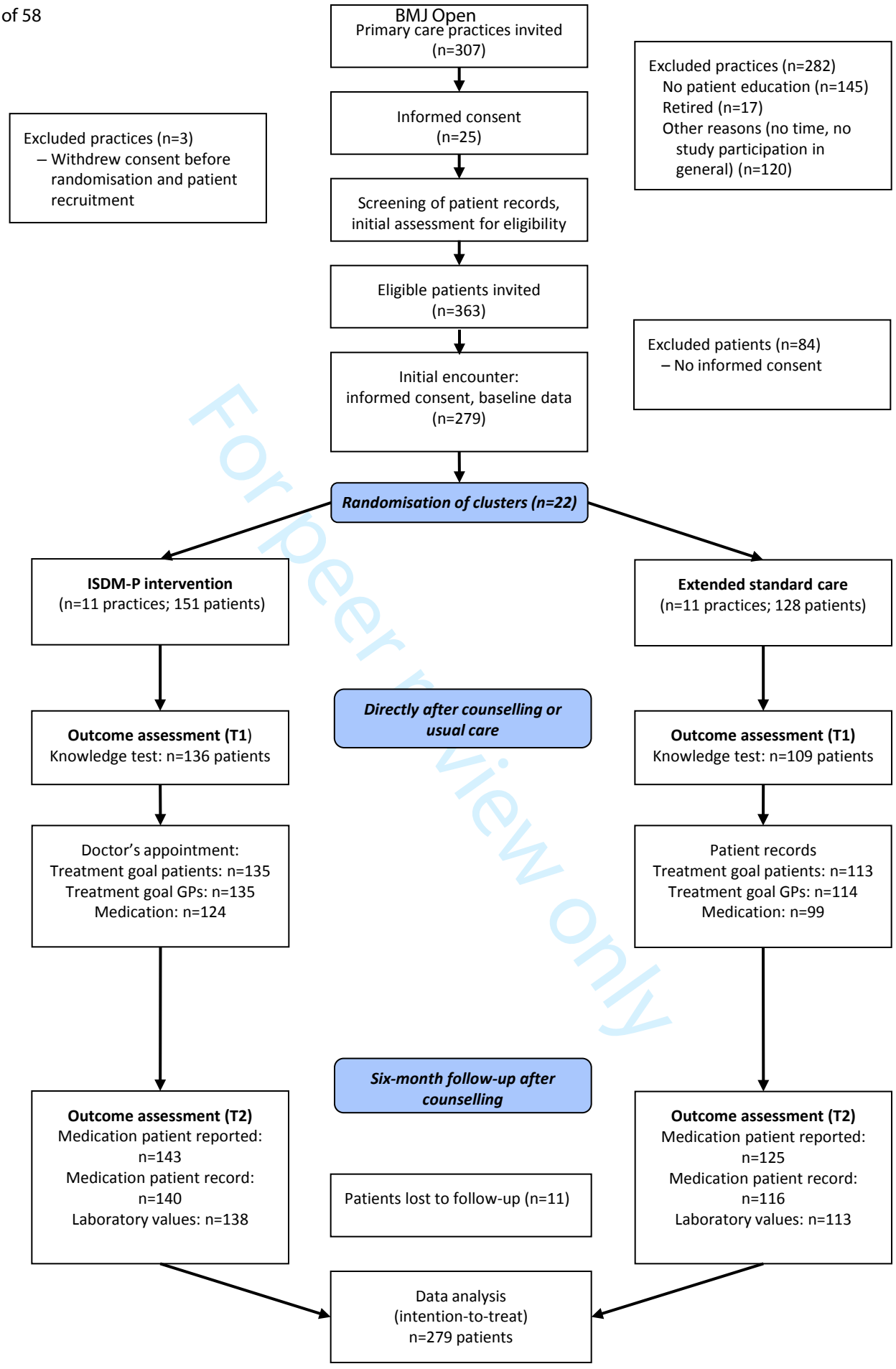

Figure legend

Figure. Study flow-chart.

ISDM-P = Informed Shared Decision Making Programme; GP = general practitioner; T1 = directly after counselling or usual care; T2 = 6-month follow-up

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.

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.

[2] Lenz M, Kasper J, Mühlhauser I. Development of a patient decision aid for prevention of myocardial infarction in type 2 diabetes - rationale, design and pilot testing. *Psychosoc Med* 2009;6:Doc05.

[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.

CONSORT 2010 checklist of information to include when reporting a cluster randomised trial

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	See table 2	3-4
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	6-7
	2b	Specific objectives or hypotheses	Whether objectives pertain to the the cluster level, the individual participant level or both	7, 10, study protocol [1]
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	7, study protocol [1]
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		12, data supplement S1
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	7-8, study protocol [1]
	4b	Settings and locations where the data were collected		7-8, study protocol [1]

Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	9, data supplement S2, study protocol [1]
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Whether outcome measures pertain to the cluster level, the individual participant level or both	10, study protocol [1], data supplement S3
	6b	Any changes to trial outcomes after the trial commenced, with reasons		Data supplement S1
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or *k*), and an indication of its uncertainty	10-11, study protocol [1]
	7b	When applicable, explanation of any interim analyses and stopping guidelines		n.a.
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		11, study protocol [1]
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	11, study protocol [1]
Allocation concealment	9	Mechanism used to implement the random allocation sequence (such	Specification that allocation was based on clusters rather than individuals and whether	11, study protocol [1]

mechanism		as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	allocation concealment (if any) was at the cluster level, the individual participant level or both	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	8-9, data supplement S1
	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	8-9, data supplement S1
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those		10-11

		assessing outcomes) and how		
	11b	If relevant, description of the similarity of interventions		9, data supplement S2, study protocol [1]
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	11-12, study protocol [1]
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		11-12, study protocol [1]
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	12, Fig 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members	12, Fig 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up		8-9, data supplement S1
	14b	Why the trial ended or was stopped		n.a.
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Baseline characteristics for the individual and cluster levels as applicable for each group	Table 1, data supplement S9

Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	Tables 2-4, data supplement S4-S8
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	12-13, Tables 2-4, data supplement S4-S8
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		12-13, Tables 2-4, data supplement S4-S8
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		12-13
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)		14-15, data supplement S9
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		15-16

Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	15, 17-18
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		15-16, 18
Other information				
Registration	23	Registration number and name of trial registry		4
Protocol	24	Where the full trial protocol can be accessed, if available		7, study protocol [1]
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders		20

** Note: page numbers optional depending on journal requirements*

[1] Buhse S, Mühlhauser I, Kuniss N 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.

