

Revisión

Patient education programmes and decision aids - evaluation of complex interventions*

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**This is a reduced version without tables. The extended version including tables is available at www.sediabetes.org*

Abstract

Patients have the right to make informed decisions on treatment goals and treatment regimens and also to be provided with reliable information necessary for decision-making. Evidence-based medicine explicitly integrates patients' values and preferences in treatment decisions. Both are regarded as crucial to increase both the patients' quality of care and independence. Education programmes or patient decision aids are complex interventions, typically comprising separate components acting interdependently (e.g. content, structure, and media of an education programme). They are heterogeneous in their goals, methods and target populations. Development and evaluation of complex interventions are sophisticated processes requiring both qualitative and quantitative methods. In a previous review we showed that common methodologies used in systematic reviews do not allow adequate appraisal of complex interventions. Patient education programmes were used as an example. The present review outlines present developments in patient education and shared decision making in diabetes care. It also comprises an update of the previous review. Methodological challenges of the development and evaluation of complex interventions are discussed. Methods of current systematic reviews do still not meet the challenges to appraise patient education and self-management programmes. Since these are complex and heterogeneous interventions, consideration of aggregated evidence is necessary. Information necessary for the evaluation of such programmes is difficult or impossible to identify. In conclusion we propose to establish a scientific network and database, which supports scientific exchange and systematic tagging of self-management programmes, patient education programmes and patient decision aids.

Keywords: self-management, education, diabetes, hypertension, systematic reviews.

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Introduction

Patients have the right to self-determination, to make free decisions regarding themselves. Patients have the right to make informed decisions on treatment goals and treatment regimens and to reliable information necessary for decision-making.¹ Evidence-based medicine explicitly integrates patients' values and preferences in treatment decisions.²⁻⁴ The successful implementation of patient education in diabetes has resulted in knowledgeable and independent patients. Recent approaches such as evidence based patient information and patient decision aids can support people to participate in decision making about health care options.

Traditionally, diabetes patient education was expert-based rather than evidence-based as reflected by a variety of non-evidence based dogmas.⁵ Diabetes education was restricted to dietary training. Regular self-monitoring (of urine glucose) was not an obligatory part of treatment, and patients with type 1 diabetes were not allowed to change insulin dosages themselves. The primary educational goal was to increase patient compliance to strict dietary regimens. Towards the end of the 1970s, the increasing acceptance of a causal relationship between glycemic control and microangiopathy led to an agreement for the primary therapeutic goal, i.e. near-normalization of metabolic control. Education, encouragement, and training of the patient to actively take over increasing parts of his/her therapy in order to stepwise render him/her more independent from physicians and medical institutions became primary objectives of patient education. The success of this approach has been documented in a large number of controlled trials carried out by a variety of research groups all over the world.^{6,7}

The present review outlines present developments in patient education and shared decision making in diabetes

care. It comprises an update of the previous review.⁸ We discuss methodological challenges of the development and evaluation of complex interventions and propose a set of key criteria, which should be taken into account when undertaking a systematic review on complex interventions. To resolve methodological problems related to the development and evaluation of education programmes and patient decision aids, we propose to establish an international scientific network.

Evidence-based patient choice and shared decision making in diabetes care

The successful implementation of patient education in diabetes has resulted in knowledgeable and independent patients. Their right to actively participate or eventually even to assume responsibility in medical decision-making processes is becoming obvious. The basis for informed patient choice is an unbiased communication of evidence-based scientific data in a format that can be understood by non-medically trained persons. The British General Medical Council published ethical guidelines for the procedures necessary to obtain patients' informed consent prior to undergoing any medical intervention.⁹ These are quite specific in stating that patients must be given sufficient information to enable them to exercise their right to make informed decisions about their care. For instance, this information needs to include details of the diagnosis, and the likely prognosis if the condition is left untreated; potential uncertainties about the diagnosis and options for further investigation prior to treatment; options for treatment or management of the condition, including the option not to treat. For each therapeutic option, the probabilities of success, the risks of failure, or harm as well as any lifestyle changes which may be caused by or necessitated by the treatment need to be explained using accurate data. The patient should be given time to reflect before and after making a decision, especially where the information is complex. The physician should abstain from making assumptions about patients' views; and information must not be withheld because of the possibility that the patient might become upset or decide to refuse a suggested investigation or treatment.⁹

The active involvement of patients in decision making about medical interventions has been increasingly advocated. In particular, in the chronic care setting, decision

making requires an active patient role.¹⁰ Previous systematic reviews found that interventions targeting patient autonomy (such as empowering group education) can result in measurable improvements in quality of life and in physiological markers of disease control.¹¹⁻¹³ In 1997 medical sociologists introduced the concept of shared decision making (SDM). SDM can be defined as the involvement of patients with their providers in making health care decisions that are informed by the best available evidence about treatment/screening/illness management options, potential benefits, and harms, and that consider patient preferences.¹⁴ The physician and patient together go through all phases of the decision-making process, share treatment preferences, and reach an agreement on treatment choice.

However, diabetes is usually not considered a typical disease for SDM even by protagonists of SDM.¹⁵ The belief is still widely held that control of blood glucose and other cardiovascular risk factors are beyond any doubt beneficial and therefore, supporting patients in adherence increasing behaviour rather than SDM has been standard procedure in diabetes care.¹⁶⁻¹⁸ By contrast, the large variety of available treatment options to improve prognosis on one hand and the poor adherence to long-term treatment on the other hand,^{19,20} urge SDM in diabetes care. Patients should be supported to define a hierarchy of individual goals and to triage interventions. This might facilitate long-term adherence to albeit a few but individually acceptable and possibly the most effective treatment interventions. From this point of view diabetes might even be prototypic for SDM.

