Diabetologia (2002) 45:1723–1733
DOI 10.1007/s00125-002-0987-2

Diabetologia

For debate

Patient education – evaluation of a complex intervention

I. Mühlhauser[1, 2], **M. Berger**[2,†]

[1] Unit of Health Sciences and Education, University of Hamburg, Germany
[2] Department of Metabolic Diseases and Nutrition (WHO-Collaborating Centre for Diabetes), Heinrich-Heine University of Düsseldorf, Germany

Abstract

Diabetes education or self-management programmes are complex interventions. Their evaluation is difficult because of problems in identifying and separately assessing the effect of the various components of the intervention. A phased approach defining sequential stages of a continuum of increasing evidence has been proposed as a framework for the design and evaluation of such complex interventions. As an example we present the available evidence for diabetes treatment and teaching programmes implemented in Germany. Evidence is compiled for structured group treatment and teaching programmes for Type I diabetes, non-insulin dependent Type II diabetes, and hypertension according to the following sequential stages of increasing evidence: (i) preclinical or theoretical phase; (ii) modelling the components of the intervention; (iii) exploratory trials; (iv) randomized controlled trials; (v) phase of implementation including replication and transfer to different settings. Evidence for most of these phases has been generated for the three programmes, although individual studies do not fulfill all important quality criteria by today's standards. The time span for gathering the evidence from the theoretical phase to surveillance after implementation was about 20 years. It can only be speculated which parts of the programmes are the most active ones. The presentation of a continuum of increasing evidence for diabetes education or self-management programmes could provide useful information for the appraisal of such complex interventions. Since this evidence cannot be readily extracted from databases we suggest that other research groups present their data in a similar way. [Diabetologia (2002) 45:1723–1733]

Keywords Diabetes mellitus, patient-education, self-management, health-education, evaluation, systematic-review, complex-interventions.

Evaluation of patient education remains a challenging endeavour. The randomized controlled trial is the most valid method to evaluate an intervention and is particularly reliable for a single intervention, such as a drug. Non-pharmacological interventions, however, are often complex including several components; their evaluation is difficult because of problems in identifying and separately assessing the effect of the various elements of the intervention.

This applies in particular to diabetes education or self-management programmes which consist of various interconnected components. Though indispensable, knowledge by itself might not yet improve outcome. The relevance of the information and how it is transmitted are decisive. The outcome of intensified insulin therapy is dependent on the appropriateness of the insulin regimen used and the quality of the teaching process to empower patients to carry it out effectively and safely. Patient education is an integral part of diabetes treatment and cannot be evaluated separately [1]. Furthermore, the success of diabetes treat-

Received: 5 August 2002 / Revised: 6 September 2002
Published online: 30 October 2002

† deceased

Corresponding author: Dr. I. Mühlhauser, Universität Hamburg, IGTW-Gesundheit, Martin-Luther King Platz 6, 20146 Hamburg, Germany. E-mail: Ingrid_Muehlhauser@uni-hamburg.de.

ment and teaching programmes depends on the motivation and competence of the health care team and structural, organisational and financial conditions. It might be impossible to identify the most important components of such a complex intervention.

Several systematic reviews on the effectiveness of patient education and self-management training programmes in diabetes have recently been published [2, 3, 4, 5]. Typically, they attempt to dissect the programmes into single components and to evaluate them separately. Studies using complex interventions are usually excluded or included only if the reviewers feel that they can isolate the educational component to examine it separately. We suggest that the methodologies used in these systematic reviews are not suitable to evaluate complex interventions such as structured diabetes treatment and teaching programmes.

Recently, the U.K. Medical Research Council has proposed a framework for the design and evaluation of complex interventions to improve health [6, 7]. They define sequential stages of a continuum of increasing evidence requiring use of qualitative and quantitative evidence. The first step, a preclinical or theoretical phase, is to explore the relevant theory and to identify evidence showing that the intervention might work. The second step defines the modelling components of the intervention and the underlying mechanisms by which they work. The third step is an exploratory trial which tests the feasibility of delivering the intervention and its acceptance by providers and patients. It might help to determine the consistency with which the intervention is delivered. During this phase the protocol for the main randomized controlled trial should be developed. Following the definite randomized controlled trial the long-term implementation into practice has to be documented. This includes replication of the intervention in different settings and assessment of outcome under uncontrolled conditions in the long-term. In this final phase attention is to be paid on the rate of uptake, the stability of the intervention, any broadening of subject groups, and possible adverse effects [6, 7].

The description of the continuum of increasing evidence for an education, self-management or treatment and teaching programme as a complex intervention into health can provide important information about the achieved degree of evidence for a particular programme. At present it is not possible to readily extract the information on such a continuum of evidence for diabetes programmes from databases such as MedLine or The Cochrane Library. Replication, transferability and implementation trials might have been carried out by different authors than the core (randomized) controlled trials. In addition, the identity of the intervention can become apparent only by scrutinising the original articles. Hence such publications usually can not be identified by conventional methods of searching databases and screening abstracts.

We aim to present the available information on treatment and teaching programmes for patients with diabetes implemented in Germany as examples for a continuum of evidence. As the authors have been instrumental in the development, evaluation and implementation of these programmes they had direct access to the information. For the above mentioned reasons we can not report a similar continuum of evidence on programmes of other research groups. In addition, traditional systematic reviews do not permit identifying the whole package of available evidence for a particular education programme [2, 3, 4, 5]. Perhaps this article stimulates other research groups to present their data using a comparable format. In addition, we hope that the present contribution evokes new ideas on how to better compile and critically appraise evidence on complex interventions such as patient education and self-management training programmes in diabetes.