BMJ Open

An informed shared decision making programme for patients with type 2 diabetes in primary care: cluster randomised controlled trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-024004.R1
Article Type:	Research
Date Submitted by the Author:	22-Aug-2018
Complete List of Authors:	Buhse, Susanne; University of Hamburg, Faculty of Mathematics, Informatics and Natural Sciences, Health Sciences and Education Kuniss, Nadine; Jena University Hospital, Department of Internal Medicine III, Endocrinology and Metabolic Diseases; Diabetes Centre Thuringia Liethmann, Kathrin; University of Hamburg, Faculty of Mathematics, Informatics and Natural Sciences, Health Sciences and Education; University Medical Center Schleswig Holstein, Institute of Medical Psychology and Sociology Müller, Ulrich; Jena University Hospital, Department of Internal Medicine III, Endocrinology and Metabolic Diseases; Diabetes Centre Thuringia Lehmann, Thomas; Universitätsklinikum Jena, Institute of Medical statistics Mühlhauser, Ingrid; University of Hamburg, Faculty of Mathematics, Informatics and Natural Sciences, Health Sciences and Education
Primary Subject Heading:	General practice / Family practice
Secondary Subject Heading:	Patient-centred medicine, Evidence based practice, Diabetes and endocrinology
Keywords:	PRIMARY CARE, Diabetes Mellitus, Type 2, Decision Support Techniques, Patient Education as Topic, Health Educators, Health Knowledge, Attitudes, Practice

An informed shared decision making programme for patients with type 2 diabetes in primary care: cluster randomised controlled trial

Susanne Buhse[1], Nadine Kuniss[2,3], Kathrin Liethmann[1,4], Ulrich A Müller[2,3], Thomas Lehmann[5,] Ingrid Mühlhauser[1]

[1]Health Sciences and Education, University of Hamburg, Hamburg, Germany,

[2]Department of Internal Medicine III, Endocrinology and Metabolic Diseases, Jena University Hospital, Jena, Germany

[3]Diabetes Centre Thuringia, Jena, Germany

[4]Institute of Medical Psychology and Sociology, University Medical Center Schleswig Holstein, Kiel, Germany

[5]Centre for Clinical Studies, Jena University Hospital, Jena, Germany

Susanne Buhse, senior researcher

Nadine Kuniss, research fellow

Kathrin Liethmann, psychologist

Ulrich Alfons Müller, professor of internal medicine

Thomas Lehmann, biostatistician

Ingrid Mühlhauser, professor of health sciences and education

Corresponding author: Susanne Buhse, Email: Susanne.Buhse@uni-hamburg.de

University of Hamburg, Faculty of Mathematics, Informatics and Natural Sciences, Health Sciences and Education, Martin-Luther-King-Platz 6, 20146 Hamburg

Word count of main text: 4299 words

Keywords

Diabetes Mellitus, Type 2; Decision Making; Decision Support Techniques; Patient Education as Topic; Health Knowledge, Attitudes, Practice; Evidence-Based Medicine; Hypertension; Family Practice; Health Educators; Physicians, Primary Care

Abstract

Objective To translate an informed shared decision making programme (ISDM-P) for patients with type 2 diabetes from a specialized diabetes centre to the primary care setting.

Design Patient-blinded, two-arm multicentre, cluster RCT of 6 months follow-up; concealed randomisation of practices after patient recruitment and acquisition of baseline data.

Setting 22 general practices providing care according to the German Disease Management Programme (DMP) for type 2 diabetes.

Participants 279 of 363 eligible patients without myocardial infarction or stroke.

Interventions The ISDM-P comprises a patient decision aid, a corresponding group teaching session provided by medical assistants and a structured patient-physician encounter. Control group received standard DMP care.

Primary and secondary outcome measures Primary endpoint was patient adherence to antihypertensive or statin drug therapy by comparing prescriptions and patient-reported uptake after 6 months. Secondary endpoints included informed choice, risk knowledge (score 0 to 11 from 11 questions) and prioritised treatment goals of patients and doctors.

Results ISDM-P: 11 practices with 151 patients; standard care: 11 practices with 128 patients; attrition rate: 3.9%. There was no difference between groups regarding the primary endpoint. Mean drug adherence rates were high for both groups (80% for antihypertensive and 91% for statin treatment). More ISDM-P patients made informed choices regarding statin intake, 34% vs 3%, Odds Ratio [OR] 16.6 (95% CI 4.4 to 63.0), blood pressure control, 39% vs 3%, OR 22.2 (5.3 to 93.3) and HbA1c, 43% vs 3%, OR 26.0 (6.5 to 104.8). ISDM-P patients achieved higher levels of risk knowledge, with a mean score of 6.96 vs 2.86, difference 4.06 (2.96 to 5.17). In the ISDM-P group, agreement on prioritised treatment goals between patients and doctors was higher, with 88.5% vs 57%.

Conclusions The ISDM-P was successfully implemented in general practices. Adherence to medication was very high making improvements hardly detectable.

Trial registration ISRCTN77300204

Strengths and limitations of this study

- This cluster RCT followed the UK MRC framework for complex interventions and is the final step of the development and evaluation of an informed shared decision making programme (ISDM-P) for patients with type 2 diabetes.
- Efficacy of the ISDM-P was demonstrated in a former RCT under high fidelity conditions in a diabetes centre. In this cluster RCT, the ISDM-P was integrated into routine care by addressing implementation barriers.
- The cluster RCT was meticulously designed and conducted with a low drop-out rate; practices were only randomised after completion of patient recruitment and acquisition of baseline data.
- It was planned to keep the patients blinded, but it was impossible to keep the health care providers (practices) blinded.
- Since there is no gold standard to assess SDM in routine care, the patient-held sheet for personal treatment goals might be used as a surrogate indicator for SDM in diabetes care.

Introduction

Diabetes guidelines explicitly recommend shared decision making (SDM) to help patients and physicians to make informed choices and to select the treatment that best fits individual patient needs, values and preferences.[1 2] Patients increasingly want to participate in making decisions about their health, and they have the right to be involved.[3] However, SDM is not yet implemented in diabetes care[4], and a number of barriers have been identified that are hindering this.[5] While many clinicians believe that they already practice SDM, they in fact do not involve patients in treatment decision making.[5 6] Physicians are used to deciding what they consider best for their patients. Even if healthcare professionals are aware of such misconceptions about SDM, organisational structures (and mainly time constraints) are often perceived as barriers for patient involvement. Another challenge is the generally poor science literacy among health professionals and patients, and a lack of competencies for communicating and understanding risk information.[7-9] Finally, there is a paucity of evidence-based patient information material such as decision aids or drug facts boxes, which display probabilities of benefits and harms of options and are the basis for informed decision making.[10 11] There are only a few projects on decision aids and SDM in diabetes care; these address different treatment regimens,[12] statin treatment,[13-15] oral antidiabetic agents,[16 17] starting insulin injections,[18] or prevention of macro- and microvascular complications.[19] Results about efficacy or implementation are ambiguous.

We have developed an informed shared decision making programme (ISDM-P) for patients with type 2 diabetes that targets implementation barriers.[20 21] The ISDM-P comprises an evidence-based patient decision aid, a corresponding teaching session provided by specially trained medical assistants (MAs) and a structured patient-physician encounter. MAs and doctors are trained to provide risk information and to conduct consultations based on SDM principles. The ISDM-P is designed to be easily integrated in the structured treatment and teaching programme[22-25] used in the German Disease Management Programme (DMP).[26] We have compared the ISDM-P to a structurally equivalent control intervention in a proof-of-concept

randomised controlled trial at a single diabetes centre.[21] About half of the ISDM-P patients, but none of the patients in the usual care group, attained adequate risk knowledge to make informed decisions. Nonetheless, patients' treatment preferences were not adequately considered by physicians in decision making. Although physicians expressed a positive attitude towards SDM, they had not been specifically trained in SDM. Therefore, we developed additional programme components to facilitate SDM-based patient-physician consultations.[27]

In the present study, we investigated whether the results of the proof-of-concept RCT[21] could be repeated under routine care conditions for patients with type 2 diabetes.. The aim was to translate the optimised ISDM-P to the primary healthcare setting.