Decision aids for people with diabetes

Patient decision aids are tools designed to help people participate in decision making about health care options.^{21,22} They typically provide information on the health problem and available treatment options. They are designed to help patients clarify and communicate the personal value they associate with different features of the options. Decision aids may include an estimate of probable treatment effects based on a patient's risk factors, exercises to help patients clarify their preferences, and proposed strategies for making informed decisions. Decision aids are supposed to be used when there is no single "best" choice among equally effective options or when the best choice depends on how patients balance benefits versus harms.

Patient decision aids typically consist of various elements (related to different topics, e.g. glucose control, blood pressure treatment), address a variety of health decisions (e.g. on preventative or curative treatment or diagnostic procedures), use various formats (e.g. decision boards, booklets, interactive software and videos),²¹ and aim to achieve various goals (e.g. to enhance knowledge, to generate realistic expectations and satisfaction with the decisions, and to strengthen patient autonomy).²¹ A decision aid can also be part of a decision-making programme, which additionally comprises a strategy for patient counselling or an introductory educational module. Effectiveness of decision aids has not been shown in general.²¹ Different tools developed to facilitate critical appraisal of decision aids include other important quality criteria (e.g. ethical aspects and theoretical basis).^{23,24} The International Patient Decision Aids Standards (IPDAS) Collaboration established internationally consented quality criteria²⁵ (table 1). Our research group developed MATRIX, a guide designed to structure a systematic development and evaluation of decision aids^{23,24} (for key criteria of MATRIX see table 1).

Transparency is an important quality criterion for the development of a decision aid. Authors should state whether and in which way a decision aid includes patient-relevant evidence-based information (including the strength of available evidence), and whether and in which way users are supported to deliberate about positive and negative features of options.^{23,24}

We have browsed the Internet perpetually and undertook systematic literature searches in October 2008 using the “Ottawa Inventory”,²⁶ PubMed, EMBASE, CINAHL, PsycINFO, and PSYNDExplus. Three evidence based decision aids specifically designed for people with diabetes were identified.²⁷⁻³¹ One additional decision aid was identified by personal contact.³² One publication about a diabetes decision aid was identified, which is still under evaluation and currently not available.³³ Our research group has developed an evidence based decision aid for coronary prevention in type 2 diabetes, which has been pilot-tested but is not yet available.

Characteristics of the four currently available diabetes-specific decision aids and related quality criteria according to IPDAS and MATRIX are summarised in table 1.

One of the identified decision aids refers to the use of an insulin pump in type 1 diabetes.²⁸ Patients are asked to deliberate about positive and negative features of options. Scientific references are cited. However, probabilities of benefits and harms are lacking. The second decision aid²⁷ was designed for women with type 1 diabetes deliberating about getting pregnant. The contents rely on expert recommendations. Evidence-based risk information that could help to deliberate about options is not provided. Sources of information are not transparently reported. The Health Dialog decision aid for patients with type 2 diabetes³² promotes modification of health behaviour in addressing smoking, diet and physical activity. A hierarchy of targets is suggested with emphasis on control of blood pressure and cholesterol rather than on blood glucose. Risk information on benefits and harms of options is not provided. Rather, patients are referred to their physicians. References are not listed. The “Statin Choice” decision aid targets treatment with statins in patients with type 2 diabetes.³⁰ This decision aid meets nearly all IPDAS-criteria (table 1). One limitation is that the external validity of the included risk calculator is unclear and problems with reliability of risk prognosis are not discussed.

Evidence about the implementation of these decision aids in clinical practice is lacking. Background information on development and evaluation was identified for one decision aid only.²⁹⁻³¹ Weymiller et al.³¹ randomly assigned 98 patients to the decision aid or a standard educational pamphlet. The decision aid was rated to be more helpful, enhanced knowledge, improved the estimation of the cardiovascular risk, reduced decisional conflict and also led to potential risk reduction with statin drugs. The follow-up was 3 months so long-term effects are unknown.

Development and evaluation of complex interventions

In diabetes care, single interventions (e.g. a single drug) coexist with complex interventions (e.g. treatment regimens, patient education and patient decision aids). Complex interventions typically comprise a number of components that may act interdependently and seem essential to their proper functioning.³⁴ A self-management programme for type 1 diabetes may illustrate the complexity.³⁵ Decisive components are the insulin regimen used and the quality of the teaching process to empower pa-

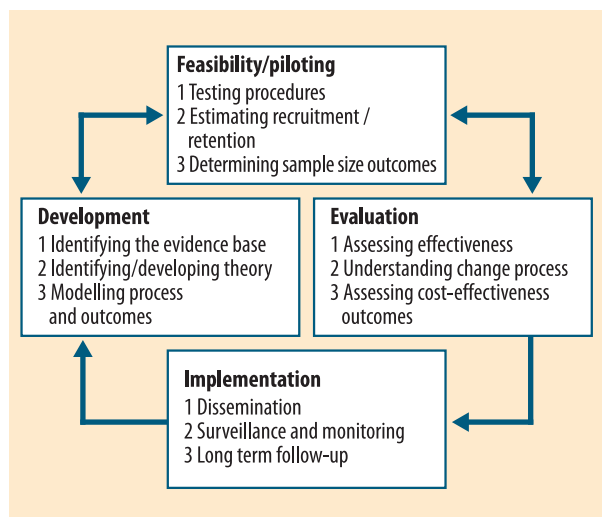


Figure 1. Key elements of the development and evaluation process (extracted from³⁴)

tients to carry it out effectively and safely. Empowerment of patients to set individual treatment goals and to balance favourable blood glucose targets and an acceptable risk of hypoglycaemia by self-adaptation of insulin dosages to adjust to lifestyle may be more effective than defining normoglycaemia as the primary treatment goal and asking patients to adapt their lifestyle to match prescribed doses of insulin.³⁶ Liberalisation of the diet may be important for motivation of patients to carry out an intensified insulin therapy regimen in the long-term.³⁷ Though indispensable, knowledge by itself may not improve outcomes. The information and how it is transmitted is decisive. Blood glucose self-monitoring may be at best useless unless patients have learned to interpret results and to react by adjusting insulin dosages.³⁵ In addition, the success of a diabetes self-management programme depends on the motivation and competence of the health care team and structural, organisational and financial conditions.