Treatment and teaching programme for Type I diabetes: Preclinical or theoretical phase

A most paternalistic way of diabetes treatment prevailed in post-war Germany. Patients were frequently admitted to diabetes hospitals to stabilize glycaemic control. Diabetologists favoured keeping patients glucosuric to prevent hypoglycaemia. The routine therapeutic approach was one or two daily injections of medium-acting insulin preparations. Patients did not do any kind of metabolic self-monitoring and were not allowed to change insulin dosages themselves. Patient education had degenerated to obedience training to follow dietary prescriptions. The diabetes diet was rigid based on fixed amounts of carbohydrates, proteins and fats distributed over 6 to 7 meals to be consumed at fixed prescheduled times of the day. Sugar consumption was prohibited (Zuckerverbot). Systematic assessment of the outcome of this approach was missing, but acute and late complications were frequent.

Towards the end of the 1970's, the increasing acceptance of a causal relation between glycaemic control and microangiopathy led to the formulation of near-normalization of metabolic control as a primary therapeutic goal [8]. The introduction of glycosylated haemoglobin measurements confronted physicians and patients with their failure to achieve this ambitious objective. In Europe, a number of diabetologists felt that patient education in the original sense of Joslin [9] and Stolte [10] aiming at self-control and self-treatment should be the key elements for better care of patients with Type I diabetes (Table 1).

Modelling

In 1979 the Diabetes Education Study Group (DESG) of the European Diabetes Association (EASD) was founded [11]. Education, encouragement, and training

Table 1. Phases of development and evaluation of a treatment and teaching programme for Type I diabetes in Germany 1978–2000

Phases	Results	Publications
Preclinical – theory		
Definition of treatment goals and methods	5-day group treatment and teaching programme	[11, 13, 68]
Phase I – modelling		
Adaptation of the Geneva programme with adult educationalists; pilot evaluation with two community hospitals	Curriculum, educational material for staff and patients	[12, 14, 15, 16, 17, 69]
Phase II – exploratory trials		
Before-after trials at tertiary care centers; formative evaluation of knowledge, skills, behavior	Decrease of HbA_{1c}, hospital days and sick-day leaves	[19, 20, 21, 22]
Phase III – randomized controlled trial		
Bucharest-Düsseldorf study at tertiary care center	Decrease of HbA_{1c}, ketoacidosis, hospital days, severe hypoglycaemia unchanged	[23]
Phase IV – long term implementation		
Transfer of the programme to community hospitals; controlled trial with 1, 2, and 3 years follow-up; postgraduate training course for diabetes educators and physicians	Demonstration of transferability with reproducible results in nine general hospitals	[24, 25, 26]
Implementation in Germany as routine treatment of Type I diabetes; national working group, quality assurance programme	Reproducible 1-year follow-up results in 8000 patients from 150 centers during 1992–1999, decrease of HbA_{1c}, severe hypoglycaemia, ketoacidosis, hospital days	[27, 28, 70]
Long-term outcome; 6–year follow-up of approximately 650 patients; observational study of approximately 4000 patients with mean follow-up of 10 years	Stability of outcome; dietary and self-monitoring behavior; quality of life measures; risk factors of late complications and mortality	[29, 30, 31, 32, 33, 34]
Outcome on a population level; cross-sectional and prospective study	80% of patients participated in the programme	[35, 36]
Replication in other health care systems; prospective controlled study in Moscow, before-after trials in Argentina and Bulgaria	Replication of results, cost-effectiveness, quality of life measures	[37, 39]
Effectiveness as an outpatient programme in diabetes clinics in Austria (before-after trial) and Great Britain (randomized-controlled-trial)	Replicaton of results on an out patient basis; improvement of quality of life due to liberalization of the diet	[40, 41]

of the patient to actively take over increasing parts of his/her therapy to be more independent from physicians and medical institutions became primary objectives of patient education. Within the DESG, a number of models for structured diabetes treatment and teaching programmes were developed. At the University of Geneva J.P. Assal had implemented a 5-day in-patient teaching programme for small groups of 6 to 10 patients [12]. This programme was transferred to the university hospital of Düsseldorf with some adaptations [13]. The teaching was done by a nurse and a dietitian. In the beginning, treatment was based on urine-glucose self-monitoring; later on patients opted for blood glucose self monitoring. Over the years the diabetes diet was increasingly liberalized and insulin treatment increasingly intensified. NPH insulin was injected twice daily and regular insulin immediately before meals. Protein or fat was not counted. Sugar consumption was not prohibited. Meals could be skipped altogether. No snacks were prescribed. A main objective of diabetes education was to train the patients to adapt insulin dosages to variable amounts and timing of carbohydrate intake. No sliding scales were used but patients were trained to calculate insulin dosages prospectively taking into account blood glucose control during the preceding hours, days and anticipated activities. The education was based on a written curriculum [14] and teaching materials for teachers and patients were made available [15, 16, 17, 18].

Exploratory trials

In a prospective before and after trial including 88 patients with Type I diabetes carried out at two tertiary

diabetes care centers, a significant reduction of glycosylated haemoglobin values was found over 22 months [19]. Hospital days and sick-day leaves were substantially reduced and the programme was well received by patients and health care providers [19, 20]. Formative evaluation studies were carried out to document knowledge, skills and behavior, e.g. accuracy of blood glucose self measurements or the use of glucagon for severe hypoglycaemia [21, 22]. For these early studies, critics had argued that the patients were self-selected and that the positive results achieved might therefore not be applicable to the average person with Type I diabetes.

Randomized controlled trial

A group randomized controlled trial including 300 consecutively referred patients with Type I diabetes was carried out in a cooperative project at a tertiary diabetes care center in Bucharest, Romania [23]. The intervention led to a significant and lasting reduction in glycosylated haemoglobin values without an increase in the risk of severe hypoglycaemia for up to 2 years. In addition, ketoacidosis was almost eliminated and hospital admissions reduced. However, by today's standards this study would not qualify as a randomized controlled trial of high quality.