Methods

Study design

The study was a two-arm, multicentre cluster randomised controlled trial with six months follow-up. According to international standards for the development and evaluation of complex interventions, we additionally focused on implementation conditions and process parameters.[28-31] A detailed protocol has been published.[27]

Patient involvement

In order to address patient and public involvement, patients participated in the development of the intervention material. We did not involve patients in the design of this study. After publication of the study we will write a plain language summary and design a leaflet for distribution to patient groups. It will also be available on the project website (www.diabetes-und-herzinfarkt.de).

Context and setting

In Germany, care for patients with type 2 diabetes is usually provided by family physicians at the primary health care level. The study took place in 21 primary care practices in East Germany

(Free State of Thuringia and Saxony-Anhalt) and one in the city of Hamburg. Practices were included if they provided structured teaching and treatment according to the German DMP for type 2 diabetes.[32 33] Patient education was provided by diabetes educators or MAs with special training in diabetes education.[34] All practices gave informed consent. A more detailed description is given in the protocol.[27]

Participants

Patients between 40 and 69 years who had been diagnosed with type 2 diabetes, had HbA1c levels of <9% and had previously participated in structured DMP teaching sessions were included. Exclusion criteria were a history of ischemic heart disease (ICD I20-I25) or stroke (ICD I63), proliferative retinopathy, chronic kidney disease stage 3 or higher or care by a legal guardian. All participants gave informed written consent.

Study recruitment

A total of 307 general practices of the study regions were informed about the project by mail (Figure). Two weeks later, the practices were called and asked whether they were interested in participating in the study. Supported by the research associate, MAs and general practitioners (GPs) of each practice screened the patient records for eligibility. Patients of the included practices were then informed about the study by a letter and invited to participate during the next consultation with their GPs. After patients who were willing to participate had given informed consent, baseline data were retrieved directly from patients and supplemented by standard data extracted from the electronic patient records.

Concealed external randomisation of practices (cluster) started only after conclusion of patient recruitment and collection of baseline data at the study centre.

The study was approved by the ethics committee of the Medical Association of the Federal State of Thuringia in April 2014. It was submitted to registration in February 2015. The study protocol

was published in March 2015.[27] In order to avoid undue delays in recruitment of study participants, we started enrolment of family practices and patients in December 2014. During that time, we checked if prescription rates of statins and antihypertensive agents were comparable between our former proof-of-concept study and the primary care setting to make sure that our sample size calculation is adequate. Practices were randomised only after trial registration and after publication of the study protocol. In fact, we did not change our original sample size calculation. We think that our approach did not bias our study results. The last practice was enrolled in August 2015, and the last patient, in April 2016. The overall trial end date should have been July 2016, but as some practices required more time for patient recruitment, data collection was completed in March 2017. Please refer to data supplement: S1 Study procedure and registration, for in depth detail of this.

Intervention

The ISDM-P comprises a number of interrelated components (data supplement S2).[27] Those components that had already been tested in the proof-of-concept RCT[21] were: 1) an evidence-based patient decision aid about the primary prevention of myocardial infarction and other diabetes-related complications [20]; 2) a structured group teaching session provided by MAs; and 3) a provider training for MAs. The additional components developed for implementation in routine care were: 4) a patient-held documentation sheet with patient-defined treatment goals, to be shared and discussed by the patient with the GP; and 5) a six-hour training to prepare GPs for consultations in terms of SDM.[27]

The ISDM-P addresses various facilitators and barriers of SDM implementation.[5 35 36] In the patient-teaching session, MAs provided evidence-based risk information and assured that the patients understood it by using question cards to identify knowledge gaps and to repeat content, if necessary. Further, they helped patients to set individual treatment goals and to document them on the patient-held sheet. The sheet ensured that individual patient set goals were

discussed in the subsequent patient-physician encounter. Finally, both, patients and GPs documented their common goals on the patient-held sheet. A copy remained in the patient record. Please refer to data supplement S3 for details on the sheet – note that this has been translated from German to English.

Comparison

The control group received standard care supplemented with a brief extract of the patients' version of the German National Disease Management Guidelines on the treatment of patients with type 2 diabetes, with a link to the full version of the guideline.[37]

Outcome measures

The primary outcome measure was adherence to antihypertensive or statin therapy, operationalised as adherence to prescribed medication as documented in the patients' records at the six-month follow-up. Our hypothesis was that patients would be more adherent when they defined personal treatment goals together with their healthcare professionals. For more details on selection of the primary endpoint, please refer to the protocol.[27]

A blinded external study assistant conducted telephone interviews with all patients to assess the primary endpoint after 6 months. She was specifically trained by the psychologist who co-authored the study (KL) to perform the interview. A standardised interview guide was used. Patients were considered to have been adherent if their answers were consistent with the prescription documented in the patients' record.

Secondary endpoints included: 1) informed choices about statin treatment, blood pressure control, glucose control and smoking cessation; 2) risk knowledge; 3) realistic expectations about individual heart attack risks and effects of preventive options; 4) achievement and 5) prioritisation of treatment goals.[27]

The adapted multi-dimensional parameter *informed choice*[38] tests for adequate knowledge (e.g., correctly answering 8 out of 11 items of the validated questionnaire [27]) and achievement of treatment goals. A patient with adequate knowledge and who had achieved the personal treatment goal was considered as having made an informed choice. How well the treatment goals (including prioritisation of goals) of patients and GPs matched was assessed as an indicator of SDM. In addition, changes in medication prescriptions and clinical parameters, including HbA1c levels, cholesterol and blood pressure, was assessed from baseline to follow-up.

Sample size

It was assumed that 80% of patients in the ISDM-P group would adhere to prescriptions of antihypertensive and statin medication, as compared to 60% of the control group.[27] An intra-cluster correlation coefficient (ICC) of 0.03, and a mean cluster size of 13 patients, were estimated. Using estimations of 1.36 for design effect (DE), 80% power, 5% significance level and a 20% drop-out rate, the calculated sample size was 306 patients distributed over 24 practices (clusters).

Randomisation and blinding

Concealed randomisation was performed in blocks of four practices using a computer-generated allocation sequence, after patient recruitment and collection of baseline data, by the Centre for Clinical Studies at the Jena University Hospital. Blinding of practices was not feasible. However, an attempt to conceal allocation for patients was made. At follow-up, patients were asked *"In your opinion, did you receive new or more-of-the-same information?"* Assessment of the primary endpoint, data entry and analyses were kept blinded against study allocation.