The U.K. Medical Research Council (UKMRC) proposed guidance on the development, evaluation and implementation of complex interventions.³⁴ Four stages of the development and evaluation process were defined (in the following “stages of evidence”, figure 1). Stage one comprises the “development” of the complex intervention. Before conducting substantial evaluation, the intervention should be developed to the point where it can reasonably be expected to have a worthwhile effect. It includes identifying the evidence base (e.g. systematic

review), identifying or developing appropriate theory about what changes are expected and how these changes can be achieved, and the modelling of process and outcomes. The latter includes prior evaluation to a full-scale evaluation to achieve information about the design of both the intervention and further evaluation (i.e. design and outcomes). Stage two (“feasibility and piloting”) includes testing procedures for their acceptability, estimating the likely rates of recruitment and retention of subjects, and the calculation of appropriate sample sizes for the full-scale evaluation. A mixture of qualitative and quantitative methods is likely to be needed. Stage three and four comprise quantitative methods: Core of stage three (“evaluation”) is the (randomised) controlled trial to assess the effectiveness. Stage four comprises the implementation of the complex intervention and long-term surveillance. Figure 1 summarises the key activities of each stage. The authors underline that the process would not follow a linear or even a cyclical sequence, which is indicated by the arrows between the “stages of evidence”.

Evaluation of complex interventions in systematic reviews

A high quality randomised controlled trial (RCT) is considered the most valid method to evaluate a medical intervention and a systematic review of high quality RCTs the most powerful evidence available.² A systematic review may, but need not, include meta-analysis as a statistical method for combining the results of individual studies. If used appropriately, meta-analysis is a powerful tool for investigating overall effects. However, if studies are clinically or methodologically heterogeneous, data-pooling may be meaningless and genuine differences in effects may be obscured.³⁸

Complex interventions are heterogeneous in their goals, methods and target populations. Thus, using meta-analysis to evaluate complex interventions may disregard the complexity of efficacy measures of the original studies. For example, GHb should not be used as a single outcome variable without considering individual treatment goals, and effects on hypoglycaemia, body weight or quality of life. Similarly, blood pressure values should not be used in isolation without taking into account intended changes in drug and non-drug therapy. Lowering of blood pressure may be associated with more or less drug prescriptions and linked adverse effects.³⁹

In a previous methodological review we described and critically appraised available methodologies of systematic reviews on complex interventions.⁸ Three patient education programmes of diabetes and hypertension self-management were used as an example (table 2). We had access to the bulk of publications on these programmes. Evidence for almost all phases of development had been generated; relevant components and outcome measures had been defined previously. The available evidence of these programmes was used as a reference to assess whether the included reviews consider the complexity of the programmes. Detailed information about the search strategies and methods of data collection and synthesis have been reported in the previous review.⁸ We updated the systematic searches and data analysis in October 2008. A total of 18 reviews were finally appraised (table 3). We identified several methodological problems.

Systematic searches

The majority of reviews report their (mostly comprehensive) search strategies transparently. In nine reviews the excluded studies were not reported.⁴⁰⁻⁴⁸ It was therefore not traceable whether or why particular programmes were not identified or not included. Experts in the field to identify additional publications were contacted in eight reviews.^{11,12,46,47,49-52} Reference tracking or hand searching was performed in 13 reviews.^{11,41,45-55} Only, one review reported that authors of the included publications were contacted to identify additional publications or unpublished material.¹¹ A systematic contact including all authors has not been reported in any review.

Stages of evidence

The selection criteria used in most of the reviews excluded study types other than RCTs; other important types of publications concerning the “stages of evidence” were rarely included (table 3). In some reviews limitations to publication year and/or publication type prevented the detection of publications referring to pilot or implementation studies of our three reference programmes, since some of these were published more than 20 years ago and do not always fulfil all quality criteria of nowadays standards. Nevertheless, all studies are part of the “stages of evidence” and could have been considered when evaluating the overall evidence.

No review differentiates between the core controlled trials and the controlled replication trials referring to the same programme. Those trials may differ in their methodology, which depends on their specific research question. However, the “stages of evidence” are closely related to each other and should be considered as parts of the same evaluation process.

Theoretical basis

The importance to consider the theoretical basis of a patient education programme was widely discussed^{11,12,40,43-45,47,48,52,53,55,56} but we could not identify any approach to systematically assess the theoretical basis and its influence on judging the quality of an education programme. Without considering the underpinning theory it is not possible to identify which components of the programmes are the most important ones, which goals are aimed at being achieved, and which outcome measures are appropriate to show efficacy. There might be only few authors of efficacy trials who report on all “stages of evidence” of their intervention. We have to acknowledge that the problems of considering theoretical funding may also be due to space limitations in printed journals.

Active components

All included reviews reported at least some features of the assessed interventions, which were either active components (e.g. setting, duration, interventionist, formal syllabus) or study characteristics (e.g. follow-up, age of participants, study quality). The investigated features were heterogeneous. Six reviews used regression or subgroup analysis in order to analyse the impact of single active components.^{11,42,46,49,52,55}

The majority of reviews reported that the included programmes had been “multifaceted” or “multidimensional” or “consist of multiple active components”. In two reviews the authors considered “multi-component interventions” only if the effects of the educational component could be examined separately.^{45,46} However, the separate analysis of the impact of certain single active components is problematic since the components can be closely inter-related. For example, within our reference programme for patients with type 2 diabetes the primary patient-oriented educational part may be as important as the preparatory course for the physicians and their assistants. Both are interdependent parts of the same complex intervention.