Long-term implementation

Transferability to community hospitals. As the next step, the conditions for transferring the programme from diabetes centres to non-specialized community hospitals were documented for Germany. In a prospective controlled trial with follow-up periods of 1, 2 and 3 years it was shown that the programme could be translated to general hospitals with the same degree of effectiveness and safety, namely lasting reductions of HbA_{1c} values, and at the same time, a decrease in the incidence rates of severe hypoglycaemia and ketoacidosis [24, 25].

Implementation on a national basis. Precondition for successful implementation of the programme on a national basis was the training of physicians, nurses and dietitians. A national postgraduate training programme for nurses and dietitians to become diabetes educators was initiated in the early 1980's [26]. Long-term implementation of the programme on a national basis and quality assessment was enforced in the early 1990's by the foundation of a working group of hospitals dedicated to this therapeutic approach [27]. Over the years about 200 hospital departments of internal medicine joined the association. Member institutions agreed to carry out continuous quality assurance measures. This included re-examination of a random sample of patients 12 to 15 months after participation in the programme. In addition, as visiting observers, physicians and educators exchanged experiences on educational methods. Results were presented and discussed at annual meetings. In a sample of about 8000 Type I diabetic patients followed and re-examined by the members of the working group a significant reduction of glycosylated haemoglobin values, ketoacidosis, hypoglycaemia and hospital days was documented [27, 28]. A reduction in severe hypoglycaemia in association with improved glycosylated haemoglobin values was observed in various prospective studies [24, 25, 27, 28, 29].

Long-term follow-up. A cohort of approximately 650 patients was re-examined for up to 6 years. In these patients the stability of outcome measures could be documented [29, 30, 31]. In addition, it was shown that dietary habits were increasingly liberalized and that a high degree of diet liberalization was not associated with worse glycaemic control [32]. A cohort of about 4000 Type I diabetic patients were re-examined after a mean follow-up period of 10 years analysing various prognostic factors related to diabetic late complications and mortality [33, 34]. The study found that in this group of comparably well controlled patients general risk factors such as smoking, blood pressure control and socioeconomic status became increasingly relevant for the prognosis of the patients.

Outcome on a population level. Finally, the effect of the programme on the quality of care was examined on a population basis in a representative sample of about 680 adult Type I diabetic patients in a geographically defined area of Germany [35, 36]. In this group of patients with a mean age of about 36 years and a mean diabetes duration of about 18 years about 80% had participated in a structured treatment and teaching programme for intensification of insulin therapy. Mean glycosylated haemoglobin was 8% and the incidence of severe hypoglycaemia was 0.21 cases per patient per year.

Transferability to other health care systems. In a prospective controlled trial the effectiveness and safety of the inpatient programme was shown at a tertiary diabetes care center in Moscow, Russia [37]. Under the study conditions glucosuria self monitoring was equally effective and safe as blood glucose monitoring and cost effective. Substantial improvement of HbA_{1c} values was associated with unchanged frequency of severe hypoglycaemia. Ketoacidosis was almost eliminated and hospital days were substantially reduced. Comparable results were seen in Argentina, where the 5-day group programme is delivered in a hostel-like setting [38] and in Bulgaria [39].

Effectiveness as an out-patient programme. The identical 5-day group intervention was evaluated as an

Table 2. Phases of development and evaluation of a treatment and teaching programme for non-insulin treated Type II diabetes in Germany 1983–2000

Phases	Results	Publications
Preclinical – Theory		
Empirical evidence for non-drug therapy, urine glucose self-monitoring, foot care; individual treatment goals; paramedics as educators; primary health care level	First draft curriculum, qualitative evaluation	[43]
Phase I – Modellng		
Multidisciplinary group; education for small groups of patients in four weekly sessions; preparatory course for staff	Curriculum, educational material, booklets for patients, formative evaluation	[44, 45]
Phase II – Exploratory trials	not performed	
Phase III - (Randomized) controlled trial		
Prospective controlled (non-randomized) trial including eight practices and 114 patients	Reductions of body weight, medication for blood glucose control, and triglyceride concentrations at unchanged HbA_{1c}	[46]
Phase IV – Long-term implementation		
Replication in other health care systems; prospective controlled studies in Austria and Argentina	Replication of results, in addition decrease of HbA_{1c} values by 1% and of blood pressure	[47, 48]
Implementation in Germany; reimbursement, preparatory training courses; two implementation studies	feasibility, acceptability and reproducibility of results	[49, 50, 51]
Implementation in Latin America; multinational before-after trial	Reproducibility of results, in addition decrease in medication for blood pressure and lipids by about 60%	[52]

outpatient programme at the university hospital in Graz, Austria [40]. Improvements in HbA_{1c} values were associated with a substantial decrease in the frequency of severe hypoglycaemia. In the Dose Adjustment For Normal Eating project (DAFNE) the programme has recently been evaluated in an out-patient setting in the United Kingdom [41]. In this randomized-controlled multicentre trial the decrease of HbA_{1c} values was associated with a substantial improvement in the patients' quality of life due to the liberalization of the diabetes diet.

Treatment and teaching programme for non-insulin treated Type II diabetes: Preclinical or theoretical phase

In the early 1980's in Germany the care of Type II diabetes was characterised by non-compliance to non-drug therapy, overuse of oral agents, and an increasing proportion of elderly patients with diabetes. General physicians were not prepared to provide effective care to the growing population of patients with Type II diabetes. Thus, an intervention programme would have to be implemented on the primary health care level taking into account the different treatment goals for younger and elderly patients. Empirical evidence indicated the feasibility of effective treatment by emphasizing non-drug therapy, urine glucose self monitoring, foot care and training of nurses as educators [42] (Table 2).