Statistical analysis

Statistical analyses were carried out by intention-to-treat.[27] For main endpoints, missing data was imputed using the method of multiple imputations. Therefore, an extensive set was used of baseline covariates and, when appropriate, outcome specific variables, i.e., blood pressure, age, gender, graduation status and prescribed medication.

Generalised mixed models were fitted to compare the groups with respect to rates of adherence, informed choice and individual goal achievement, with intervention as a fixed effect and practices as a random effect. Cluster-adjusted OR and 95% confidence intervals (CI) were calculated. We used linear mixed models to compare study groups regarding average differences between planned and achieved values of blood pressure and HbA1c, the level of knowledge, realistic expectations and change of clinical parameters (from baseline to 6-months follow-up). Cluster-adjusted mean differences with 95% CI were calculated. No central laboratory analysis was carried out for the study, as practices contract various laboratories. Deviations from the protocol are described in data supplement: S1.

Process evaluation

Barriers and facilitators of implementing the ISDM-P in routine care were identified using the documentation from the MAs for the teaching sessions as well as interviews with MAs and GPs of each ISDM-P practice. Interviews focused on workload and attitudes towards the ISDM-P as well as on experiences with teaching, such as organisational aspects or use of teaching material.

Results

Of the 307 invited general practices, 22 were recruited; of the 363 eligible patients, 279 participated (with informed consent). Eleven practices (with 151 patients) were randomised to ISDM-P, and 11 practices (with 128 patients), to standard care (Fig. 1). Baseline characteristics were comparable between groups (Table 1). Fifteen patients of the ISDM-P group did not

participate in the teaching session and eight were lost to follow-up. In the control group, three patients were lost to follow-up. About half of the patients in both groups thought they received the usual information. More patients in the ISDM-P group responded that they received new information (38% compared to 19%).

Primary outcome

At follow-up, 218 patients were prescribed antihypertensive drugs and 107 patients, statins. Adherence rates to antihypertensive and statin medications were high for both groups, with no difference between groups (Table 2). Missing data did not affect the results.

Secondary outcomes

More ISDM-P patients made informed choices regarding statin intake, blood pressure control and glucose control (Table 3). There were less than 20% smokers in both groups. We found no difference in informed choices regarding smoking cessation. A total of 136 ISDM-P patients (90%) and 109 control group patients (85%) completed the knowledge test (score of 0 to 11). The mean score was 6.96 for ISDM-P, versus 2.86 for the control group (adjusted mean difference 4.06 [2.96 to 5.17]; <0.001). The mean score for the domain realistic expectations (score of 0 to 5) was 3.09 for ISDM-P patients, versus 0.92 for standard care patients (2.18 [1.67 to 2.69]; <0.001) (data supplement S4). Significantly more ISDM-P patients had adequate risk knowledge (Table 3).

For estimating personal heart attack risk, 131 ISDM-P and 96 standard care patients participated. The absolute difference of the patient estimated individual risks and objective risks was greater in the control group (5.5% versus 31.1%; adjusted difference –25.6% [–30.4% to –20.8%]; <0.001). This result was confirmed after multiple imputation of missing data. Notably, most patients in the control group overestimated their personal heart attack risk (data supplement S5 and S6).

There was no difference between groups with respect to meeting treatment goals at follow-up. Most patients in both groups achieved their goals regarding statins (85.8% of ISDM-P patients versus 87% of control group patients), blood pressure (93.7% versus 90%), and HbA1c (94.7% versus 89.1%) (data supplement S7). No substantial changes within groups from baseline to follow-up were observed for HbA1c levels, systolic blood pressure values, total cholesterol levels, LDL cholesterol levels or medication prescriptions (data not shown).

Prioritisation of treatment goals differed significantly between groups. More ISDM-P patients prioritised blood pressure control rather than HbA1c targets (28% versus 12%; $p < 0.015$) (data supplement S8).

Matching of treatment goals of GPs and patients were higher for the ISDM-P group (Table 4). Significant differences in favour of the ISDM-P group were found for treatment goals regarding blood pressure values, HbA1c-levels and the prioritised goal. These results remained unchanged after multiple imputation of missing data.

Process evaluation

Characteristics of practices, such as numbers of employed MAs, GPs and patients, were comparable between groups (data supplement S9).

ISDM-P patient teaching module

Overall, 35 teaching sessions were provided by ISDM-P practices. MAs conducted 2 to 6 sessions that lasted between 50 and 120 minutes. Group sizes varied from one to seven patients. MAs stated that they felt well prepared for the ISDM teaching module. Role playing and question cards related to the content of the ISDM-P were identified as facilitators for training success. Before the study, MAs were unfamiliar with risk communication. Some MAs and some patients indicated that there was too much statistics to explain/understand, while a few patients stated that there was not enough information about statistics. Overall, MAs felt that patients were

appreciative for the opportunity to participate in the decision making process and to define their own treatment goals.

ISDM-P consultations

Patients consulted their GPs directly after the teaching session or within one to three weeks afterwards. The consultations lasted between 5 and 20 minutes (mean 11.4 minutes). GPs stated that the patients had been well prepared for decision making by their MAs, which was *"better than expected"* and *"better than usual"*. They experienced changes in communication following the ISDM-P teaching module. One GP stated that former consultations were more *"instructive, demanding, and in some ways authoritarian"*, and found that after training, patients and professional teams "*meet on an equal footing"*.

Workload

MAs described the efforts of training and practicing for the teaching module as similar as for standard DMP patient education modules. Most GPs and MAs described the overall workload as appropriate. GPs considered the intended distribution of work within the team as helpful and reduced workload. Most practices would provide the ISDM-P in routine care if it was covered by health insurances. See supplement S9 for more details.

Discussion

Statement of principle findings

Results from our single centre proof-of-concept RCT[21] were confirmed in this multicentre cluster RCT. The programme could be translated from a university-based diabetes centre to everyday primary care. ISDM-P patients were more likely to make informed choices, while the standard care control group did not make informed decisions. The ISDM-P group showed increased knowledge and realistic expectations regarding their individual cardiac risk and probabilities of the benefits and harms of preventive treatment options. Treatment goals between patients and their physicians were more matched for the intervention group. The patient-held documentation

sheet of personal treatment objectives supported patients and GPs in deliberating treatment goals and preferences. In fact, better informed patients appeared to trigger more rational evidence-based goal setting among physicians. Contrary to our predefined hypotheses, adherence to medication was very high overall in this study population, making further improvements undetectable. Overall, we believe that the ISDM-P was successfully implemented in the general practices.

Strengths and weaknesses of the study

Our study has several strengths. The intervention has been developed and evaluated according to the UK MRC framework for complex interventions.[28] Efficacy was demonstrated in an RCT under high fidelity conditions.[21] Findings of the RCT and qualitative process data were used to optimize the ISDM-P.[27] A recent publication has reviewed important barriers of SDM.[5] Our programme already addresses these barriers.

In order to facilitate integration into everyday practice, the structure and duration of the ISDM-P teaching session were adapted to standard teaching modules of the DMP.[22-25] The cluster RCT was meticulously designed and conducted with a low drop-out rate. Additional qualitative methods were used to gain insight into implementation processes.