Categories of interventions

In 15 reviews^{11,12,40,42,44-46,48-55} the included programmes were allocated into categories of interventions. Those were defined according to the active components of the included interventions (e.g. setting, duration, interventionist, formal syllabus), to the type of the interventions (e.g. type of disease, type of activity, organisational interventions) targeted on patients or health professionals, or to the study characteristics (e.g. follow-up, age of participants, study quality). The applied categories varied and often seemed to be arbitrary. Each review used different categories; none of them explained the rationale of their categorization.

Allocation of complex interventions into categories can be problematic, even if categories are derived from core components of programmes (e.g. education directed to the patient). If the categories refer to single but interdependent components, the compartmentalization of efficacy is not possible. Regression and subgroup analyses were performed in eight reviews.^{11,42,46,47,49,51,52,55} Those tools are best used to explore heterogeneity.³⁸ However, these techniques should not be misused to identify the contribution of the various active components (e.g. intensity or duration of the program) on the overall effect (e.g. knowledge of the target group or the importance perceived by the provider).

Outcome assessment

We compared the outcome measures explored in the included reviews with the outcomes of our reference studies. The analysed reviews did not consider all patient relevant outcome parameters. Components of complex outcome measures were singled out, especially if they used meta-analysis. The complex interdependency between individual treatment goals and outcomes (e.g. changes in medication and metabolic or blood pressure control) remained unexplored.

Implications for research

Methodological challenges of evaluating complex interventions especially in systematic reviews have been increasingly discussed.^{7,8,57} The first version of the UKMRC approach of the evaluation of complex interventions⁵⁸ was published in 2000, which has recently been updated.³⁴ In our previous review on complex interventions in systematic reviews we identified and described several methodological problems.⁸ The

present update has shown that the same problems still exist.

Therefore, we again propose to take the following criteria into account when undertaking a systematic review on complex interventions:

- All studies referring to the development, evaluation and implementation should be considered. The reviewers should differentiate between “stages of evidence”. A comprehensive analysis of the underpinning theory should be performed.
- Information necessary for the evaluation of complex interventions is difficult or impossible to identify.^{8,55,59} Therefore, specific search strategies need to be developed and validated that aim at identifying publications concerning all “stages of evidence”. Literature searches should not be limited by criteria such as certain types of studies, specific target groups and publication dates. Reference tracking should be performed and authors should be contacted systematically.
- Interdependencies between the active components should be taken into account. Components should be identified, described and assessed, but only be examined separately if they are independent and should not be disassembled if they work interdependently. Complex interventions should not be allocated into categories referring to interdependent components.
- All relevant patient orientated outcome parameters should be included. Pooling of outcome measures across different complex interventions is usually inappropriate. Instead, the relative importance of outcomes⁶⁰ and the complex interdependency between treatment goals and outcomes should be described in detail.

In addition, we propose to establish an international scientific network to resolve the methodological problems related to the development and evaluation of education programmes and patient decision aids. The network should include a database, which supports scientific exchange and systematic tagging of self-management programmes, patient education programmes, and patient decision aids. In particular, the structure of the database should allow systematic identification of components that appear indispensable for best practice approaches for such programmes’ development, evaluation, and implementation. The database should be structured according to the UKMRC framework. Re-

searchers/authors should be asked to provide publications and materials in whatever language, which can be continuously supplemented and updated. Materials and publications could be translated in agreement with copyright regulations. The system should be opened to critical exchange between users (WIKI-approach). Distinct scientific rules for reporting and critical appraisal should be implemented.

Conclusions

Various different approaches in patient education exist, varying across diseases and health care systems. Despite the availability of various evaluation strategies, development, systematic identification and appraisal of educational remain challenging. A web-based international scientific network and database of self-management programmes for chronic diseases could facilitate further research. ■

Declaration of potential conflicts of interest

None of the authors have a duality of interest with regard to this work.

Practical considerations

- Patients have the right to make informed decisions on treatment goals and treatment regimens and also to be provided with reliable information necessary for decision-making.
- Methods of current systematic reviews do still not meet the challenges to appraise patient education and self-management programmes.
- A scientific network and database, which supports scientific exchange and systematic tagging of self-management programmes, patient education programmes and patient decision aids, is currently needed.

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BOLETÍN DE INSCRIPCIÓN

Rellena este formulario y remítelo por fax a **M.^a Eugenia Ruiz** (914 020 227)



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Presentado por

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Domiciliación bancaria (cuota anual 52,50 €)

Entidad	Sucursal	D.C.	N.º cuenta
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Firma

Appendix

Table 1. Decision aids for people with diabetes

Title	Should I get an insulin pump?	I have diabetes. Should I get pregnant now?	Living with diabetes. Making life style changes to last a life time	Statin choice
Publisher	Healthwise, US	Healthwise, US	Health Dialog, Foundation for Medical Informed Decision Making, US	Mayo Foundation, US
Scientific background publication(s)	Unknown	Unknown	Unknown	Available ²⁹⁻³¹
Type of diabetes	Type 1 diabetes	Type 1 diabetes	Type 2 diabetes	Type 2 diabetes
Topics	Insulin pump	Getting pregnant	Losing weight, physical activity, healthy eating quitting smoking, controlling blood pressure, controlling cholesterol, controlling blood sugar	Statin use
Last update	2007	2008	2007	2008
Format	Web	Web	Video, booklet, diabetes management worksheet, and "Questions to Ask My Doctor About my Diabetes"-form	Booklet, Coronary Heart Disease Calculator; decision sheets (average, elevated, and high coronary risk)
Language	English	English	English	English, Spanish
Availability	Publicly available for free from a number of Web sites	Publicly available for free from a number of Web sites	The DA can be requested from the Foundation for Medical Informed Decision Making	Publicly available for free from http://mayoresearch.mayo.edu
IPDAS-Criteria (IPDAS 2005)				
The DA describes the condition related to the decision	Yes	Yes	Yes	Yes
The DA describes the decision that needs to be considered	Yes	Yes	Yes	Yes
The DA lists the options	Yes	Yes	Yes	Yes
The DA describes what happens in the natural course of the condition if no action is taken	No	NA	Yes	Yes
The DA has information about the procedures involved	Yes	NA	Yes	Yes
The DA has information about the positive features of the options	Yes	Yes	Yes	Yes
The DA has information about negative features of the options	Yes	Yes	Yes	Yes
The information about outcomes of options (positive and negative) includes the chances they may happen	No	No	Only for quitting smoking	Yes