Modelling

Programme development was carried out by a multidisciplinary group of health care professionals including experts in adult learning. The programme was to be organised in the family doctor's surgery without unnecessarily imposing on the practitioner's time. The programme aimed to achieve individual treatment goals primarily by non-pharmacological means, on the basis of group teaching delivered by the practice's paramedical personnel [43]. The teaching was based on a written curriculum [44]. Group education was for 3 to 8 patients comprising 4 weekly sessions. A set of teaching materials were made available for personnel and patients [44, 45]. Essential components of the programme were definition of individual treatment goals, glucosuria self-monitoring, simple nutritional recommendations, trial of withdrawal of oral agents, foot care, involvement of patients in the monitoring of complications. The teaching was based on learning theories taking into account the emotional, cognitive and sensory-motor levels of learning. A preparatory course for physicians and assistants of about 10 and 20 hours respectively, was deemed indispensable for successful implementation of the programme.

Prospective controlled trial

The intervention was studied in a non-randomized controlled clinical trial including 8 practices and 114 pa-

tients in the city of Cologne [46]. At the one-year follow-up in the intervention group body weight had decreased by 2.7 kg and the use of sulfonylureas decreased from 68% to 38% of patients, glycosylated haemoglobin remained unchanged at 7.1% and triglyceride concentrations improved. In the control group none of these indices was changed during the study year, and 10% of patients were started on insulin treatment.

Replication and transferability

The effectiveness of the programme was replicated in a rural area of Austria in a controlled trial with 6-months follow-up [47]. Comparable outcomes of reduction of body weight and use of sulfonylurea were observed. In addition to improvement of triglyceride concentrations, glycosylated haemoglobin concentrations were reduced by almost 1% and blood pressure was lowered. In a further 1-year prospective controlled trial with comparable results, it was shown that the programme was transferable to Argentina [48]. For this latter project the teaching materials were translated and adapted to the special cultural conditions of Latin America.

Long-term implementation

The national implementation of the programme in Germany required several steps. Since 1991 the programme, including teaching materials, was reimbursed by the German health insurance funds. The prerequisite for the remuneration was the completion of the specific postgraduate training course by the physician and the office staff. The training courses are organized by the Central Research Institute of Ambulatory Health Care in cooperation with the German Diabetes Association. The courses are conducted nationwide by 1300 diabetologists and their diabetes educators who were previously trained to conduct courses for office-based physicians and their staff during multidisciplinary seminars [49, 50]. The implemenation has been documented by two studies. One study included all 139 family physicians of the city of Hamburg that had participated in the preparatory course during 1991 [50]. The second study included 150 family physicians' offices and a random sample of 695 patients that had participated in the programme [51]. The studies documented the feasibility, acceptance and reproducibility of patient outcome improvement on the population level. At the end of the year 2001 about 20 000 practices had participated in the postgraduate training for implementation of the programme and teaching materials had been reimbursed for about 600 000 patients.

In 2001, it has been shown that the programme could be successfully implemented in Latin America [52]. In a multinational study including centres in 10 countries and 446 patients, HbA_{1c} values had decreased by 1.2% and weight by 3.4 kg after one year. In addition, blood pressure and lipid concentrations had improved. At the same time medication for blood sugar, lipids and blood pressure was reduced by about 60%. In accordance with the original programme [46] only urine glucose self monitoring was used and hence the programme was estimated to be cost-effective.

Treatment and teaching programme for hypertenison: Preclinical or theoretical phase

Based on the experiences gained during the development of the diabetes treatment and teaching programme for non-insulin dependent diabetes the development and evaluation of a hypertenison treatment and teaching programme was initiated in the mid 1980's [53]. Care for patients with hypertension was and still is characterized by under- and overdiagnosis and under- and overtreatment. Similar to Type II diabetes, hypertension is often asymptomatic and its optimal control needs daily and lifelong adherence to a medical regimen that entails possible side effects. Patient compliance is poor. In diabetes antihypertensive drug therapy can be additionally compromised by the presence of vascular and neuropathic late complications eliciting symptoms that can overlap with side effects of antihypertensive drug therapy. Factors determining patient compliance with antihypertensive therapy have been studied extensively. Providing patients with sufficient information about the disease and its treatment in combination with blood pressure self-monitoring have been found to increase patient adherence to dietary and drug treatment regimens and to improve control of hypertension (Table 3).

Modelling

Components of the progamme and conditions for long-term success are comparable for Type II diabetes and hypertension. Thus, the hypertension programme is similar in design and organisation: education for small groups of patients comprising four weekly sessions, delivered by paramedics in out-patient clinics or in the physician's office, written curriculum and teaching materials [54]; structured preparatory course for the physician and staff [55]. Important components of the programme are correct blood pressure measurements, a validated diagnosis of hypertension and systematic blood pressure self monitoring by the patients, active involvement of patients in decision making and adaptation of drug therapy [53, 45, 55, 56].

Prospective controlled trials

The hypertension programme was evaluated in various controlled before and after trials and one random-

Table 3. Phases of development and evaluation of a treatment and teaching programme for hypertension in Germany 1985–2000

Phases	Results	Publications
Preclinical – Theory		
Empirical evidence for non-drug therapy, blood pressure self-monitoring, participation of patients in treatment decision making; need for correct blood pressure measurements	Assessment of patients' desires to participate in treatment decisions; programme for correct blood pressure measuring by physicians	[53, 55, 56]
Phase I – Modelling		
Education for small groups of patients in four weekly sessions; preparatory course for staff	Curriculum, educational material, booklets for patients, formative evaluation	[54, 55]
Phase II – Exploratory trials		
Before-after trial with hypertensive Type I diabetic patients at tertiary care centre	Improvement of blood pressure control, improvement of adherence to drug therapy	[53]
Before-after trial with hypertensive and blind Type I diabetic patients	Replication of results; stabilization of renal function	[58]
Before-after trial with hypertensive Type II diabetic patients at tertiary care centre	Replication of results in Type II diabetes	[60]
Phase III - (Randomized) controlled trial		
Primary health care level; randomized controlled trial; 1.5 and 3 years follow-up	Improvement of blood pressure control, decreased prescription and change of drug therapy	[57, 59]
Tertiary diabetes care centre; non-randomized controlled trial including hypertensive patients with Type I diabetes; comparison of usual care with specialized care including participation in the hypertension treatment and teaching programme; follow-up at 5 and 10 years	Decrease in mortality from 48% of patients to 16% and renal replacement therapy from 46% to 26% at 10 years	[61, 62]
Phase IV – Long-term implementation		
Gradual implementation in Germany since 1993; since 1995 integral part of the postgraduate training for diabetes educators	Limited data available	[63]

ized-controlled trial including different groups of patients (Type I diabetes, Type II diabetes and non-diabetic patients with hypertension) in various settings, such as diabetes outpatient clinics and in family physicians' offices [53, 54, 57, 58, 59, 60]. Blood pressure control could be improved for up to 3 years of follow-up [59]. Better blood pressure control was associated with better adherence to prescribed therapy, and reductions of prescriptions and changes of antihypertensive drugs and of body weight [53, 57, 58, 59, 60].