The weaknesses of the study include the inability to blind the study for the healthcare team for study allocation, due to the nature of the intervention. It also remains unclear to what degree patients were kept blinded. Further, we could not document the extent of SDM. There is no gold standard to quantify patient involvement,[27 39] and the use of decision aids does not accurately reflect SDM.[40] Video-taping and available instruments, such as MAPPIN'SDM, are not applicable for routine care conditions.[41] Thus, we had to define surrogate parameters. Risk knowledge is a prerequisite of informed SDM. The proof-of-concept RCT[21] showed that patients with standard care lack the necessary risk knowledge. Therefore, we used knowledge and informed choice as secondary endpoints. We hypothesised that successful ISDM would enable more patients to set

and achieve realistic and personally defined treatment goals. However, patients were already well controlled at the beginning of the study. Study participants were followed in the German DMP for type 2 diabetes. All had received structured education and were closely monitored. The proof-of-concept RCT indicated lower adherence rates to statin prescriptions in the standard care group. Adherence is a patient relevant endpoint that may reflect successful ISDM when it is based on adequate knowledge and mutual agreement on treatment goals between patients and health professionals. We hypothesised that patients would be more adherent to medication when prescriptions were based on SDM principles. However, in the present cluster RCT, adherence to antihypertensive medication and statins was very high already under standard care. Patients' self-reported adherence to medication uptake was used to assess the primary endpoint. Telephone interviews were conducted independently from practices, but socially desirable answers cannot be completely ruled out. The interviewer asked patients to read out the substance that was labelled on the medication boxes. To do that, patients had to have the medication box at home. No changes from baseline to follow-up were observed for prescription rates or clinical parameters (such as levels of HbA1c, blood pressure and cholesterol). Thus, it is very likely that adherence was already high at baseline. Generalizability of our results to other health care systems remains speculative. Our study participants had unexpectedly high adherence rates to prescribed medications and overall good control of diabetes and hypertension. This might be a result of diabetes care within the disease management programme for patients with type 2 diabetes in Germany. In populations with lower adherence rates, the ISDM¬ P could presumably improve adherence to medication. Our patient-held documentation sheet improved matching of treatment goals between patients and GPs and therefore might be used as a surrogate indicator for SDM. This sheet is an integral part of the intervention for supporting patient participation and, at the same time, a tool for the documentation of common treatment goals.

Strengths and weaknesses in relation to other studies, discussing important differences in results

The S*tatin Choice Decision Aid* was tested regarding statin adherence in a specialised clinic,[14] one primary care centre,[13] and several primary care practices in Spain.[15] Improvement of adherence was only found in the specialised clinic.[14] The *Diabetes Medication Choice Decision Aid* had no impact on adherence,[17] while one study even reported a better outcome in the control group.[16] In all publications, adherence rates were very high already under standard care. This is consistent with our study.

In a recent cluster RCT from the Netherlands (OPTIMAL), an SDM intervention also aimed at enhancing patients' achievement of treatment goals.[12] Patients were asked to choose between an intensive treatment strategy according to the ADDITION protocol and a less intensive treatment based on guideline recommendations. The findings showed no significant difference between the groups. Almost half of the patients in the intervention group switched from less intensive to intensive treatment.[12] However, benefits from intensifying therapy in type 2 diabetes are questionable. In our previous RCT on the ISDM-P, more patients achieved their HbA1c level goals because they set slightly higher HbA1c targets after the teaching session.[21] We offered and supported patients to prioritise and set realistic treatment goals. GPs of the OPTIMAL trial found the decision aid helpful, but it remains unclear if patients understood the information.[12] Most of the ISDM-P consultations with the GP did not take longer than usual consultations, with a mean duration of about 11 minutes. The implementation trial of the S*tatin Choice Decision Aid* in Spain reported consultation times of almost 20 minutes without significant differences between intervention and control groups.[15] In our study, GPs just had to perform the last steps of the SDM process, as patients had been well prepared for decision making by MAs. Hence, GPs could discuss four health topics—blood glucose, blood pressure, statin use and smoking—and related treatment options with their patients in a single encounter. The duration of the group teaching session provided by MAs was comparable to other DMP teaching sessions.

Recently, Ballard et al. (2017) assessed the routine use of the *Statin Choice Decision Aid* and the *Diabetes Medication Choice Decision Aid* in a tertiary care centre under routine care.[40] Half of the clinicians used the statin choice decision aid and 9% the medication choice decision aid. Reasons for not using the material were lack of awareness that the tools were available, time constraints and attitudinal barriers, e.g. clinicians found the decision aids not helpful or not accurate.[40] Recommendations to address such barriers are workshops to improve SDM skills, development of brief evidence-based consultation tools, interventions to prepare patients in decision making and the development of measurements to be used in practice to identify knowledge gaps and preferences.[5] Our ISDM intervention already addresses all these aspects. The ISDM-P training included a demonstration of a patient teaching session and role play in order to help teams gain more insight into differences between usual counselling and SDM-based consultations. Our training took longer than trainings in other studies, but this time duration was perceived as appropriate by participants.

Meaning of the study: possible explanations and implications for clinicians and policymakers

In our study, we determined that patients under standard care did not have adequate risk knowledge to make informed decisions. Healthcare providers do not have access to education and patient information material which fulfil the criteria for evidence-based health information. The ISDM-P remedies this: it not only provides understandable and relevant risk information to healthcare personnel and patients, it also enables a patient-physician communication on equal footing and helps patients and GPs to pursue common treatment goals as recommended in DMP guidelines. Our study shows that the ISDM-P can be integrated in everyday practice without large extra effort. It meets the criteria to be covered by health insurance companies.

Unanswered questions and future research

Further research will focus on extending the ISDM-P concept to other clinical decisions. In particular, drug facts boxes on the increasing number of oral antidiabetic agents should be made available. Structured treatment and teaching programmes need to be updated and optimised based on criteria for evidence-based patient information and SDM.[22 25 42] Web-based formats allowing individual training and exchange with health care professionals have to be developed. This will also allow a more personalised selection of teaching modules on diabetes or hypertension care.

Current clinical practice guidelines do not provide well-structured information on benefits and harms of medication or other treatments that could readily be used within consultations with patients. Fact boxes or other decision tools should be considered in guideline development.[3 43]

Finally, open access trainings in evidence-based medicine, risk information and SDM for healthcare providers are required. Maintaining and updating an entire ISDM treatment and teaching programme, will require an up-to-date online platform for patients and healthcare providers.

The implementation of the ISDM-P concept would meet national and international guideline recommendations as well as the patients' ethical and legal rights on true involvement in decision making.

Acknowledgements

We thank the medical assistants, physicians and participating patients of all 22 primary care practices. We also thank Susanne Kählau-Meier for her valuable support in data collection and administration as well as Veronica A. Raker for editing the manuscript.