Continued

Table 1. Decision aids for people with diabetes

Title	Should I get an insulin pump?	I have diabetes. Should I get pregnant now?	Living with diabetes. Making life style changes to last a life time	Statin choice
The DA presents probabilities using event rates in a defined group of people for a specified time	No	No	No	Yes
The DA compares probabilities of options using the same denominator	No	No	No	Yes
The DA compares probabilities of options over the same period of time	No	No	No	Yes
The DA uses the same scales in diagrams comparing options	No	No	No	Yes
The DA asks people to think about which positive and negative features of the options matter most to them	Yes	Yes	No	Yes
The DA makes it possible to compare the positive and negative features of the available options	Yes	Yes	Only for quitting smoking	Yes
The DA shows the negative and positive features of the options with equal detail	Yes	Yes	No	Yes
Users (people who previously faced the decision) were asked what they need to prepare them to discuss a specific decision	No	Unknown	General policy of Health Dialog	Yes
The DA was reviewed by people who previously faced the decision who were not involved in its development and field testing	No	Unknown	Unknown	Yes
People who were facing the decision field tested the decision aid	Unknown	Unknown	Unknown	Yes
Field testing showed that the DA was acceptable to users	Unknown	Unknown	Unknown	Yes
Field testing showed that people who were undecided felt that the information was presented in a balanced way	Unknown	Unknown	Unknown	Unknown
The DA provides references to scientific evidence used	Yes	No	Yes	Yes
The DA reports the date when it was last updated	Yes	Yes	Yes	Yes

Continued

Table 1. Decision aids for people with diabetes

Title	Should I get an insulin pump?	I have diabetes. Should I get pregnant now?	Living with diabetes. Making life style changes to last a life time	Statin choice
The DA reports whether authors of the DA or their affiliations stand to gain or lose by choices people make after using the decision aid	No	No	Yes	Yes
There is evidence that the DA helps people know about the available options and their features	Unknown	Unknown	Unknown	Yes
There is evidence that the DA improves the match between the features that matter most to the informed person and the option that is chosen	Unknown	Unknown	Unknown	Unknown
Additional Criteria according to MATRIX (Lenz 2007)*				
The objectives of the DA are reported	No	No	No	Yes
An explicit rationale for the selection of the objectives is reported	No	No	No	Yes
The contents of the DA are evidence-based	NA (references not cited)	NA (references not cited)	NA (references not cited)	Yes
Structure, complexity, and used media are appropriate und support users to deliberate about options	Yes	Yes	Yes	Yes
Randomised controlled trial(s) is/are published assessing the efficacy of the decision aid	No	No	No	Yes
Design and methods (randomisation, allocation, blinding etc.) of these trial(s) is/ are transparently described	NA	NA	NA	Yes
Used outcome measures are patient relevant and represent the particular objectives of the decision aid	NA	NA	NA	Yes
Implementation trials assessed the effectiveness under uncontrolled conditions (reproducibility)	No	No	No	No