Most significant results were achieved in a prospective controlled study including patients with Type I diabetes and nephropathy-associated hypertension [61, 62]. The intervention consisted of a combination of participation in the programme and specialized care in comparison to standard care. After 5 and 10 years, respectively, there were significant differences in outcomes, at the 10 year follow-up whereby 16% versus 48% of patients had died, and 26% versus 46% were on renal replacement therapy [62]. In addition, there was a reduction in other complications that result from uncontrolled hypertension in association with deterioration of renal function such as visual loss and amputations.

Long-term implementation

Since 1993 the hypertension programme has been gradually implemented into the German health care system, although a national reimbursement policy comparable to the Type II diabetes programme is still lacking [63]. Since 1995 the programme is integral part of the postgraduate training for diabetes educators. An implementation study over a 3-year period including patients with hypertension and Type II diabetes is ongoing.

Discussion

A recent review on 'interventions to improve the management of diabetes mellitus in primary care, outpatient and community settings' [5] has analysed studies on professional, financial and organisational strategies aimed at improving care for people with Type I or Type II diabetes. In all studies the intervention was multifaceted. The authors included studies in which patient education was added to professional and organisational interventions, but studies that only eval-

uated patient oriented interventions such as patient education were excluded. The impossibility to clearly separate interventions according to these criteria is reflected by the handling of three publications on an identical intervention that is the group treatment and teaching programme for patients with Type II diabetes as described in the present article. The review included the publication by Pieber et al. [47], but not those by Kronsbein et al. [46] and Domenech et al. [48]. All three studies had a similar study design. The studies by Pieber and Domenech were replication trials of the Kronsbein study showing the feasibility to transfer the programme into other health care settings. On personal contact, the first author of the review explained that they had considered the study by Kronsbein a patient-oriented intervention. In fact, the treatment and teaching programme consists of various interrelated parts that cannot be evaluated as isolated components. The primarily patient-oriented educational part is as important as the preparatory course for the physicians and their assistants. It is not possible to implement such a complex programme into the family physician's office without a structured training course for the health care team.

In two other recent systematic reviews [3, 4] only randomized controlled trials were included. Interventions were categorized based on their educational focus that is information, lifestyle behaviors, mechanical skills, and coping skills. Studies with multicomponent interventions were included only if the effects of the educational component could be examined separately. The treatment strategies were not considered. Previously, we have argued that such an approach presents a misconception of diabetes education [1]. As examples we referred to three frequently cited publications that allegedly showed that education was not successful [64, 65, 66]. The three studies have again been included in the two recent reviews [3, 4]. These studies reflect a profound misunderstanding about what diabetes education is, what it can and what it cannot achieve [1]. A consequential misconception is that diabetes education could compensate for deficiencies of inappropriate insulin treatment regimens. Usually, we do not expect somebody to travel a distance of 100 kilometers within 1 hour by just equipping the person with a bicycle. However, in the studies failing to demonstrate the effect of diabetes education on metabolic control, typically patients were merely provided with rudimentary equipment for insulin therapy, which by no effort would have allowed them to improve glycaemic control to a significant extent. Thus, in one study 65% of the clearly insulin-dependent patients were supplied with only one and 22% with two injections of intermediate acting insulin without regular insulin at their disposal [64]. In the second study obese patients were recruited [65]. Information was not given on the insulin treatment used, but it was mentioned that "the programme was not designed as a therapeutic intervention aimed at improving metabolic control per se with self-monitoring of blood glucose and algorithms for insulin dose adjustment...". Instead, the so-called education programme comprising nine teaching sessions (with a drop-out rate of almost 50%) imposed on the patients a series of constraining nutritional prescriptions with the unrealistic and hence demotivating goal of achieving ideal body weight. It is clear that under the described insulin-treatment conditions any efforts of patients to eat less will come to a frustrating end as soon as they start to experience hypoglyaemia and the only remedy they have at their disposal is to eat more, rather than to prevent hypoglycaemia by reducing their insulin dosages. The third study is a further example of the vain enterprise to submit patients to a so-called education programme without paying attention to insulin therapy [66]. The education programme did not show any relevant effect on metabolic control, quality of life or costs of therapy. On average, the relatively young and clearly insulin-dependent patients injected insulin less than twice daily and less than 50% used regular insulin. Accordingly, the teaching programme lacked theoretical and practical training of the patients on how to adjust insulin dosages by themselves to improve their blood glucose values. At best, such teaching programmes, which are separated from rather than integrated into an adequate insulin-treatment programme, will increase the patients' awareness of their insufficient metabolic control. But unfortunately they will leave them without the necessary tools and the necessary knowledge to improve it [1].

The concept of a phased evaluation of complex interventions seems more appropriate for diabetes care. In the present article we have outlined the available continuum of evidence for various group treatment and teaching programmes for patients with diabetes as currently used in Germany. The time span for gathering the evidence from the theoretical phase to surveillance after implementation was about 20 years. Evidence for almost all phases has been generated for these programmes. The individual studies, however, do not fulfil all important quality criteria by today's standards. Only a few studies have been randomized, no study has blinded the randomization process or outcome assessment, cluster randomization has not been taken into account, and the retrieval rate was low in some of the surveillance studies.