Contributors

The study was carried out in collaboration between all authors. SB and IM designed the study. SB and KL designed and tested the provider training. SB, NK and UAM were involved in the

planning, coordination and management of data acquisition at the study sites (primary care practices). TL did the statistical planning and analyses of the study. SB and IM wrote the first draft of the manuscript. NK, KL and UAM contributed to the draft of the manuscript. All authors critically revised the manuscript and approved the final version. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

Funding

This study was funded by the European Foundation for the Study of Diabetes (EFSD) on behalf of the European Association for the Study of Diabetes (EASD). NK's salary has been partly financed by the non-profit association "Diabeteszentrum Thüringen e.V." [Diabetes Centre Thuringia]. The EFSD and the Diabetes Centre Thuringia had no role in the design of the study, collection, analysis, and interpretation of data, and preparation and approval of the manuscript.

Competing interest

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: SB, NK, KL, and TL report grants from the EFSD during the conduct of the study; NK reports grant from the Diabetes Centre Thuringia during the conduct of the study; UAM and IM received no support from any organisation for the submitted work; all authors had no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Ethics approval

The study protocol was approved by the ethics committee of the Medical Association of Thuringia in April 2014 (ref: 29739/2014/31). All participants gave informed consent before taking part.

Data sharing

The corresponding author can be contacted to forward request for data sharing.

Transparency

The lead author (SB) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported. No important aspects of the study have been omitted. Discrepancies from the study as planned have been explained.

Copyright

References

[1] German Medical Association, National Association of Statutory Health Insurance Physicians, Association of the Scientific Medical Societies. Nationale VersorgungsLeitlinie Therapie des Typ-2-Diabetes – Langfassung 2013; Available from http://www.leitlinien.de/nvl/diabetes/therapie. Accessed 19 Mar 2018 [Guideline in German].

[2] Inzucchi SE, Bergenstal RM, Buse JB et al. Management of hyperglycemia in type 2 diabetes, 2015: a patient-centered approach: update to a position statement of the American Diabetes Association and the European Association for the Study of Diabetes. *Diabetes Care* 2015;38:140-49.

[3] Rutten GEHM, Alzaid A. Person-centred type 2 diabetes care: time for a paradigm shift. *Lancet Diabetes Endocrinol* 2017;Jun 9: doi: 10.1016/S2213-8587(17)30193-6.

[4] Rodriguez-Gutierrez R, Gionfriddo MR, Ospina NS et al. Shared decision making in endocrinology: present and future directions. *Lancet Diabetes Endocrinol* 2016;4:706-716.

[5] Joseph-Williams N, Lloyd A, Edwards A et al. Implementing shared decision making in the NHS: lessons from the MAGIC programme. *BMJ* 2017;357:j1744.

[6] Agoritsas T, Heen AF, Brandt L et al. Decision aids that really promote shared decision making: the pace quickens. *BMJ* 2015;350: g7624.

[7] Scholte op Reimer WJ, Moons P, De Geest S et al. Cardiovascular risk estimation by professionally active cardiovascular nurses: results from the Basel 2005 Nurses Cohort. *Eur J Cardiovasc Nurs* 2006;5:258-63.

[8] Mühlhauser I, Kasper J, Meyer G. Understanding of diabetes prevention studies: questionnaire survey of professionals in diabetes care. *Diabetologia* 2006;49:1742-1746.

[9] Gigerenzer G, Gaissmaier W, Kurz-Milcke E, Schwartz LM, Woloshin S. Helping doctors and patients to make sense of health statistics. *Psychol Sci Public Interest* 2007;8:53-96.

[10] Montori VM, Kunneman M, Brito JP. Shared decision making and improving health care: the answer is not in. *JAMA* 2017;318: 617-8.

[11] Stacey D, Legare F, Lewis K et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev* 2017;4:Cd001431.

[12] Den Ouden H, Vos RC, Rutten GEHM. Effectiveness of shared goal setting and decision making to achieve treatment targets in type 2 diabetes patients: a cluster-randomized trial (OPTIMAL). *Health Expect* 2017;20:1172-80.

[13] Mann DM, Ponieman D, Montori VM, Arciniega J, McGinn T. The statin choice decision aid in primary care: a randomized trial. *Patient Educ Couns* 2010;80:138-40.

[14] Weymiller AJ, Montori VM, Jones LA et al. Helping patients with type 2 diabetes mellitus make treatment decisions: statin choice randomized trial. *Arch Intern Med* 2007;167:1076-82.

[15] Perestelo-Perez L, Rivero-Santana A, Boronat M et al. Effect of the statin choice encounter decision aid in Spanish patients with type 2 diabetes: a randomized trial. *Patient Educ Couns* 2016;99:295-9.

[16] Mullan RJ, Montori VM, Shah ND et al. The diabetes mellitus medication choice decision aid: a randomized trial. *Arch Intern Med* 2009;169:1560-8.

[17] Karagiannis T, Liakos A, Branda ME et al. Use of the diabetes medication choice decision aid in patients with type 2 diabetes in Greece: a cluster randomised trial. *BMJ Open* 2016;6:e012185.

[18] Mathers N, Ng CJ, Campbell MJ, Colwell B, Brown I, Bradley A. Clinical effectiveness of a patient decision aid to improve decision quality and glycaemic control in people with diabetes making treatment choices: a cluster randomised controlled trial (PANDAs) in general practice. *BMJ Open* 2012;2:e001469.

[19] Denig P, Schuling J, Haaijer-Ruskamp F, Voorham J. Effects of a patient oriented decision aid for prioritising treatment goals in diabetes: pragmatic randomised controlled trial. *BMJ* 2014;349:g5651.

[20] Lenz M, Kasper J, Mühlhauser I. Development of a patient decision aid for prevention of myocardial infarction in type 2 diabetes - rationale, design and pilot testing. *Psychosoc Med* 2009;6:Doc05.

[21] Buhse S, Mühlhauser I, Heller T et al. Informed shared decision-making programme on the prevention of myocardial infarction in type 2 diabetes: a randomised controlled trial. *BMJ Open* 2015;5:e009116.

[22] Grüsser M, Bott U, Ellermann P, Kronsbein P, Jörgens V. Evaluation of a structured treatment and teaching program for non-insulin-treated type II diabetic outpatients in Germany after the nationwide introduction of reimbursement policy for physicians. *Diabetes Care* 1993;16:1268-75.

[23] Kronsbein P, Mühlhauser, Jörgens V, Scholz V, Venhaus A, Berger M. Evaluation of a structured treatment and teaching programme on non-insulin-dependent diabetes. *Lancet* 1988;2:1407-11.

[24] Grüsser M, Hartmann P, Schlottmann N, Jörgens V. Structured treatment and teaching programme for type 2 diabetic patients on conventional insulin treatment: evaluation of reimbursement policy. *Patient Educ Couns* 1996;29:123-30.

[25] Müller UA, Müller R, Starrach A et al. Should insulin therapy in type 2 diabetic patients be started on an out- or inpatient basis? Results of a prospective controlled trial using the same treatment and teaching programme in ambulatory care and a university hospital. *Diabetes Metab* 1998;24:251-55.

[26] Busse R. Disease management programs in Germany's statutory health insurance system. *Health Aff (Millwood)* 2004;23:56-67.

[27] Buhse S, Mühlhauser I, Kuniss N 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.

[28] Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008;337:a1655.

[29] 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.