Table 2. Reference programmes used for methodological review

Type of programme	Treatment and teaching programme hypertension	Treatment and teaching programme for type 1 diabetes	Treatment and teaching programme for type 2 diabetes
Active components	Implementation at specialized centres and the primary health care level; written curriculum; preparatory course for physicians and assistants; group education for 4 to 6 patients by physicians' assistants (4 weekly sessions, 90 minutes each); teaching materials for personnel; teaching materials for patients; blood pressure self-monitoring; active involvement of patients in decision making on therapies; self-adaptation of drug therapy by patients	Implementation at specialized centres; written curriculum; postgraduate training courses for diabetes educators; postgraduate training for physicians; group education for up to 10 patients (5-days); teaching materials for patients; teaching materials for teachers; metabolic self-monitoring (urine, blood glucose, ketenes); dietary freedom; training of patients to self-adapt insulin dosages; treatment of severe hypoglycaemia by relatives with glucagons injection	Implementation at the primary health care level; written curriculum; preparatory course for physicians and assistants; group education; team education by physicians and 'assistants' (4 weekly sessions, 90 minutes each); teaching materials for staff; teaching materials for patients; definition of individual treatment goals; glucosuria self-monitoring; simple nutritional recommendations; foot care; involvement of patients in monitoring of complications
Evaluation ("Stages of evidence")			
Stage 1 (Development):	<ul style="list-style-type: none"> • Empirical evidence for non-drug therapy, blood pressure self-monitoring, participation of patients in treatment decision making; need for correct blood pressure measurements⁶¹⁻⁶³ • Education for small groups of patients in 4 weekly sessions; preparatory course for staff^{63,64} 	<ul style="list-style-type: none"> • Definition of treatment goals and methods⁶⁵⁻⁶⁷ 	<ul style="list-style-type: none"> • Empirical evidence for non-drug therapy, urine glucose self-monitoring, foot care; individual treatment goals; paramedics as educators; primary health care level⁶⁸
Stage 2 (Feasibility/piloting):	<ul style="list-style-type: none"> • Before-after trial with hypertensive type 1 diabetic patients at tertiary care centre⁶¹ • Before-after trial with hypertensive and blind type 1 diabetic patients⁶⁹ • Before-after trial with hypertensive type 2 diabetic patients at tertiary care centre⁷⁰ 	<ul style="list-style-type: none"> • Adaptation of the Geneva programme with adult educationalists; pilot evaluation with 2 community hospitals⁷¹⁻⁷⁶ • Before-after trials at tertiary care centres; formative evaluation of knowledge, skills, behaviour⁷⁷⁻⁸⁰ 	<ul style="list-style-type: none"> • Multidisciplinary group; education for small groups of patients in 4 weekly sessions; preparatory course for staff^{81,82}
Stage 3 (Evaluation):	<ul style="list-style-type: none"> • Primary health care level; randomised controlled trial; 1.5 and 3 years follow-up^{39,83} • Tertiary diabetes care centre; non-randomised controlled trial including hypertensive patients with type 1 diabetes; comparison of usual care with specialized care including participation in the hypertension treatment and teaching programme; follow-up at 5 and 10 years^{84,85} 	<ul style="list-style-type: none"> • Randomised controlled trial: Bucharest-Düsseldorf study at tertiary care centre⁸⁶ 	<ul style="list-style-type: none"> • Prospective controlled (non-randomised) trial including 8 practices and 114 patients⁸⁷
Stage 4 (Implementation):	<ul style="list-style-type: none"> • Gradual implementation in Germany since 1993; since 1995 integral part of the postgraduate training for diabetes educators⁸⁸ 	<ul style="list-style-type: none"> • Transfer of the programme to community hospitals; postgraduate training course for diabetes educators and physicians⁸⁹⁻⁹¹ • Implementation in Germany as routine treatment of type 1 diabetes⁹²⁻⁹⁴ • Long term outcome; 6 years and 10 years follow-up^{37,95-99} • Outcome on a population level^{100,101} • Replication in other health care systems: Moscow, Argentina and Bulgaria¹⁰²⁻¹⁰⁴ • Effectiveness as an outpatient programme in Austria and Great Britain^{105,106} 	<ul style="list-style-type: none"> • Replication in other health care systems; prospective controlled studies in Austria and Argentina^{107,108} • Implementation in Germany; reimbursement, preparatory training courses; implementation studies¹⁰⁹⁻¹¹¹ • Implementation in Latin America; multinational before-after trial¹¹²

Table 3. Characteristics of and data synthesis in included systematic reviews

First author	Topic	Selection criteria	No. of incl. studies	Data synthesis
Boren ⁴⁰	Interventions that address reducing risk in diabetes self-management	Inclusion criteria: Articles published in English Exclusion criteria: Published prior to 1990; non-interventional studies; descriptive or opinion papers	n= 39	Descriptive assessment of quantitative studies within categories according to categories of interventions: smoking cessation, eye examination, foot care; oral health, vaccination, cardiovascular risk reduction, combined risk reduction.
Boulware ⁴⁰	Patient centred counselling, patient self-monitoring of BP and structured training courses in hypertension	Inclusion criteria: Peer-reviewed English articles; primarily patient centered interventions; focusing on counselling (individual or group), structured training courses, and patient self-monitoring of BP (curriculum based); published 1970 to July 1990 Exclusion criteria: Centred primarily on diet and weight loss; focused on specific diet prescription; efficacy studies of drug therapy; studies without clinical outcome measure; sample size <50 or <25 in each study arm; study groups containing any other interventions beside the three interventions of interest	n= 16	1. Meta-analysis across prespecified categories ^a of interventions according to study characteristics: single-intervention group analysis; between-intervention group analysis 2. Subgroup-analysis according to active components: articles focusing counselling by categorizing articles by publication year; leader of intervention; duration of intervention; age of participants; percentage of white participants; and quality scores of articles
Corabian ⁴¹	Outpatient education for self-management in adults with type 2 diabetes	Inclusion criteria: Articles published in English or French; controlled trials or comparative studies or meta-analyses which evaluated efficacy/effectiveness of any diabetes patient education; qualitative studies; published 1990 – 1999; outpatient orientated; formalized (class, course, sessions...); adults with type 2 diabetes (may include both type 2 and type 1 diabetes); offered to heterogeneous patients (age, sex, race); follow-up > 1 year; one or more of objective outcomes (physiological or physical outcomes; utilization of health-care services) and one or more of subjective outcomes (patient knowledge; self-care behaviour; psychosocial outcomes; QoL; patient satisfaction) Exclusion criteria: Professional interventions; multifaceted interventions (patient and professional interventions); sample size less than 15 patients in each arm; diabetes education designed and offered to homogeneous ethnic groups	n= 24 ^b	1. Descriptive assessment of quantitative studies within categories according to study characteristics: meta-analyses; primary studies on effectiveness; comprehensive and systematic reviews; Canadian studies 2. Qualitative assessment of qualitative research to identify factors that potentially influence the impact of diabetes care and education regimen
Deakin ¹¹	Group-based, patient-centered training in type 2 diabetes	Inclusion criteria: RCT (until 2003); CCT (until 2003); group based (at least 6 participants) educational programmes specific for people with type 2 diabetes, delivered in primary or secondary care; based on learner/ patient-centered education; included or excluded family and friends; a minimum of one session lasting one hour; control group undergoing routine treatment, remaining on waiting list, or experiencing no intervention; follow-up 4 to 6 months, 6 to 12 months, or more than 12 months; prespecified main (e.g. GHb) and additional outcome measures Exclusion criteria: Narrative and qualitative papers; no control group; interventions specific for maturity onset diabetes of the young or for pregnant women; receipt of individual appointments as part of the intervention; short follow-up (<6 months); studies that recruited patients with type 1 and type 2 diabetes; lacking GHb as outcome measure	n= 11	1. Meta-analysis: overall summary effects across prespecified categories of interventions according to duration of follow up: 4 to 6 months; 6 to 12 months; 12 to 14 months; 2 years 2. Subgroup-analyses according to theoretical model; educator (nurse, dietician or a combination of both); ethnicity; primary or secondary care interventions; larger groups of participants in the education programmes 3. Qualitative subgroup-analysis: studies are descriptively summarized according to outcome measures ^a