It is not possible to identify which components of the programmes are the most important ones. However, we suggest that for all programmes the structured group approach including clear cut definitions of the treatment regimen and the goals, contents and methods of the educational part, based on a written curriculum are indispensable. Participation of the patients in the definition of individual treatment goals

and selection of treatment regimens is fundamental for long-term success. Motivation of patients is conferred through metabolic or blood pressure self-monitoring and liberalization of the diet to the extent that no restrictions are given. Participation of the health care team in a structured preparatory course and the supply of evaluated teaching materials for trainers and patients are important. The teaching is preferably provided by paramedics, although individual physicians can qualify as teachers. Blood glucose self-monitoring is not necessary for non-insulin dependent Type II diabetes. Evidence for the superiority of blood glucose monitoring compared to urine-glucose monitoring in non-insulin-dependent diabetes is lacking [67]. Reimbursement is not essential for the effectiveness of the programmes, but could be decisive when it comes to long-term implementation into the health care system.

We do not suggest that the randomized controlled trial should be abandoned, rather it is the core of the continuum of evidence for diabetes programmes. For the design of such randomized evaluation studies recommendations as provided in the CONSORT statement have to be followed [71]. Clinically relevant outcome parameters rather than surrogate parameters should be used [70].

We do not claim that it would not be sensible or possible to evaluate certain single aspects of complex interventions. However, isolated components can only be evaluated within a programme that not only has been described in detail but has also been proven to be effective. In addition, only components that are not interdependent can be evaluated separately. Thus, blood glucose self monitoring could be compared to urine-glucose self monitoring in a randomized controlled trial for an effective programme for non-insulin dependent Type II diabetes. On the other hand, coping skills or lifestyle behaviors can not be evaluated in isolation, separated from the specific treatment regimens used or the quality of the physician to patient relationship. Adherence to dietary prescriptions are clearly not valid outcome measures in management programmes in which liberalization of the diabetes diet is a fundamental component. The facts stand against the traditional approach of summarizing different diabetes patient education and self-management programmes by systematic reviews that try to isolate educational components from complex diabetes interventions that are not accessible to separation.

In conclusion, we have presented for discussion a new system for reporting the evaluation of complex interventions such as diabetes treatment and teaching programmes. Further research is necessary on how evidence compiled in such a manner could be made accessible through searching medical databases and how it could be critically appraised.

References

1. Mühlhauser I, Berger M (1993) Diabetes education and insulin therapy: when will they ever learn? J Intern Med 233:321–326
2. Corabian P, Harstall C (2001) Patient diabetes education in the management of adult Type 2 diabetes. HTA 23 http://www.ahfmr.ab.ca/publications.shtml (Accessed 25 May 2002)
3. Norris SL, Engelgau MM, Narayan KMV (2001) Effectiveness of self-management training in Type 2 diabetes. A systematic review of randomized controlled trials. Diabetes Care 24:561–587
4. Norris SL, Lau J, Smith SJ, Schmid CH, Engelgau MM (2002) Self-management education for adults with type 2 diabetes. A meta-analysis of the effects on glycemic control. Diabetes Care 25:1159–1171
5. Renders CM, Valk GD, Griffin S, Wagner EH, Eijk van JT, Assendelft WJJ (2001) Interventions to improve the management of diabetes mellitus in primary care, outpatient, and community settings (Cochrane Review). In: The Cochrane Library, Issue 4, 2001. Oxford: Update Software (also: Diabetes Care 2001; 24:1812–1833)
6. Medical Research Council MRC (2000) A framework for development and evaluation of RCTs for complex interventions to improve health. http://www.mrc.ac.uk/complex_packages.html (Accessed 25 May 2002)
7. Campbell M, Fitzpatrick R, Haines Aet al. (2000) Framework for design and evaluation of complex interventions to improve health. BMJ 321:694–696
8. Cahill GF Jr, Etzwiler DD, Freinkel N (1976) "Control" and diabetes. New Engl J Med 294:1004–1005
9. Joslin EP, Gray H, Root HF (1922/1923) Insulin in hospital and home. J Metabol Res 2:651–699
10. Stolte K, Wolff J (1939) Die Behandlung der kindlichen Zuckerkrankheit bei frei gewählter Kost. Ergebn Inn Med Kinderheilkunde 56:154–193
11. Assal JP, Berger M, Gay N, Canivet J (1983) Diabetes education. How to improve patient education. Amsterdam-Oxford-Princeton, Excerpt Med, Int Congr Ser 624
12. Assal JP, Mühlhauser I, Pernet A, Gfeller R, Jörgens V, Berger M (1985) Patient education as the basis for diabetes care in clinical practice and research. Diabetologia 28:602–613
13. Berger M, Jörgens V, Mühlhauser I, Zimmermann H (1983) Die Bedeutung der Diabetikerschulung in der Therapie des Typ-I-Diabetes. Dtsch Med Wochenschr 109:424–430
14. Department of Metabolic Diseases and Nutrition (2000). Curriculum for a treatment and training program for patients with type 1 diabetes University Düsseldorf. http://www.uni-duesseldorf.de/WWW/MedFak/MDN/ (Accessed 26 May 2002)
15. Berger M, Jörgens V (2001) Praxis der Insulintherapie 6th edn. Springer, Berlin Heidelberg New York
16. Grüsser M, Hartmann P, Jörgens V (1998) Behandlungs- und Schulungsprogramm für Typ 1 Diabetiker. Kirchheim, Mainz
17. Jörgens V, Grüsser M, Berger M (2001) Mein Buch über den Diabetes mellitus – für intensivierte Insulinbehandlung, 15th edn. Kirchheim, Mainz
18. Berger M, Mühlhauser I (1995) Implementation of intensified insulin therapy: a European perspective. Diabet Med 12:201–208
19. Mühlhauser I, Jörgens V, Berger M et al. (1983) Bicentric evaluation of a teaching and treatment programme for Type 1 (insulin-dependent) diabetic patients: improvement of metabolic control and other measures of diabetes care for up to 22 months. Diabetologia 25:470–476