[30] Pfadenhauer LM, Gerhardus A, Mozygemba K et al. Making sense of complexity in context and implementation: the Context and Implementation of Complex Interventions (CICI) framework. *Implement Sci* 2017;12:21.

[31] Pinnock H, Barwick M, Carpenter CR et al. Standards for Reporting Implementation Studies (StaRI) Statement. *BMJ* 2017;356:i6795.

[32] Busse R, Blumel M, Knieps F, Barnighausen T. Statutory health insurance in Germany: a health system shaped by 135 years of solidarity, self-governance, and competition. *Lancet* 2017;390:882-97.

[33] Fuchs S, Henschke C, Blumel M, Busse R. Disease management programs for type 2 diabetes in Germany: a systematic literature review evaluating effectiveness. *Dtsch Arztebl Int* 2014;111:453-63.

[34] German Medical Association, National Association of Statutory Health Insurance Physicians, Association of the Scientific Medical Societies. Nationale VersorgungsLeitlinie Diabetes – Strukturierte Schulungsprogramme – Langfassung. Available from http://www.leitlinien.de/nvl/diabetes/schulungsprogramme 2012; Accessed 19 Mar 2018 [Guideline in German].

[35] Joseph-Williams N, Elwyn G, Edwards A. Knowledge is not power for patients: a systematic review and thematic synthesis of patient-reported barriers and facilitators to shared decision making. *Patient Educ Couns* 2014;94:291-309.

[36] Légaré F, Adekpedjou R, Stacey D et al. Interventions for increasing the use of shared decision making by healthcare professionals. *Cochrane Database Syst Rev* 2018;7: CD006732.

[37] 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].

[38] Marteau TM, Dormandy E, Michie S. A measure of informed choice. *Health Expect* 2001;4:99-108.

[39] Gärtner FR, Bomhof-Roordink H, Smith IP, Scholl I, Stiggelbout AM, Pieterse AH. The quality of instruments to assess the process of shared decision making: A systematic review. *PLoS One* 2018;13:e0191747.

[40] Ballard AY, Kessler M, Scheitel M, Montori VM, Chaudhry R. Exploring differences in the use of the statin choice decision aid and diabetes medication choice decision aid in primary care. *BMC Med Inform Decis Mak* 2017;17:118.

[41] Kasper J, Heesen C, Köpke S, Fulcher G, Geiger F. Patients' and observers' perceptions of involvement differ. Validation study on inter-relating measures for shared decision making. *PLoS One* 2011;6:e26255.

[42] Mühlhauser I, Sawicki PT, Didjurgeit U, Jörgens V, Trampisch HJ, Berger M. Evaluation of a structured treatment and teaching programme on hypertension in general practice. *Clin Exp Hypertens* 1993;15:125-42.

[43] Mühlhauser I, Meyer G. Evidence base in guideline generation in diabetes. *Diabetologia* 2013;56:1201-9.

Tables

Table 1. Baseline characteristics of patients.

Characteristic	ISDM-P group (n = 151)	Control group (n = 128)
Women	67 (44.4)	59 (46.1)
Age, years	59.5 (6.5)	58.7 (7.9)
Duration of diabetes, years[a]	8.5 (6.5)	7.5 (6.2)
Systolic blood pressure, mmHg[b]	140 (15.1)	140 (16.0)
Diastolic blood pressure, mmHg[b]	81 (8.9)	84 (8.5)
Body mass index, kg/m^2 [c]	33.6 (5.3)	31.5 (6.7)
HbA1c, %[d]	7.0 (0.7)	7.0 (1.0)
Total cholesterol[b], mmol/l	5.2 (1.1)	5.3 (1.1)
HDL cholesterol[e], mmol/l	1.3 (0.4)	1.3 (0.4)
LDL cholesterol[e], mmol/l	3.2 (0.9)	3.4 (1.0)
Smoker (%)[f]	29 (19.2)	18 (14.5)
Diagnosis hypertension (%)[b]	134 (88.7)	115 (90.6)
Medication for blood pressure control (%)	129 (85.4)	104 (81.3)
Medication for glucose control	124 (82.1)	95 (74.2)
Insulin	36 (23.8)	28 (21.9)
Metformin	111 (73.5)	88 (68.8)
Sulfonylurea	21 (13.9)	10 (7.8)
Other antidiabetic agents	52 (34.4)	40 (31.3)
Statin medication	50 (33.1)	41 (32.0)
Participation in teaching session for hypertension[g] (%)	28 (21.1)	11 (10.1)
Graduation		
None	1 (0.7)	1 (0.8)
Junior high school	29 (19.2)	24 (18.8)
High school	93 (61.6)	86 (67.2)
Qualification for technical college or university	28 (18.5)	17 (13.3)

Values are given as patient number (percentage) or as means (SD); ISDM-P = Informed Shared Decision Making Programme;
[a]ISDM-P n = 151, control group n = 125; [b]ISDM-P n = 151, control group n = 127; [c]ISDM-P n = 150, control group n = 126; [d]ISDM-P n = 151, control group n = 128; [e]ISDM-P n = 150, control group n = 117; [f]ISDM-P n = 151, control group n = 124; [g]Patients with diagnosis of hypertension, ISDM-P n = 133, control group n = 109

Table 2: Primary endpoint: Adherence to antihypertensive or statin therapy

	ISDM-P group	Control group	adjusted OR [95% CI]; P value	MI: adjusted OR [95% CI]; *p* value	ICC
Antihypertensive drugs	96/118 (81.4)	71/90 (78.9)	1.2 [0.5 to 2.6]; 0.696	1.1 [0.5 to 2.4]; 0.812	0.176
Statins	51/58 (87.9)	43/45 (95.6)	0.4 [0.1 to 2.0]; 0.271	0.4 [0.1 to 1.4]; 0.139	0.000

Values are given as patient number (percentage); ISDM-P = Informed Shared Decision Making Programme; OR=odds ratio; MI=multiple imputation (N=279); ICC = intracluster coefficient

Table 3: Informed choice and adequate knowledge

	ISDM-P group	Control group	Adjusted OR [95% CI]; P value	MI: adjusted OR [95% CI]; *p* value
Adequate knowledge[a]	61/136 (44.9)	3/109 (2.8)	29.3 [6.9 to 124.6]; <0.001	21.4 [6.8 to 67.4]; <0.001
Informed choice: statins	43/128 (33.6)	3/105 (2.9)	16.6 [4.4 to 63.0]; <0.001	6.2 [2.4 to 16.0]; <0.001
Informed choice: blood pressure	50/129 (38.8)	3/109 (2.8)	22.2 [5.3 to 93.3]; <0.001	10.0 [3.3 to 30.4]; <0.001
Informed choice: HbA1c	57/134 (42.5)	3/109 (2.8)	26.0 [6.5 to 104.8]; <0.001	11.5 [4.0 to 33.1]; <0.001
Informed choice: smoking	3/23 (13.0)	0/16 (0)	5.1 [0.2 to 135.1]; 0.322	-

Values are given as patient number (percentage); ISDM-P = Informed Shared Decision Making Programme; OR=odds ratio; MI = multiple imputation (n = 279)