Continued

Table 3. Characteristics of and data synthesis in included systematic reviews

First author	Topic	Selection criteria	No. of incl. studies	Data synthesis
Ellis ⁴²	Patient education in type 1 and type 2 diabetes	Inclusion criteria: RCT (1990 to 2000); adults with diabetes; outpatient setting; non-pharmacological interventions aiming at improving health; pre- and post-intervention GHb values assessed; GHb assessed at least 12 weeks post-intervention Exclusion criteria: Non English language	n= 21	1. Meta-analysis: overall summary effects 2. Meta-analysis: sub-group analysis in categories of interventions according to active components: type of delivery; content; teaching method; intensity of intervention
Fahey ^{50,51}	Different strategies of care (e.g. self-management and patient education) used to improve the control and follow up of patients with hypertension	Inclusion criteria: RCT (all languages); Adult patients with essential hypertension treated or not currently treated with blood pressure lowering drugs; in a primary care, outpatient or community setting; interventions aimed at improving control of blood pressure or clinic attendance: 1) self monitoring, 2) educational interventions directed to the patient, 3) educational interventions directed to the health professional, 4) health professional nurse or pharmacist led care, 5) organisational interventions that aimed to improve the delivery of care, 6) appointment reminder systems; studies reported on any of the following: 1) mean SBP and/or mean DBP, 2) control of blood pressure 3) proportion of patients followed up at clinic. Exclusion criteria: Interventions not intended to increase blood pressure control by organisational means, particularly drug trials and trials of non-pharmacological treatment	n= 59 ¹¹³ n= 56 ⁵⁰	Meta-analysis in pre specified categories according to the types of intervention: self-monitoring education; education intervention directed to patients; education intervention directed to health professionals; health professional lead care; organisational interventions; appointment reminder systems
Gary ⁵²	Educational and behavioural interventions for individuals with type 2 diabetes	Inclusion criteria: RCT; English language; evaluation of educational and behavioural interventions (clear behavioural components) if long term effects were assessed; sample size ≥10 participants; studies that randomised clinicians, only if patient outcomes were evaluated Exclusion criteria: none	n= 18	1. Studies are descriptively summarized according to study characteristics and outcome measures 2. Meta-analysis: overall summary effects 3. Sub-group analysis in categories of interventions according to active components: interventionist (physicians; nurse; dietician); mode of instruction (individual; group); topic of instruction (diet; medication); exercise; blood glucose self-monitoring)
Jack ⁴³	Educational methods in type 2 diabetes	Inclusion criteria: English language; RCT; quasi-experimental before- and after-studies; diabetes self-management education; implementation in community settings; description of processes of establishing community partnerships; evidence delivered on outcome improvement Exclusion criteria: none	n= 8	Studies are descriptively summarized according to outcome measures
Loveman ¹²	Structured educational interventions for diabetes self-management	Inclusion criteria: RCTs and CCTs that compared a specific educational programmes with usual care or with another educational programme; RCTs or CCTs that compared models of group education with individual education; CCTs including concurrent control group. Exclusion criteria: Trials that only evaluated specific, specialised psychological interventions aimed at changing an individual's perceptions, such as cognitive/behavioural or psychoanalytic therapy, or counselling; Studies of education solely about specific complications (e.g. foot care); educational interventions that were not described in sufficient detail to allow them to be reproduced	n= 21	The clinical effectiveness data were synthesised through a descriptive review with full tabulation of results without categorisation according to components of the interventions included. Meta-analysis was not undertaken due to differences in study populations and comparators.

Continued

Table 3. Characteristics of and data synthesis in included systematic reviews

First author	Topic	Selection criteria	No. of incl. studies	Data synthesis
Newman ⁴⁴	Self-management interventions for chronic illness (type 2 diabetes, arthritis, and asthma)	Inclusion criteria: English language; RCT (1997 to 2002); adults (> 18); studies assessing group and individual setting Exclusion criteria: Studies with interventions that only provided information in a didactic format (e.g. telephone consultations)	n = 63	1. Studies are descriptively summarized within categories of interventions according to types of intervention: group based; problem solving; stress management; cognitive behavioural; expressive writing; programme delivered by mail; combination of education with an action plan; exercise 2. Qualitative analysis to examine whether particular outcomes were focused upon, those in each study were classified into seven broad categories.
Norris ⁴⁵	Self-management training in type 2 diabetes	Inclusion criteria: English language; RCT; most or all participants with diabetes; any degree of disease severity; all settings; delivered by any provider type and involving any medium; including active components if effects could be examined separately Exclusion criteria: the educational component could not be identified; only abstracts; only dissertations	n = 72	Studies are descriptively summarized within categories of primary educational focus: Knowledge or information (didactic education or collaborative education); lifestyle behaviours; skill development; coping skills
Norris ⁴⁶	Self-management training in type 2 diabetes	Inclusion criteria: English language; RCT; most or all participants with diabetes; if type of diabetes was unclear participants included if age >30 years; all settings; if several interventions were studied effects should be examined separately Exclusion criteria: no GHb-measures	n = 31	1. Meta-analysis: sub-group analysis according to study characteristics by the length of follow-up (follow-up ≥4 months after end of the intervention; follow-up 1-3 months after end of the intervention; follow-up during or immediately after the intervention) 2. Meta-analysis: Regression-analysis to investigate potential treatment interactions: patient age; baseline GHb; treatment (insulin, diet only, oral hypoglycaemic agents); number of contacts; total contact time; time frame over which the intervention was delivered; group vs. individual presentation of the intervention; who delivered the intervention; educational focus (life-style, skills, knowledge, coping skills, or mixed); follow in months; setting in the US vs. other countries
Norris ⁴⁷	Self-management training in type 1 and type 2 diabetes in community settings	Inclusion criteria: Studies that evaluated the effectiveness of diabetes self-management programmes delivered outside of traditional clinical settings; English language; studies with concurrent or before-and-after comparison groups; conducted in established market economies; provide information pre-specified outcomes; meet minimum quality standards Exclusion criteria: none	n = 30	1. Meta-analysis: overall summary effect sizes for evidence on effectiveness; summarized for each setting (community gathering places, home, camps, schools, and worksite) 2. Qualitative analysis: assessment within categories: applicability; other positive and negative effects; economic efficiency; barriers for implementation; summarized for each setting (community gathering places, home, camps, schools, and worksite) 3. Additional descriptive information on positive and negative effects; applicability, economic efficiency, and barriers for implementation are described for each study