20. Mühlhauser I, Klemm AB, Boor B, Scholz V, Berger M (1986) Duration of hospital stay and of work incapacity in patients with type 1 diabetes: effect of a treatment and training program [in german]. Dtsch Med Wochensch 111:854–857
21. Mühlhauser I, Broermann C, Bartels H, Berg R, Schwarz S, Berger M (1984) Quality control of self-monitoring of blood-sugar levels in a group of unselected type 1 diabetics: importance of training the patients [in german]. Dtsch Med Wochensch 109:1553–1557
22. Mühlhauser I, Berger M, Sonnenberg GE et al. (1985) Incidence and management of severe hypoglycemia in 434 adults with insulin-dependent diabetes mellitus. Diabetes Care 8:268–273
23. Mühlhauser I, Bruckner I, Berger M et al. (1987) Evaluation of an intensified treatment and teaching programme as routine management of Type I (insulin-dependent) diabetes. The Bucharest – Düsseldorf Study. Diabetologia 30:681–690
24. Jörgens V, Grüsser M, Bott U, Mühlhauser I, Berger M (1993) Effective and safe translation of intensified insulin therapy to general internal medicine departments. Diabetologia 36:99–105
25. Bott U, Jörgens V, Grüsser M, Bender R, Mühlhauser I, Berger M (1993) Predictors of glycaemic control in type 1 diabetic patients after participation in an intensified treatment and teaching programme. Diabet Med 11:362–371
26. Scholz V (1984) Course for diabetes educators. Diabetes Educ 10:80–84 (special)
27. Müller UA, Femerling M, Risse A et al. (1999) Intensified treatment and education of type-1-diabetes mellitus as clinical routine: a nation-wide quality circle experience in Germany. Diabetes Care 22 [Suppl. 2]:B29–B34
28. Müller UA, Köhler S, Femerling M et al. (2000) HbA_{1c} and severe hypoglycaemia after intensified treatment and education of type 1 diabetes as clinical routine. Results of a nationwide quality-circle in Germany (ASD) 1992–1999 [in german]. Diab Stoffw 9:67–81
29. Bott S, Bott U, Berger M, Mühlhauser I (1997) Intensified insulin therapy and the risk of severe hypoglycaemia. Diabetologia 40:926–932
30. Bott U, Mühlhauser I, Overmann H, Berger M (1998) Validation of a diabetes-specific quality-of-life scale for patients with Type 1 diabetes. Diabetes Care 21:757–769
31. Heinemann L, Overmann H, Mühlhauser I (1997) Quality of blood glucose self monitoring of patients with type 1 diabetes mellitus 6 years after participation in a structured treatment and teaching program [in german]. Diab Stoffw 6:59–63
32. Mühlhauser I, Bott U, Overmann H et al. (1995) Liberalized diet in patients with Type 1 diabetes. J Intern Med 237:591–597
33. Mühlhauser I, Overmann H, Bender R, Jörgens V, Berger M (2000) Predictors of mortality and end-stage diabetic complications in patients with Type 1 diabetes mellitus on intensified insulin therapy. Diabet Med 17:727–734
34. Mühlhauser I, Sawicki PT, Blank M, Overmann H, Bender R, Berger M (2000) Prognosis of persons with type 1 diabetes on intensified insulin therapy in relation to nephropathy. J Intern Med 248:333–341
35. Mühlhauser I, Overmann H, Bender R et al. (1998) Social status and the quality of care for adult people with Type I (insulin-dependent) diabetes – a population based study. Diabetologia 41:1139–1150
36. Mühlhauser I, Overmann H, Bender R, Bott U, Berger M (1998) Risk factors of hypoglycaemia in adult patients with Type I diabetes – a prospective population based study. Diabetologia 41:1274–1282
37. Starostina EG, Antsiferov M, Galstyan GR et al. (1994) Effectiveness and cost-benefit analysis of intensive treatment and teaching programmes for Type I (insulin-dependent) diabetes mellitus in Moscow – blood glucose versus urine glucose self-monitoring. Diabetologia 37:170–176
38. Assad D, Puchulu R, Domenech MI et al. (1995) Evaluación de un programa ambulatorio de educación y tratamiento de pacientes diabéticos insulinodependientes. Perspectivas diabetologicas 3:19–22
39. Tankova T, Dakovska G, Koev D (2001) Education of diabetic patients – a one year experience. Patient Educ Couns 43:139–145
40. Pieber T, Brunner GA, Schnedl WJ, Schattenberg S, Kaufmann P, Krejs GJ (1995) Evaluation of a structured outpatient group education program for intensive insulin therapy. Diabetes Care 18:625–630
41. DAFNE Study Group (2002) Training in flexible, intensive insulin management to enable dietary freedom in people with type 1 diabetes: dose adjustment for normal eating (DAFNE) randomised controlled trial. BMJ 325:746-751
42. Davidson JK (1983) The Grady Memorial Hospital diabetes programme. In: Mann JI, Pyörälä K, Teuscher A (eds) Diabetes in epidemiological perspective. Churchill Livingstone, Edinburgh, pp 332–341
43. Mühlhauser I, Jörgens V, Kronsbein P, Scholz V, Berger M (1985) Behandlung von nicht insulinpflichtigen Typ 2 Diabetikern in der ärztlichen Praxis 2. Allgemeinmedizin 14:39–43
44. Berger M, Grüsser M, Jörgens V, Kronsbein P, Mühlhauser I (1998) Behandlungs- und Schulungsprogramm für Typ 2 Diabetiker, die nicht Insulin spritzen, 3rd edn. Deutscher Ärzteverlag, Köln
45. Jörgens V, Grüsser M, Kronsbein P (2001) Wie behandle ich meinen Diabetes – Für Typ 2 Diabetiker, die nicht Insulin spritzen, 14th edn. Kirchheim, Mainz
46. Kronsbein P, Jörgens V, Mühlhauser I, Scholz V, Venhaus A, Berger M (1988) Evaluation of a structured treatment and teaching progamme on non-insulin-dependent diabetes. Lancet ii:1407–1411
47. Pieber TR, Holler A, Brunner GA et al. (1995) Evaluation of a structured teaching and treatment programme for Type 2 diabetes in general practice in a rural area of Austria. Diabet Med 12:349–354
48. Domenech MI, Assad D, Mazzei ME, Kronsbein P, Gagliardino JJ (1995) Evaluation of the effectiveness of an ambulatory teaching/treatment programme for non-insulin dependent (Type 2) diabetic patients. Acta Diabetol 32:143–147
49. Berger M, Jörgens V, Flatten G (1996) Health care for persons with non-insulin-dependent diabetes mellitus. The german experience. Ann Intern Med 124:153–155
50. Grüsser M, Bott U, Ellermann P, Kronsbein P, Jörgens V (1993) Evaluation of a structured treatment and teaching program for non-insulin-treated Type II diabetic outpatients in Germany after nationwide introduction of reimbursement policy for physicians. Diabetes Care 16:1268–1275
51. Grüsser M, Bott U, Scholz V, Kronsbein P, Jörgens V (1992) The introduction of a structured treatment and teaching programme for type 2 diabetes in general practices [in german]. Diab Stoffw 1:229–234