[a]at least eight out of eleven questions were correctly answered

Table 4: Match of treatment goals between physicians and patients

Treatment goal	ISDM-P group	Control group	Adjusted difference [95% CI]; P value	MI: adjusted difference [95% CI]; *p* value
Blood pressure[a]	3.06 mmHg (5.21)	6.89 mmHg (6.94)	–4.0 mmHg [–6.6 to –1.4]; 0.005	–3.1 [–5.6 to –0.5]; 0.019
HbA1c[b]	0.26% (0.33)	0.49% (0.49)	–0.2 [–0.4 to –0.1]; 0.003	–0.2 [–0.39 to –0.05]; 0.012
			Adjusted OR [95% CI]; P value	**MI: adjusted OR [95% CI]; P value**
Statins	114/127 (89.8)	81/104 (77.9)	2.4 [0.9 to 6.2]; 0.077	1.9 [0.7 to 4.8]; 0.181
Stop smoking	9/17 (52.9)	6/9 (66.7)	0.5 [0.1 to 4.0]; 0.537	0.6 [0.1 to 3.6]; 0.561
Prioritized goal	92/104 (88.5)	45/79 (57.0)	6.5 [3.0 to 14.4]; <0.001	2.6 [1.3 to 5.2]; 0.009

Values are given as patient number (percentage) unless stated otherwise. ISDM-P = Informed Shared Decision Making Programme; HbA1c = glycated haemoglobin; MI = multiple imputation (n = 279); OR=odds ratio

[a]adjusted mean difference between patients' treatment goals and physicians' treatment goals; values are means (standard deviation); ISDM-P n = 127, control group n = 95

[b]adjusted mean difference between patients' treatment goals and physicians' treatment goals; values are means (standard deviation); ISDM-P n = 133, control group n = 95

Figure. Study flow-chart.
ISDM-P = Informed Shared Decision Making Programme; GP = general practitioner; T1 = directly after counselling or usual care; T2 = 6-month follow-up

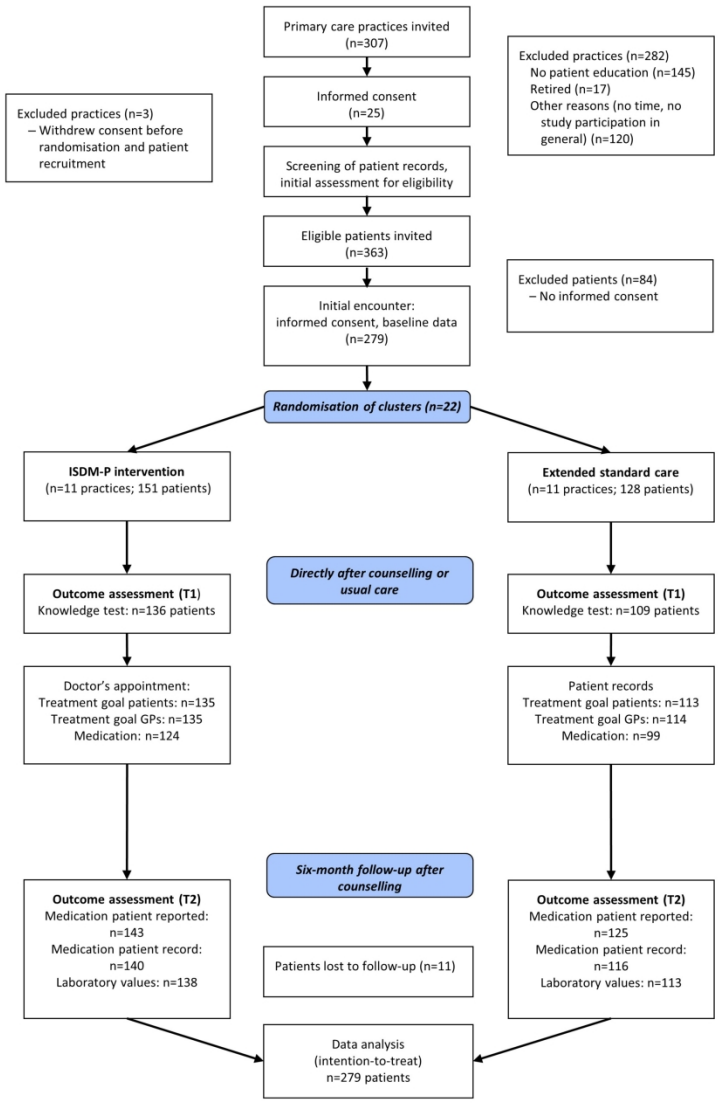

Figure. Study flow-chart.
ISDM-P = Informed Shared Decision Making Programme; GP = general practitioner; T1 = directly after counselling or usual care; T2 = 6-month follow-up

275x397mm (300 x 300 DPI)

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.

[2] Lenz M, Kasper J, Mühlhauser I. Development of a patient decision aid for prevention of myocardial infarction in type 2 diabetes - rationale, design and pilot testing. *Psychosoc Med* 2009;6:Doc05.

[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.

CONSORT 2010 checklist of information to include when reporting a cluster randomised trial

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	See table 2	3-4
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	6-7
	2b	Specific objectives or hypotheses	Whether objectives pertain to the the cluster level, the individual participant level or both	7, 10, study protocol [1]
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	7, study protocol [1]
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		12, data supplement S1
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	7-8, study protocol [1]
	4b	Settings and locations where the data were collected		7-8, study protocol [1]

Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	9, data supplement S2, study protocol [1]
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Whether outcome measures pertain to the cluster level, the individual participant level or both	10, study protocol [1], data supplement S3
	6b	Any changes to trial outcomes after the trial commenced, with reasons		Data supplement S1
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or *k*), and an indication of its uncertainty	10-11, study protocol [1]
	7b	When applicable, explanation of any interim analyses and stopping guidelines		n.a.
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		11, study protocol [1]
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	11, study protocol [1]
Allocation concealment	9	Mechanism used to implement the random allocation sequence (such	Specification that allocation was based on clusters rather than individuals and whether	11, study protocol [1]

mechanism		as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	allocation concealment (if any) was at the cluster level, the individual participant level or both	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	8-9, data supplement S1
	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	8-9, data supplement S1
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those		10-11

		assessing outcomes) and how		
	11b	If relevant, description of the similarity of interventions		9, data supplement S2, study protocol [1]
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	11-12, study protocol [1]
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		11-12, study protocol [1]
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	12, Fig 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members	12, Fig 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up		8-9, data supplement S1
	14b	Why the trial ended or was stopped		n.a.
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Baseline characteristics for the individual and cluster levels as applicable for each group	Table 1, data supplement S9

Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	Tables 2-4, data supplement S4-S8
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	12-13, Tables 2-4, data supplement S4-S8
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		12-13, Tables 2-4, data supplement S4-S8
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		12-13
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)		14-15, data supplement S9
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		15-16

Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	15, 17-18
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		15-16, 18
Other information				
Registration	23	Registration number and name of trial registry		4
Protocol	24	Where the full trial protocol can be accessed, if available		7, study protocol [1]
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders		20

** Note: page numbers optional depending on journal requirements*

[1] Buhse S, Mühlhauser I, Kuniss N 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.