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Table 3. Characteristics of and data synthesis in included systematic reviews

First author	Topic	Selection criteria	No. of incl. studies	Data synthesis
Renders ⁵³	Interventions targeted at health professionals and/or the structure of care in order to improve the management of patients with type 1 and type 2 diabetes	Inclusion criteria: RCT or quasi randomised trials; CCT; controlled before- and after- studies; interrupted time series Exclusion criteria: Studies evaluating only patient oriented interventions	n= 41	1. Qualitative analysis: influence of prespecified characteristics: types of intervention (professional, organisational, or financial); source of information (e.g. whether the intervention was carried or supported by professional organization); type of diabetes 2. Descriptive information on effects for each study categorized according to types of intervention: professional; organisational; professional and organisational in combination 3. Qualitative analyses: influence of active components of the programmes (e.g. postgraduate education of health care professionals; education for both health care professionals and patients; learner centered counselling; multidisciplinary teams in combination with arrangements for follow up and patient; including a telecommunication system)
Renders ⁵⁴	Interventions targeted at health professionals and/or the structure of care in order to improve the management of patients with type 1 and type 2 diabetes	Inclusion criteria: RCT or quasi randomised trials by patient, health care professionals or practice; interrupted time series with a clearly defined intervention and at least 3 time points before and 3 after the intervention; non-randomised studies controlled at a second site with data before and after the intervention and appropriate choice of control site; studies using reliable objective and predetermined measure of the process of health care or patient outcomes Exclusion criteria: Studies evaluating only patient oriented interventions	n= 41	1. Descriptive information on effects for each study categorized according to types of intervention: professional; organisational; professional and organisational in combination 2. Qualitative analyses: influence of active components of the programmes (e.g. postgraduate education of health care professionals; education for both health care professionals and patients; learner centered counselling; multidisciplinary teams in combination with arrangements for follow up and patient; including a telecommunication system)
Sigurdardottir ⁴⁸	Factors in educational interventions that contribute to improvement in glycaemic control	Inclusion criteria: English language; RCT Exclusion criteria: Type 1 diabetes	n= 18	Data mining methods (computer algorithms) for pattern discovery. Assessment which factors contribute to the improvement of glycaemic control (e.g. educational interventions; theory guided interventions; Setting, delivery, provider and teaching method; content of interventions)

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Table 3. Characteristics of and data synthesis in included systematic reviews

First author	Topic	Selection criteria	No. of incl. studies	Data synthesis
Warsi ⁵⁵	Patient self-management educational programmes for chronic diseases (e.g. diabetes and hypertension)	<p>Inclusion criteria: Contained self-management education components; a concurrent control group concluded; clinical outcomes evaluated; studies that integrated physical or psychosocial therapies into an educational program</p> <p>Exclusion criteria: Exclusively reported outcomes such as knowledge, compliance self- efficacy, satisfaction, or use of health care services; exclusively assessed generic outcomes such as QoL or coping skills; focused on chronic emotional disorders such as depression, post-acute care, obesity or smoking cessation programmes; exclusively involved physical or psychosocial therapies such as biofeedback, relaxation technique, exercise and group therapy</p>	n= 71	<ol style="list-style-type: none"> 1. Meta-analysis: efficacy for each outcome 2. Meta-analysis across chronic diseases to identify which components were associated with greater clinical benefits. The dependent variable was the summary effect size across all diseases. Indicator variables were each disease and its endpoint. Independent variables were percentage of dropouts, number of educational sessions, programme duration, programme format; education mode (face-to-face education), and reference to a behavioural science model
Zabaleta ⁵⁶	Group-based diabetes education programmes for patients with type 2 diabetes in primary care	<p>Inclusion criteria: Controlled trials (CCT and RCT); structured group education (detailed curriculum); primary care setting; GHb defined as an outcome; topics designed to address diabetes self-care</p>	n= 3	Qualitative analysis (tabulative) detailing the key characteristics of the interventions ("nature of intervention"; intervention provider; educational materials) with their estimations of effects

⁵⁵Some interventions (n= 3) are allocated into both categories; ⁵⁶Change at follow-up, difference between treatment groups, and difference in change between treatment groups at follow-up; ⁵⁷studies were excluded from analysis if heterogeneity was substantial; ⁵⁸if there was substantial heterogeneity between studies meta-analysis was not performed; ⁵⁹changes from baseline; ⁶⁰the effectiveness of interventions for type 1 and type 2 diabetes was examined separately. BMI= body mass index; BP= blood pressure; CCT= controlled clinical trial; GHb= glycohaemoglobin; QoL= quality of life; RCT= randomised controlled trial.