52. Gagliardino JJ, Etchegoyen G for the PEDNID-LA Research Group (2001) A model educational program for people with Type 2 diabetes. A cooperative Latin American implementation study (PEDNID-LA). Diabetes Care 24:1001–1007
53. Mühlhauser I, Sawicki P, Didjurgeit U, Jörgens V, Berger M (1988) Uncontrolled hypertension in Type 1 diabetes: assessment of patients' desires about treatment and improvement of blood pressure control by a structured treatment and teaching programme. Diabet Med 5:693–698
54. Mühlhauser I, Didjurgeit U, Sawicki PT (1998) Wie behandle ich meinen Bluthochdruck, 3rd edn. Kirchheim, Mainz
55. Mühlhauser I, Sawicki P, Didjurgeit U et al. (1990) Diagnosis of hypertension in general practice [in german]. Münch med Wschr 132:108–112
56. Werneke U, Mühlhauser I, Berger M (1988) Knowledge of medical students of the university of Düsseldorf about the technique of blood pressure measurement during their internship [in german]. Schweiz Rundsch Med Prax 77:1167–1170
57. Mühlhauser I, Sawicki PT, Didjurgeit U, Jörgens V, Trampisch HJ, Berger M (1993) Evaluation of a structured treatment and teaching programme on hypertension in general practice. Clin Exper Hypertens 15:125–142
58. Sawicki PT, Didjurgeit U, Mühlhauser I, Heinemann L, Berger M (1990) Near-normotension and near-normoglycemia in blind Type 1 diabetic patients with overt diabetic nephropathy. J Diabetes Complications 4:179–183
59. Sawicki P, Mühlhauser I, Didjurgeit U et al. (1993) Strukturoptimierung der antihypertensiven Therapie – Langzeitergebnisse einer randomisierten prospektiven Studie in Arztpraxen. Dtsch Ärztebl 90:1736–1741
60. Sawicki PT, Mühlhauser I, Didjurgeit U, Reimann M, Bender R, Berger M (1995) Mortality and morbidity in treated hypertensive Type 2 diabetic patients with micro- or macro-proteinuria. Diabet Med 12:893–898
61. Sawicki PT, Mühlhauser I, Didjurgeit U, Baumgartner A, Bender R, Berger M (1995) Intensified antihypertensive therapy is associated with improved survival in Type 1 diabetic patients with nephropathy. J Hypertens 13:933–938
62. Trocha AK, Schmidtke C, Didjurgeit U et al. (1999) Effects of intensified antihypertensive treatment in diabetic nephropathy: mortality and morbidity results of a prospective controlled 10-year study. J Hypertens 17:1497–1503
63. Grüsser M, Hartmann P, Schlottmann N, Lohmann FW, Sawicki PT, Jörgens V (1997) Structured patient education for out-patients with hypertension in general practice: a model project in Germany. J Hum Hypertens 11:501–506
64. Korhonen T, Huttunen JK, Aro A et al. (1983) A controlled trial on the effects of patient education in the treatment of insulin-dependent diabetes. Diabetes Care 6:256–261
65. Bloomgarden ZT, Karmally W, Metzger MJ et al. (1987) Randomized, controlled trial of diabetic patient education. Improved knowledge without improved metabolic status. Diabetes Care 10:263–272
66. Weerdt de I, Visser AP, Kok GJ, de Weerdt O, van der Veen EA (1991) Randomized controlled multicentre evaluation of an education programme for insulin-dependent diabetic patients: effects on metabolic control, quality of life, and costs of therapy. Diabet Med 8:338–345
67. Coster S, Gulliford MC, Seed PT, Powrie JK, Swaminathan R (2000) Monitoring blood glucose control in diabetes mellitus: a systematic review. Health Technology Assess 4:1–93 (also: Diabet Med 2000; 17:755–761)
68. Jörgens V, Berchtold P, Berger M (1979) Therapie des insulinpflichtigen Diabetes mellitus. Dtsch Med Wochenschr 104:1796–1799
69. Jörgens V, Berchtold B, Eickenbusch W, Scholz-Thielen E (1980) Beneficial effects of diabetes teaching. Diabetes 29:A108 (Abstract)
70. Berger M, Mühlhauser I (1999) Diabetes care and patient-oriented outcomes. JAMA 281:1676–1678
71. Moher D, Schulz KF, Altman DG, for the CONSORT Group (2001) The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. Lancet 357:1191–1194